Comprehensive Examination and Analyses of the Situation of Transport of Nuclear Materials

Final Report

Written by ENCO
August 2019

Energy

EUROPEAN COMMISSION

Directorate-General for Energy
Directorate D — Nuclear energy, safety and ITER
Unit D1 — EURATOM co-ordination, legal matters and international relations

E-mail: ENER-D1@ec.europa.eu

European Commission
B-1049 Brussels

EUROPEAN COMMISSION

Comprehensive Examination and Analyses of the Situation of Transport of Nuclear Materials

Final Report

Directorate-General for Energy

More information on the European Union is available on the Internet (https://europa.eu).

Luxembourg: Publications Office of the European Union, 2020

PDF	ISBN 978-92-76-25334-1	DOI 10.2833/63151	MJ-02-20-956-EN-N

FINAL REPORT

ENCO-FR-(18)-39 / August 2019

COMPREHENSIVE EXAMINATION AND ANALYSES OF THE SITUATION OF TRANSPORT OF NUCLEAR MATERIALS

(ENER/2017/NUCL/SI2.751899)

Ref.: ENER/D1/2016-89

This project is funded by the European Union

TABLE OF CONTENTS

ABSTRACT ..... **VIII**

EXECUTIVE SUMMARY ..... **IX**

RESUME ..... **XVIII**

1 INTRODUCTION **1**

2 BACKGROUND **2**

2.1 General 2

2.2 EXPERT GROUPS 3

3 OBJECTIVES **5**

4 SCOPE **6**

5 THE APPROACH **7**

5.1 General Approach 7

5.2 Data Collection 9

5.3 Analysis 10

6 INDUSTRY INFRASTRUCTURE REVIEW **17**

6.1 Basic data collection 18

6.2 Potential for errors in data 19

6.3 Other sources of information – shipment directive reports 20

6.4 Importance of airports and ports 21

6.5 Regulatory oversight 22

6.6 Summary of THE REVIEW OF industry infrastructure 22

7 REGULATORY INFRASTRUCTURE REVIEW **24**

7.1 Maintaining an Effective Regulatory Framework 26

7.2 Monitoring and Inspection of Transport Operations 28

7.3 Audits of Management systems 31

7.4 Design Assessment 32

7.5 Issuing of Approvals 33

7.6 Witnessing of Testing 34

7.7 Witnessing of Manufacture 36

7.8 Examination of Maintenance and Servicing 37

7.9 Emergency Planning and Exercises 38

7.10 Enforcement actions and Investigation of Incidents 39

7.11 Training and Distribution of Information 40

7.12 Interdepartmental liaison and cooperation 43

7.13 Summary of Regulatory Infrastructure review 43
8 SPECIFIC ISSUES 45
8.1 Effectiveness Reviews 45
8.2 State Reviews 53
8.3 Peer Reviews 55
8.4 Waste and exclusion 57
8.5 Ageing 60
8.6 Denial of Shipments 61
8.7 Good Practices 66
8.8 Documentation 67
8.9 Costs 75
8.10 Summary of specific issues 77
9 IMPLEMENTING THE BSS DIRECTIVE FOR TRANSPORT 78
9.1 Background Articles 78
9.2 Article 24 Graded approach to regulatory control 81
9.3 Article 25 Notification 86
9.4 Article 26 Exemption from notification 90
9.5 Article 27 Registration or licensing 94
9.6 Article 28 Licensing 97
9.7 Article 29 Authorisation procedure 100
9.8 Article 68 Tasks for the undertaking 103
9.9 Article 69 Emergency response 107
9.10 Article 87 Requirements for control of high-activity sealed sources 115
9.11 Article 88 Specific requirements for licensing of high-activity sealed sources 119
9.12 Article 98 Emergency preparedness 124
9.13 Summary of BSS Directive implementation for transport 127
10 CASE STUDIES 129
10.1 Urgent Medical Shipments 129
10.2 NORM 129
10.3 Dual purpose casks 130
10.4 Radioisotope Samples 130
11 CONCLUSIONS AND RECOMMENDATIONS 131
ANNEXES 1
A1 STANDING WORKING GROUP 2
A1.1 European Funded research 2
A1.2 Previous Studies 3
A1.3 Views of the EUROPEAN Parliament 4

A1.4 Issues relevant to this study 5
A2 MS IRRS REPORTS – TRAM RELEVANT TEXT 6
A2.1 BELGIUM 6
A2.2 BULGARIA 11
A2.3 CROATIA 17
A2.4 CZECH REPUBLIC 18
A2.5 FINLAND 23
A2.6 FRANCE 27
A2.7 GERMANY 32
A2.8 GREECE 33
A2.9 IRELAND 36
A2.10 ITALY 41
A2.11 LITHUANIA 48
A2.12 MALTA 52
A2.13 NETHERLANDS 53
A2.14 POLAND 57
A2.15 ROMANIA 59
A2.16 SLOVENIA 66
A2.17 SWEDEN 68
A3 QUESTIONNAIRES 72
A4 QUESTIONNAIRE RESPONSE — INDUSTRY INFRASTRUCTURE 108
A5 QUESTIONNAIRE RESPONSE — REGULATORY INFRASTRUCTURE 160
A6 CASE STUDIES 221
A6.1 Urgent Medical Shipment 221
A6.2 NORM 228
A6.3 Dual Purpose Casks 242
A6.4 Radioisotope Samples 245
A7 WORKING METHOD 246
A7.1 Workshop 1 248
A7.2 Other findings 250
A7.3 Workshop 2 252
A7.4 Specific Items from Workshop 2 272
A7.5 Items Not Considered A Priority 273
A8 DATA RECORDING 274
A8.1 Infrastructure records 274
A8.2 Compliance assurance records 275

LIST OF TABLES

Table 1: Overview of responses 18
Table 2: Review summary by Member State 25
Table 3: Relevant ICAO audit results 53
Table 4: Document requirements for consigning 67
Table 5: Requirements on notification 72
Table 6: Transposition of BSS Directive Article 24 84
Table 7: Transposition of BSS Directive Article 25 88
Table 8: Transposition of BSS Directive Article 26 92
Table 9: Transposition of BSS Directive Article 27 94
Table 10: Transposition of BSS Directive Article 28 98
Table 11: Transposition of BSS Directive Article 29 101
Table 12: Transposition of BSS Directive Article 68 104
Table 13: Transposition of BSS Directive Article 69 109
Table 14: Transposition of BSS Directive Article 87 116
Table 15: Transposition of BSS Directive Article 88 119
Table 16: Transposition of BSS Directive Article 98 125
Table 17: Expected changes for packages/consignments compared to 2016 114
Table 18: Expected changes of importance over the next few years 117
Table 19: Overview of package types 118
Table 20: Breakdown of package types consigned in 2016 119
Table 21: Number of packages split by UN numbers 121
Table 22: Number of packages split by groups 121
Table 23: Different types of shipment 134
Table 24: Expected changes to industry capacity 141
Table 25: Reported route restrictions 151
Table 26: Example for primary responsibility for safety 164
Table 27: Number of audits compared to number of audits minus top MS 175
Table 28: How many non-CA approved packages have been reviewed to confirm a design assessment has been carried out in years 2012 - 2016 177
Table 29: How many non-CA approved packages were re-assessed by the regulator in years 2012 - 2016 178
Table 30: How many shipments were assessed in years 2012 - 2016 178
Table 31: How many of these shipments (Doesn't include NL) were limited to the EU in years 2012 - 2016 ... 178
Table 32: Percent of multilateral approvals from outside of the EU 183
Table 33: How many package tests were witnessed in years 2012 - 2016 184
Table 34: How many packages not subject to CA approval had testing witnessed in years 2012 - 2016 185
Table 35: MS where maintenance takes place or where parts are sourced and associated compliance checks 192
Table 36: Cross-mapping of MS of operation and MS of servicing or parts 193
Table 37: Responsibility for planning for emergency response 196
Table 38: Legal person responsible for testing emergency plans 199
Table 39: Legal person responsible for responding to an emergency 200
Table 40: Training providers in MS 214
Table 41: Example of a simple competence framework 216
Table 42: Guidance topics suggested by MS 217
Table 43: Workshop 2 review of action areas 253
Table 44: Proposals developed by the consultants 264

LIST OF FIGURES

Figure 1: Compliance circle. 24
Figure 2: Review summary by compliance area 26
Figure 3: Audits under the auspices of organisations 55
Figure 4: Percentage of major ports reported as willing to carry radioactive material 62

Figure 5: Costs of Licence to Carry Materials. 75
Figure 6: Costs of Licence to Consign. 76
Figure 7: Costs of New B(U) Approval. 76
Figure 8: Number of packages consigned per year by MS (2016/2026/2036) 109
Figure 9: Number of packages consigned in 2016 per 100,000 persons* 110
Figure 10: Number of consignments per year by MS (2016/2026/2036) 112
Figure 11: Number of packages per consignment by MS in 2016....113
Figure 12: Total packages/consignments for all MS 2016/2026/2036 114
Figure 13: Expected changes for packages (% of 2016) 115
Figure 14: Expected changes for consignments (% of 2016)....116
Figure 15: Breakdown of the package types consigned in 2016 by MS (%)....120
Figure 16: Weighted total for reported total by package type (% reported 2016)....122
Figure 17: Weighted total for EU total by package type (Number of packages reported 2016) 123
Figure 18: Breakdown of the package type groups consigned in 2016 (Number of packages reported 2016)..124
Figure 19: Breakdown of the package type groups consigned in 2016 (MS reported 2016 %)....125
Figure 20: Breakdown of the modes of transport used for packages in 2016 (%)....126
Figure 21: Breakdown of the modes of transport used for packages in 2016 (total number reported) 127
Figure 22: Breakdown of the modes of transport used for packages in 2016 (total number of packages reported) 127
Figure 23: Breakdown of the carrier types for packages in 2016 (%) 129
Figure 24: Breakdown of the end use of material for packages in 2016 (%) 131
Figure 25: Transboundary shipments (%) 133
Figure 26: Potential simplification to Form A-1 Application for authorisation of shipment(s) of radioactive waste 136
Figure 27: Potential simplification to Form A-1 Application for authorisation of shipment(s) of radioactive waste (continued) 137
Figure 28: Potential simplification to Form A-1 Application for authorisation of shipment(s) of radioactive waste (continued) 138
Figure 29: Italian Data Recording Form....140
Figure 30: Number of people involved in TRAM in MS in 2016 141
Figure 31: Best estimate of the change in industry experience....142
Figure 32: Number of transport enterprises that carry radioactive material 143
Figure 33: Number of transport enterprises that carry radioactive material (Minus FR, PL and UK)....144
Figure 34: Number of carriers per regulatory body inspector 145
Figure 35: Number of major air/sea/inland waterways ports that permit TRAM 147
Figure 36: Route restrictions (all participating MS) 148
Figure 37: Percentage of major ports reported as willing to carry radioactive material....149
Figure 38: Any restrictions on road routes for TRAM 150
Figure 39: Any restrictions on rail routes for TRAM....150
Figure 40: Allowable border crossing points....153
Figure 41: Ratio RAM crossing points by total crossing points 154
Figure 42: Current resources (person years)....156
Figure 43: Current resource levels 157
Figure 44: Indication of resource availability in regulatory bodies....158
Figure 45: Do you have a registration scheme for TRAM in regulation? 163
Figure 46: Consignment operations witnessed in MS 2012-2016 165
Figure 47: Consignment operations witnessed 2012-2016 (EU)....166
Figure 48: Consignment operations witnessed in MS 2012-2016 166
Figure 49: COUNCIL DIRECTIVE 95/50/EC roadside check requirements 167
Figure 50: Carriage operations witnessed in 15 MS 2012-2016 170
Figure 51: Carriage operations witnessed 2012-2016 (15 MS)....170
Figure 52: Carriage operations witnessed in 15 MS 2012-2016 171
Figure 53: Packages independently monitored for contamination by or on behalf of the regulatory body 2012-2016 (7 MS) 171

Figure 54: Packages independently monitored for contamination 2012-2016 (7 MS) 172
Figure 55: Packages independently monitored for contamination by or on behalf of the regulatory body 2012-2016 (Excluding CZ).. 172
Figure 56: Do you have a registration scheme for management systems of users for RM in regulation? 173
Figure 57: Is there a national audit programme? 174
Figure 58: How many management systems were audited by the regulator? 174
Figure 59: Do you have a registration scheme for radiation protection programmes of users for RM in regulation? 176
Figure 60: Radiation protection programmes audited 2012-2016.. 176
Figure 61: How many country of origin approvals was issued in 2014 – 2016 179
Figure 62: How many multilateral approvals by re-certification were issued in 2012 – 2016.......................... 180
Figure 63: How many multilateral approvals by validation were issued in 2012 - 2016.................................. 181
Figure 64: How many re-certifications or validations of non-EU package or shipment certificates were issued in 2012 – 2016 182
Figure 65: Do you have a registration scheme for package tests for RM in regulation? 184
Figure 66: Do you have a registration scheme for package manufacturers for RM in regulation? 186
Figure 67: Manufacturing operations inspected 187
Figure 68: Manufacture of packages not subject to CA approval witnessed 188
Figure 69: Do you have a registration scheme for package maintenance for RM in regulation? 189
Figure 70: Maintenance records examined 190
Figure 71: Maintenance operations examined... 191
Figure 72: Are there any regulations requiring emergency planning for TRAM 194
Figure 73: Are there any regulations requiring emergency exercises for TRAM... 197
Figure 74: Number of emergency plans reviewed 198
Figure 75: Number of emergency exercises witnessed 199
Figure 76: First responders trained in 2016... 203
Figure 77: Requirement to report non-compliance to an enforcement authority?.. 204
Figure 78: Enforcement actions reported 2012-2016 (EU) 205
Figure 79: Enforcement actions reported by MS 2012-2016 205
Figure 80: Enforcement actions reported by MS 2012-2016 (minus AT and NL).. 206
Figure 81: Investigations of non-compliance completed 2012-2016 (EU) 207
Figure 82: Investigations of non-compliance completed by MS 2012-2016 207
Figure 83: Investigations of non-compliance completed by MS 2012-2016 (Minus BE and NL)....................... 208
Figure 84: What penalties were applied as a result of enforcement 209
Figure 85: Is there a national training regime established related to TRAM?.. 210
Figure 86: Are there any regulatory requirements for training?.. 210
Figure 87: Number of people trained 2012-2016 (all reporting MS) 212
Figure 88: Number of people trained 2012-2016 (minus UK) 213
Figure 89: Is training that was carried out in other states recognised? 214

Disclaimer:

This report has been produced for the European Commission by ENCO. The views represented in the report are those of its authors and do not represent the views or official position of the European Commission. The European Commission does not guarantee the accuracy of the data included in this report, nor does it accept responsibility for any use made thereof.

ABSTRACT

The adoption of major Directives[1] impacting the radioactive materials transport required investigating the status and challenges related with this sector in the EU.

This report relates to the DG ENER project “Comprehensive examination and analyses of the situation of transport of nuclear materials”. The work was aimed to identify areas where enhancements of transport safety, security and transparency are possible and justified.

Data was collected across all EU Member States[2] on the infrastructure, the national regulations and practices of radioactive material transport. Specific issues, case studies and the implementation BSS Directive for the transport of radioactive materials were also assessed in this report.

Key features were the participation of the Stakeholder Group, representing all those with responsibilities in transport of radioactive material, and the feedback of the Commission Task Force established to monitor and interact with the project.

This study confirms that the transport of radioactive material continues to have an excellent safety record. There is clear evidence of effective regulatory and industry response, and no evidence of significant accidents. Active processes are in place in Member States to identify and actively deal with any issues that need to be addressed. Nevertheless, a few areas remain where actions are encouraged.

[1] 2013/59/EURATOM, 2014/87/EURATOM, 2006/117/EURATOM

[2] 25 MS participated in the study (Portugal and Cyprus have failed to respond, and Hungary submitted information after this study was concluded).

EXECUTIVE SUMMARY

The information and views set out in this report are those of the authors and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein.

The advantages of the EU's common area include not only enhancing economic output, but also ensuring that the EU citizens, wherever they reside and/or travel are protected against hazards. From this perspective, the transport of radioactive materials needs to meet the highest levels of safety and security, and the regulations and their implementation must be harmonized across EU Member States. This would assure safe and secure transport, reduce impediments to commerce, and eliminate variations, however minor, between the regulations/legislation and practices in each Member State. Furthermore, given the large quantities of radioactive substances transported across the EU (estimated at 3 million packages a year), public trust and related transparency need to be assured.

The adoption of major EU Directives covering radiation and nuclear safety, including the Basic Safety Standards[3], Nuclear Safety[4] and Shipment[5] Directives, also impacts the transport of radioactive material. All of the EU MS have already finalised or are close to finalising the transposition of those in national legislation. This establishes a very opportune moment to comprehensively examine and analyse the status of the transport of radioactive material across the EU. This analysis is to identify improvements that will eventually be needed at the EU or MS levels, to assure highest standards of safety and security. It is also to examine transparency, to dispel lack of trust and enhance public confidence in transport of radioactive material. Initiating the study now was also considered rather timely, as for longer than a decade no systematic assessment of the status of transport of radioactive material in the European Union has been undertaken.

This report documents the findings of the EC DG ENER's project "Comprehensive Examination and Analyses of the Situation of Transport of Nuclear Materials", which assessed the current status across the sector against objectively established criteria that consider the latest the scientific and technological developments and perspectives in the transport of radioactive materials.

BACKGROUND, SCOPE AND APPROACH

The transport of radioactive materials is internationally regulated by a system of conventions and supporting technical requirements (for road, rail, inland waterway, sea and air), all of which are ultimately based on technical requirements set by the International Atomic Energy Agency. At the European Union level, some aspects of the transport of radioactive materials are covered under the Treaty on European Union and others under the EURATOM Treaty, by various Directives (or Regulations) including the Directive 2008/68/EC on inland transport of dangerous goods. This comprehensive system has been in place for several decades and is intended to provide a framework within which the cross-border transport of radioactive materials should be conducted without unnecessary hindrances, in a manner which is both safe and secure.

This study has carried out a comprehensive examination and analyses of the situation of transport of nuclear/radioactive materials in the European Union's Member States, with extensive involvement of MS transport practitioners (including both regulators and industry), organised through active participation in Project's "Stakeholder Group". Data were collected from all EU Member States[6] both on issues dealing with the regulatory regimes and the actual activities related with transport.

---

[3] 2013/59/EURATOM

[4] 2014/87/EURATOM

[5] 2006/117/EURATOM

[6] A total of 25 Member States participated in the study (Portugal and Cyprus did not respond, while Hungary submitted information after this study was concluded).

Specific emphasis was devoted to the infrastructure reviews, the industry's infrastructure and experience, specifically across border transport, and the regulatory infrastructure, including national regulations and practices related to the safety and security, and addressing subjects as diverse as the design reviews (e.g. of transport containers) and emergency preparedness requirements. Specific issues relevant for the transport of radioactive materials assessed in this study include effectiveness of the regulatory regime, state and peer reviews, radioactive waste, exemption and clearance levels, ageing of transport packages, denial of shipments as well as good practices in implementing or regulating transport, documentation and costs of transport.

The application of the Basic Safety Standards Directive including its new requirements related to the transport of radioactive materials was assessed in detail. This is of particular importance in identifying the gaps and possible overlaps in European Union legislation that could be best addressed at the European Union level.

The key feature of the Project implementation was the establishment of the Stakeholder Group, representing wide interests and responsibilities for transport of radioactive material in the EU. The Stakeholder Group included representatives of European Commission, Member States (primarily competent authorities), the industry's stakeholders and other bodies with interest in the subject matter. The Stakeholder Group was established at the initiation of the project, to guide the Project's activities including the finalisation of the topics to be investigated and the selection of the themes for the Case studies. Most importantly, the Stakeholder Group was tasked with thoroughly reviewing any findings and recommendations raised within the Project. Consequently, all the recommendations as detailed in the report have been fully reviewed and endorsed by the Stakeholder Group.

Two Stakeholder Group Workshops were held in the framework of this project, first one to discuss the interim results and the second to review, discuss, agree the findings of the study, as well as to endorse its recommendations.

An extensive questionnaire, covering all the elements of interest for the subject of transport of radioactive material in the EU was designed by the Project team, reviewed and endorsed by the Commission's Task Force and the members of the Stakeholder Group. The final questionnaire was distributed to the nominated contact points for transport of radioactive material in all EU MS. The received responses were reviewed, clarified, finalised and recorded in a data base. In some cases, additional information was requested in a follow-up questionnaire. Member State responses were assessed and the resulted findings are presented in the report, while the detailed responses are provided in topical annexes to the report.

OVERALL ASSESSMENT

The aim of this project was a holistic assessment of the situation in transport of radioactive material across the European Union. Therefore, to collect accurate and comprehensive information, a detailed questionnaire covering all of the areas of interest has been developed. The questionnaire was reviewed by the Stakeholder Group and after a pilot pre-fill, sent to the nominated contact points in all EU MS. The answers to the questionnaire, including the follow up clarifications undertaken by the Project team whenever some doubts existed, comprehensively examined the situation across the European Union. The highlights of the findings as related with the specific subject areas include:

TRANSPORT INFRASTRUCTURE AND PRACTICE

- Around 3,000,000 packages were consigned in the EU in a year.
- The average number of packages per consignment was two.
- The majority of packages consigned did not require competent authority's approval,
- Shipment of only 3% to 9% (depending on a MS) of packages required such approval before being shipped.
- The majority of packages, 89%, were shipped by road. 8.5% of packages were shipped by air.
- The majority of packages were shipped for medical and industrial purposes:

    - 60% of packages were shipped for medical purposes.
    - 25% were shipped for industrial purposes.
- The changes in the transport of radioactive material across the EU, in terms of quantity and organisation over the next 20 years is not expected to be significant.
- The resources available to competent authorities/regulators appear to be decreasing in comparison to demand.

REGULATORY INFRASTRUCTURE AND PRACTICE

Assuring compliance with the regulations and requirements is the most important element of guaranteeing safety and security in transport of radioactive material. Twelve areas of compliance as defined in the IAEA guidance were investigated in details:

- Around 75% of MS have a single regulator for transport of radioactive material, covering all modes of transport.
- Generally, the regulatory requirements were fully in place. Almost all MS fully complied with transport regulations (as defined in Directive 2008/68/EC):
    - Two states acknowledged they did not comply fully with the Directive 2008/68/EC at the start of the study.
    - Five states have chosen to vary from the Directive 2008/68/EC in some areas.
- There are variations in the requirements for practices to register for the activity (transport of radioactive material) under radiation protection regulations. This may introduce a significant variation in implementation of the radiation protection requirements during transport.
- Monitoring/inspection/checks on packages that are not subject to Competent Authority's approval seemed low.
- Less than half of MS had carried out an approval of a package in the last five years, indicating a limited availability of regulatory resources for this specialised area.
- There were indications that some MS might be unaware of transports operations occurring on their territory supporting a transport practice operating in another MS.
- There were wide variations in responsibilities for Emergency Preparedness and Response by MS/Mode/Activity, some of which were not consistent. In many MS it appears that there is a lack of coordination between the radiological emergency response and the transport emergency response.
- The regulatory resources appeared stretched; the indication is that regulators were not investing in training as much as it might be needed.
- Only around 25% of MS have a programme for assessing exposure of the public, which would appear to be a significant gap in measuring the effectiveness of compliance.

IMPLEMENTING THE BSS FOR TRANSPORT PRACTICES

An important aspect of the project was to assess the implementation of the Basic Safety Standards Directive in the area of transport of radioactive material. Generally, the Directive should lead to harmony in the application of transport related requirements but this does not seem to have been achieved at the time of the study. There appears to be a varied application of the graded approach in different MS, leading to differences areas such as notification, licensing and authorisation. Variations in regulations covering the low risk level transport might lead to an unjustified burden.

FINDINGS

The Study resulted in a variety of findings on different levels. The overall finding is that the general situation in transport of radioactive material could be assessed as very good, with few problems occurring. In particular as related with "denial of shipments", there is a significant reduction in the number of such events. Even when occurring, it appears that such events are due to incomplete documents and similar causes.

There are very few safety-related occurrences during transport and practically no indication of overexposure events. Furthermore, the results of the inspections undertaken shows a continuous reduction in number of findings.

Some further specific findings, grouped in four areas of interest are summarised below.

STATUS OF EXISTING ARRANGEMENT IN EU MS

The current status of industries' and regulators' activities and arrangements as related with transport of radioactive material in the EU is detailed in Section 6 and Annex 4 of the report. The main conclusion is that the industry is fulfilling its role and not failing and/or changing in any dramatic way.

One of the important findings is the failure to utilise existing arrangements for ensuring availability of accurate information regarding transport of radioactive material in the EU. The statistical data required by EU level regulations and directives are recorded in the Eurostat transport database. The responses show that the information collected in the database is significantly different from reality and could be improved. Legislation is in place at European level to allow for improved data collection but is has not been fully implemented by all EU MS.

The legal arrangements at the EU level have seen significant changes in recent years. A number of different legislative requirements, both EU regulations and directives, impact different aspects of transport of radioactive material. As a result of different purposes and legal basis of some of those, there are areas where clarity on their application still needs to be provided.

It is important to note that the transport legislation is designed to ensure smooth cross-border transport, and that has been achieved with few exceptions. The radiation protection legislation tends to be more goal setting, allowing states to vary requirements. This in turn leads to a potential for introducing differing cross border arrangements, undermining smooth cross border transport of radioactive material.

Overall, the existing arrangements specific to transport are fully implemented in most MS (with some minor variations), with the exception of data gathering and sharing. The legislation on the radiation protection, which is more generic, is implemented to a varying extent in MS. Several areas could benefit from clarity in the application to transport. A detailed review is set out in Section 9 of the report showing how each MS has applied radiation protection requirements to transport. The Shipment Directive applies to a very small percentage of shipments of radioactive material and has some overlap with transport legislation.

The assessment concluded that there are limited needs for changing or indeed new legislation, but that agreement on implementation through guidance and/or mutual understanding across the MS are the most likely options for improvements in the areas where those are needed.

KEY GAPS AND INCONSISTENCIES

The gaps and inconsistencies in the implementation of directives for transport of radioactive material across the EU have been evaluated. The findings are documented in Section 5.3.1 of the Report. One of the important conclusions is that there are overlaps in the existing arrangements rather than gaps. It was found that the requirements of transport regulations are much more specific than those of the radiation protection regulations. In addition, the transport regulations add a facilitation aspect (stricter requirements may not be applied) that is not included in the radiation protection regulations. Removing the facilitation from transport legislation or adding a facilitation purpose to radiation protection regulation is not likely to be viable, so this difference is likely to remain. This would be best managed through guided implementation. Overall, there would appear to be no gaps in legislation.

Nevertheless, there might be a need to deal with the overlapping legislation that has resulted in variable interpretations, which could potentially introduce gaps. Tables 37, 38 and 39 in the report provide details of the differences in implementation of requirements related to EP&R.

The analysis of the situation identified gaps in data collection and reporting. The improvements in these might be expected to assist in identifying developing issues. Good practices exist in some MS. Voluntary improvements by MS through the sharing of good practices would be beneficial and could be supported through EC action.

There was limited information on whether there was an appropriate level of oversight of packages that do not require approval by the competent authority. The level of inspection of packages that do not require approval appeared to be low. A greater transparency on how inspection levels are derived would be a benefit for public assurance.

Emergency preparedness and response for transport of radioactive material is the one area where urgent actions are suggested.

Overall, the study found that there is a need for improved transparency through data gathering and information sharing and that the level of safety could be improved through the production of targeted guidance.

USEFULNESS OF PEER REVIEWS

The usefulness of peer reviews was specially addressed in the Study. The data on currently implemented peer and other reviews are available in the Section 8 of the Report, while Annex 2 provides extracts of IRRS reports for MS that included transport of radioactive material in the scope of this high-level IAEA peer review services.

For air transport, there is an effective international system of reviews also addressing dangerous goods (i.e. including radioactive material). This system is operated by ICAO and covers every ICAO Member State (including all 28 EU MS). A similar system applies for sea transport. Both air and sea reviews can be used as inputs to the review of the transport of radioactive material. However, few MS seem to be aware of this possibility.

For road and rail transport, the IAEA IRRS could provide basic reviews. More than half of EU MS have taken up the option to include transport in an IRRS. These reviews focus on regulatory issues and appear to result in sometimes contradictory suggestions in relation to implementation.

The IAEA offers a service called TranSAS, which is more specific to transport and thus more comprehensive. Nevertheless, hosting such a mission requires rather extensive resources. Only 2 EU MS have taken advantage of this peer review and those were implemented a long time ago. A less resource-intensive version of the TranSAS (mini-TranSAS) was developed by IAEA for application in developing regions. So far it has not been deployed in Europe, though such a style of review could be useful in the EU MS. The added benefit of the mini-TranSAS is that it encourages neighbouring states to work together. As such, it would be effective as driver for improved harmonisation.

There are clear benefits of using peer reviews in terms of transparency and public assurance, and their use is recommended.

PROPOSALS FOR AREAS OF IMPROVEMENT

The aim of the analysis undertaken in this study was to identify the areas where improvements in the arrangements and/or regulation could lead to safer and more secure transport of radioactive material, offering higher protection of the population, but also enhancing commerce across the EU. Further to this, areas where transparency could support greater public acceptance have been looked at. An analytical process to identify key recommendations that would provide the maximum benefit over a wide range of areas was utilised. This process involved the knowledge and experience in transport of radioactive material across the EU, and encompassed the views and opinions of the Stakeholder Group. Annex 7 provides information on the process by which these key recommendations were developed and refined with the active involvement of the stakeholders.

The proposed areas for improvement, in addition to various specific proposals discussed next, include:

- The harmonisation of the assessment of transport containers, and/or mutual recognition of certificates. Regulatory bodies were cautious about this area, however they supported that more systematic sharing of information is a valuable step forward. Systematic information sharing has potential to reduce pressure on regulatory resources, which is of specific relevance for smaller regulators.

- Emergency Preparedness and Response. While there were no manifested failures so far, it is important to note that any gaps in this area might be revealed if an emergency occurs. Nevertheless, different approaches to EP&R plans are likely to be critically challenged in particular if an emergency occurs in cross border transport. This area deserves guidance and higher scrutiny in the future.

KEY RECOMMENDATIONS

The data collected through questionnaires and the information gleaned through interviews and Stakeholder workshops confirm that the transport of radioactive materials in the EU continues to have an excellent safety record. The assessment identified only two transport related events rated as INES 2 or above that were reported in the EU for the last five years.

The Study reviewed the information provided by each MS and analysed it in detail, to identify areas where potential for improvements might exist. These were thoroughly discussed with the Stakeholder Group, initially via email and then during the Workshop specifically organised with the aim of assessing and agreeing on the key recommendations of the study. Through this interaction the stakeholders agreed to the list of potential issues that would need to be actively addressed.

While the initial stage of the study identified a number of potential challenges, the (vast) majority were subsequently determined to be appropriately managed by the industry and/or regulators. This may be, perhaps, one of the most important conclusions of the study – that there are active processes in place in the industry and in competent authorities in the EU Member States to identify any issues related with transport of radioactive material, and there is clear evidence that issues are being actively dealt with. Nevertheless, a few areas remain where actions are encouraged or indeed necessary.

The potential challenges identified within the study were reduced to a number of priority issues. An “entity” (e.g. the EC, MS authorities, etc.) best placed to address each of those was identified. The priority issues, as endorsed by the Stakeholder Group, include the following:

1. Review the different reporting provisions, including Council Directive 2006/117/Euratom and its single standard document, Regulation 1493/93, which address information reporting on transport:

    - Outline the goals for the simplification of reporting requirements.

The EC is best placed to lead on this recommendation.

2. Reflecting on existing best practice establish better communication between Competent Authorities regarding the assessment of package designs, effectively enhancing harmonisation and the time scale of regulatory assessment:

    - Communicate between Competent Authorities on the assessment of packages.

Competent Authorities of MS are best placed to lead on this recommendation.

3. Establish a European Package Information System, reflecting on the experience with the IAEA’s PACKTRAM. The extent of the information stored and the packages recorded would be established as part of the planning phase. The extent to which it could enable simplification of information sharing on packages not requiring Competent Authority approval is worth considering:

- Based on experience with PACKTRAM, identify useful information (and information that creates a collection burden);
- Consider whether an existing system can be adapted to the purpose;
- Determine the system specifications, at a minimum including package approval information (e.g. package type, approval date, expiry date);
- Consider hosting and long-term operation (e.g. JRC);
- Create an information system and populate from existing data;
- Define a sustainable system for maintaining the database.

The EC and the Competent Authorities of MS are best placed to lead on this recommendation, but it will require wide industry participation and support.

4. Enhance the level of training of regulators, industry, and first responders in the short term; in the long(er) term, establish a comprehensive capacity building system, possibly reflecting UK good practices.

Short term:

- Develop cross-training of transport experts and radiation protection experts.

Long term:

- Gather information in a coordinated manner on short- and long-term requirements;
- Establish a co-ordinated programme (including industry/regulator partnerships) for developing adequate competence for transport.

Member States are best placed to lead on this recommendation.

5. Ensure effective coordination between groups dealing with different aspects of the safety of radioactive material, by enhancing communication between experts using modern technology:

- Share Member States' expert contacts between the three groups (radiation protection, waste and transport) to encourage coordination at the national level (making use of groups such as EACA);
- Establish European Commission contact points for each group and ensure that information on expert opinions and proposals is shared.

The European Commission is best placed to lead on this recommendation.

6. Assign responsibility to facilitate the transport of radioactive materials to a group of EC and MS industry bodies, which shall be separate from the competent authorities. An initial task proposed for such a group is a review of all ports in the European Union, to establish their ability to handle radioactive materials, including restrictions in terms of times and paperwork. In addition, the proposal is to carry out a legal review of the barriers currently in place:

- Request Member States to appoint a non-regulatory government body to facilitate the transport of radioactive materials, and ensure that this is made public;
- Implement activities related to Denial of Shipments as required, including:
    - Review of the costs of any new regulatory proposals affecting the transport of radioactive materials;

- Review of all ports in the EU to establish their ability to handle radioactive materials, including restrictions in terms of times and paperwork;
- Legal review of the barriers reported as being currently in place due to diverging implementation of directives.

The EC and industry are best placed to lead on this recommendation.

7. Ensure the transparency of reports related to transport of radioactive material, and encourage the publication of other relevant information. Consider making use of a simple consolidated report as an efficient means of promulgating information.

Ensure that the report remains simple, but consider including the following:

- Collecting consolidated incident data;
- Conducting a peer review of the data;
- Assessing public exposure information (see BSS Directive Article 66).

The EC and Member States are best placed to lead on this recommendation.

8. Continue and coordinate reviews of the need for necessary safety improvements.

Consider building on existing groups (e.g. EACA, MedNet) for reviews of regulatory issues. In addition, establish a prioritised list of issues which may require significant changes to regulations, including:

- Air segregation requirements;
- Administrative requirements for former fissile-excepted material;
- Definition of waste. The European Commission will decide whether there is a need for an activity;
- Consideration of ageing management of dual-purpose casks prior to loading;
- Examination of issues related to self-approved packages, including current best practices.

The EC and Member States' Competent Authorities are best placed to lead on this recommendation.

9. Consider adopting the simplest means of encouraging harmonised compliance, mainly through the production of guidance documents. Important aspects, such as those listed below, should be identified and prioritised.

- Establish a prioritised list of guidance documents, considering:
    - Consignor and carrier responsibilities (taking into account the ADR);
    - Application of the graded approach in compliance assurance;
    - Assessment of public exposure (see BSS Directive Article 66).
- Produce the documents on a prioritised basis;
- Establish a transport operational learning forum for industry for producing guidance from lessons learned.

Member States' Competent Authorities are best placed to lead on this recommendation.

Some additional items that were identified by the Stakeholder Group as worth noting are presented in an annex[7] to the report. In conclusion, it can be stated that **there is effective response from Member States to issues related to transport of radioactive materials**, although specific concerns remain. Addressing concerns in a targeted manner appears to be most appropriate. This approach does not require extensive efforts, although improving information sharing remains essential for the radioactive materials transport sector.

The importance of the new regional groups EACA and MedNet became clear through this project, and there would be clear synergies should the European Commission choose to engage further with these bodies.

[7] In the process of refining the work to be carried out to produce a manageable list, a number of items were removed at the second workshop. However, a request was made that these items should be retained for future reference. These items are also presented in the respective annex to the report.

RESUME

Les informations et points de vue exposés dans ce rapport sont ceux des auteurs et ne reflètent pas nécessairement l'opinion officielle de la Commission. La Commission ne garantit pas l'exactitude des données incluses dans cette étude. Ni la Commission ni aucune personne agissant au nom de la Commission ne peut être tenue responsable de l'utilisation qui pourrait être faite des informations qui y figurent.

Les avantages de l'espace commun de l'UE comprennent non seulement l'amélioration de la production économique, mais également la protection des citoyens de l'UE contre les dangers, où qu'ils résident et où qu'ils se rendent. Dans cette perspective, le transport de matières radioactives doit respecter les plus hauts niveaux de sûreté et de sécurité, et les réglementations et leur mise en œuvre doivent être harmonisées entre les États membres de l'UE. Cela garantirait des transports sûrs et sécurisés, réduirait les obstacles au commerce et éliminerait les différences, même mineures, entre les réglementations / législations et les pratiques de chaque État membre. En outre, étant donné les grandes quantités de substances radioactives transportées dans l'UE (estimées à 3 millions de colis par an), la confiance du public et la transparence qui en découle doivent être garanties.

L'adoption des principales directives de l'UE en matière de radioprotection et de sûreté nucléaire, y compris les normes de sûreté de base[8], ainsi que des directives sur la sûreté nucléaire[9] et les expéditions[10], ont également un impact sur le transport de matières radioactives. Tous les États membres de l'UE ont déjà finalisé ou sont sur le point de finaliser la transposition de ceux-ci dans la législation nationale. Cela constitue un moment très opportun pour examiner et analyser de manière exhaustive l'état du transport de matières radioactives dans l'UE. Cette analyse vise à identifier les améliorations qui seront éventuellement nécessaires au niveau de l'UE ou des États membres, afin de garantir les normes de sûreté et de sécurité les plus élevées. Il s'agit également d'examiner la transparence, de dissiper le manque de confiance et de renforcer la confiance du public dans le transport de matières radioactives. Commencer l'étude maintenant était également considérée comme opportun, car aucune évaluation systématique de l'état du transport de matières radioactives dans l'Union Européenne n'a été entreprise depuis plus de dix ans.

Ce rapport documente les conclusions du projet de la DG ENER de la Commission Européenne intitulé "Examen approfondi et analyse de la situation du transport de matières nucléaires", qui évalue la situation actuelle dans ce secteur par rapport à des critères établis de manière objective, qui tiennent compte des dernières évolutions et perspectives scientifiques et technologiques en matière de transport de matières radioactives.

CONTEXTE, PORTÉE ET APPROCHE

Le transport des matières radioactives est réglementé au niveau international par un système de conventions et d'exigences techniques (pour les transports sur routes, voies ferrées, voies navigables, maritimes et aériennes), qui reposent toutes sur des exigences techniques définies par l'Agence internationale de l'énergie atomique. Au niveau de l'Union Européenne, certains aspects du transport de matières radioactives sont couverts par le traité sur l'Union Européenne et d'autres par le traité Euratom, par diverses directives (ou réglementations), y compris la Directive 2008/68/EC sur le transport intérieur de marchandises dangereuses sur le transport intérieur de marchandises dangereuses. Ce système complet est en place depuis plusieurs décennies et vise à fournir un cadre dans lequel le transport transfrontalier de matières radioactives doit être effectué sans entraves inutiles, de manière à la fois sûre et sécurisée.

Cette étude a réalisé un examen et des analyses approfondis de la situation du transport de matières nucléaires dans les États membres de l'Union Européenne, avec une implication importante des praticiens du transport des

[8] 2013/59/EURATOM
[9] 2014/87/EURATOM
[10] 2006/117/EURATOM

États membres (y compris les régulateurs et l'industrie), organisée par le biais d'une participation active au « groupe de parties prenantes » du projet. Des données ont été collectées auprès de tous les États membres de l'UE[11], à la fois sur des questions relatives aux régimes de réglementation et aux activités réelles liées aux transports.

Un accent particulier a été mis sur les examens de l'infrastructure, l'infrastructure et l'expérience de l'industrie, en particulier le transport transfrontalier, et l'infrastructure réglementaire, y compris les réglementations et pratiques nationales relatives à la sûreté et à la sécurité, et portant sur des sujets aussi divers que les examens de conception (p. ex., des conteneurs de transport) et les exigences en matière de préparation et d'intervention en cas d'urgence. Les problèmes spécifiques relatives au transport des matières radioactives évaluées dans le cadre de cette étude comprennent l'efficacité du régime réglementaire, les examens par l'État et par les pairs, les déchets radioactifs, les niveaux d'exemption et d'autorisation, le vieillissement des colis de transport, le refus des expéditions ainsi que les bonnes pratiques en matière de mise en œuvre ou de réglementation du transport, de documentation et de coûts du transport.

L'application de la directive BSS sur les normes de sûreté de base, y compris ses nouvelles exigences relatives au transport de matières radioactives, a été évaluée en détail. Ceci est particulièrement important pour identifier les lacunes et les chevauchements possibles dans la législation de l'Union Européenne qui pourraient être mieux traités au niveau de l'Union Européenne.

L'élément clé de la mise en œuvre du projet a été la création du groupe des parties prenantes, qui représente de vastes intérêts et responsabilités pour le transport de matières radioactives dans l'UE. Le groupe des parties prenantes comprenait des représentants de la Commission Européenne, des États membres (principalement des autorités compétentes), des parties prenantes de l'industrie et d'autres organismes ayant un intérêt dans le domaine. Le groupe des parties prenantes a été créé au début du projet, pour guider les activités du projet, y compris la finalisation des sujets à étudier et la sélection des thèmes pour les études de cas. Plus important encore, le groupe des parties prenantes a été chargé d'examiner en profondeur les conclusions et les recommandations formulées dans le cadre du projet. Par conséquent, toutes les recommandations détaillées dans le rapport ont été entièrement examinées et approuvées par le groupe des parties prenantes.

Deux ateliers de travail du groupe des parties prenantes ont été organisés dans le cadre de ce projet, le premier pour discuter des résultats intermédiaires et le second pour examiner, discuter, convenir des conclusions de l'étude et approuver ses recommandations.

Un vaste questionnaire couvrant tous les éléments d'intérêt pour le transport de matières radioactives dans l'UE a été conçu par l'équipe du projet, puis examiné et approuvé par le groupe de travail de la Commission Européenne et les membres du groupe des parties prenantes. Le questionnaire final a été distribué aux points de contact désignés pour le transport de matières radioactives dans tous les États membres de l'UE. Les réponses reçues ont été examinées, clarifiées, finalisées et enregistrées dans une base de données. Dans certains cas, des renseignements supplémentaires ont été demandés dans un questionnaire de suivi. Les réponses des États membres ont été évaluées et les résultats obtenus sont présentés dans le rapport, tandis que les réponses détaillées figurent dans les annexes thématiques du rapport.

EVALUATION GLOBALE

L'objectif de ce projet était une évaluation globale de la situation du transport de matières radioactives dans l'Union Européenne. Par conséquent, pour recueillir des renseignements exacts et complets, un questionnaire détaillé couvrant tous les domaines d'intérêt a été élaboré. Le questionnaire a été examiné par le groupe des parties prenantes et, après un pré-remplissage pilote, il a été envoyé aux points de contact désignés dans tous les États membres de l'UE. Les réponses au questionnaire, y compris les clarifications de suivi entreprises par l'équipe projet chaque fois que des doutes existaient, ont permis d'examiner de manière exhaustive la situation

[11] Un total de 25 États membres ont participé à l'étude (le Portugal et Chypre n'ont pas répondu, alors que la Hongrie a soumis les informations après la conclusion de l'étude).

dans l'ensemble de l'Union Européenne. Les faits saillants des constatations en ce qui a trait aux domaines particuliers sont les suivants :

INFRASTRUCTURE ET PRATIQUES DE TRANSPORT

- Environ 3 000 000 colis ont été expédiés dans l'UE en un an.
- Le nombre moyen de colis par envoi était de deux.
- La majorité des colis expédiés n'avaient pas besoin de l'approbation de l'autorité compétente.
- Un envoi de seulement 3 % à 9 % (selon les États membres) des colis devait être approuvé avant d'être expédié.
- La majorité des colis, soit 89 %, ont été expédiés par la route. 8,5 % des colis ont été expédiés par avion.
- La majorité des colis ont été expédiés à des fins médicales et industrielles :
    - 60 % des colis ont été expédiés à des fins médicales.
    - 25 % ont été expédiés à des fins industrielles.
- Les changements dans le transport de matières radioactives à travers l'UE, en termes de quantité et d'organisation au cours des 20 prochaines années, ne devraient pas être significatifs.
- Les ressources mises à la disposition des autorités/régulateurs compétents semblent diminuer par rapport à la demande.

INFRASTRUCTURE ET PRATIQUES DE RÉGLEMENTATION

Assurer la conformité avec les réglementations et les exigences est l'élément le plus important pour garantir la sûreté et la sécurité du transport des matières radioactives. Douze domaines de conformité définis dans les documents guide de l'AIEA ont fait l'objet d'une enquête détaillée :

- Environ 75 % des États membres ont un seul régulateur pour le transport de matières radioactives, couvrant tous les modes de transport.
- En général, les exigences réglementaires étaient pleinement en place. Presque tous les États membres se sont pleinement conformés aux réglementations en matière de transport (telles que définies dans la directive 2008/68/EC) :
    - Deux États ont reconnu qu'ils ne se conformaient pas entièrement à la directive 2008/68/EC au début de l'étude.
    - Cinq États ont choisi de s'écarter de la directive 2008/68/EC dans certains domaines.
- Il existe des variations dans les exigences relatives aux pratiques d'enregistrement pour l'activité (transport de matières radioactives) en vertu des réglementations sur la radioprotection. Cela peut entraîner une variation importante dans la mise en œuvre des exigences en matière de radioprotection pendant le transport.
- La surveillance, l'inspection et les contrôles des colis qui ne sont pas soumis à l'approbation de l'autorité compétente semblent peu nombreux.
- Au cours des cinq dernières années, moins de la moitié des États membres ont approuvé un colis, ce qui indique une disponibilité limitée des ressources réglementaires pour ce domaine spécialisé.
- Il y a des indications que certains États membres n'étaient peut-être pas au courant des opérations de transport qui se déroulaient sur leur territoire et qui appuyaient une pratique de transport qui se déroulait dans un autre État membre.
- Il y a de grandes variations dans les responsabilités en matière de préparation et d'intervention en cas d'urgence par État membre/mode/activité, dont certaines n'étaient pas uniformes. Dans de nombreux États membres, il semble y avoir un manque de coordination entre l'intervention d'urgence radiologique et l'intervention d'urgence en matière de transport.
- Les ressources réglementaires semblent limitées, ce qui indique que les organismes de réglementation n'ont pas investi autant que nécessaire dans la formation.
- Environ seulement 25 % des États membres ont un programme d'évaluation de l'exposition radiologique du public, ce qui semble être une lacune importante dans la mesure de l'efficacité de la conformité.

MISE EN ŒUVRE DE LA BSS POUR LES PRATIQUES DE TRANSPORT

Un aspect important du projet a été l'évaluation de la mise en œuvre de la directive sur les normes de sécurité de base (BSS) dans le domaine du transport des matières radioactives. D'une manière générale, la directive devrait aboutir à une application harmonieuse des exigences relatives aux transports, mais cela ne semble pas avoir été achevé au moment de l'étude. Il semble y avoir une application variée de l'approche graduée dans différents États membres, ce qui entraîne des différences dans des domaines tels que la notification, l'octroi de licences et l'autorisation. Les variations dans la réglementation concernant le transport à faible niveau de risque peuvent entraîner une charge injustifiée.

CONCLUSIONS

L'étude a donné lieu à diverses conclusions à différents niveaux. La conclusion générale est que la situation générale du transport des matières radioactives pourrait être jugée très bonne, avec peu de problèmes. En particulier, en ce qui concerne le « refus d'expédition », il y a une réduction importante du nombre de ces événements. Même lorsque cela se produit, il semble que ces événements soient dus à des documents incomplets et à des causes similaires.

Il y a très peu d'événements liés à la sûreté pendant le transport et pratiquement aucune indication d'événements de surexposition. De plus, les résultats des inspections effectuées montrent une réduction continue du nombre de constats.

Quelques autres résultats spécifiques, regroupés en quatre domaines d'intérêt, sont résumés ci-dessous.

SITUATION DES DISPOSITIONS EXISTANTES DANS LES ÉTATS MEMBRES DE L'UE

L'état actuel des activités et des dispositions des industries et des organismes de réglementation en matière de transport de matières radioactives dans l'UE est décrit en détail à la section 6 et à l'annexe 4 du rapport. La principale conclusion est que l'industrie remplit son rôle et n'échoue pas et/ou ne change pas de façon spectaculaire. L'une des principales constatations est l'échec pour utiliser les dispositions existantes pour garantir la disponibilité d'informations précises sur le transport de matières radioactives dans l'UE. Les données statistiques exigées par les réglementations et directives de l'UE sont enregistrées dans la base de données d'Eurostat sur les transports. Les réponses montrent que l'information recueillie dans la base de données est très différente de la réalité et pourrait être améliorée. La législation est en place au niveau européen pour permettre une meilleure collecte des données, mais elle n'a pas été pleinement mise en œuvre par tous les États membres de l'UE.

Les dispositions juridiques au niveau de l'UE ont connu des changements importants ces dernières années. Un certain nombre d'exigences législatives différentes, tant les réglementations que les directives de l'UE, ont une incidence sur différents aspects du transport de matières radioactives. En raison des objectifs et des fondements juridiques différents de certains de ces dispositions, il y a des domaines où leur application doit encore être clarifiée. Il est important de noter que la législation sur les transports est conçue pour assurer le bon déroulement des transports transfrontaliers, ce qui a été réalisé à quelques exceptions près. La législation sur la radioprotection tend à être plus orientée sur la fixation d'objectifs, ce qui permet aux États de varier les exigences. Cela conduit à introduire des dispositions transfrontalières différentes, compromettant ainsi le transport transfrontalier harmonieux de matières radioactives.

Dans l'ensemble, les dispositions existantes spécifiques au transport sont pleinement mises en œuvre dans la plupart des États membres (avec quelques variations mineures), à l'exception de la collecte et du partage des données. La législation sur la radioprotection, qui est plus générique, est mise en œuvre dans une mesure variable dans les États membres. Plusieurs domaines pourraient bénéficier d'une plus grande clarté dans l'application aux transports. La section 9 du rapport présente un examen détaillé de la façon dont chaque État membre a appliqué les exigences de radioprotection au transport. La directive sur les expéditions s'applique à un très faible pourcentage des expéditions de matières radioactives et présente quelques chevauchements avec la législation sur le transport.

L'évaluation a permis de conclure qu'il existe des besoins limités en matière de modification ou même de nouvelle législation, mais qu'un accord sur la mise en œuvre par le biais d'un document guide et/ou d'une compréhension mutuelle dans l'ensemble des États membres sont les solutions les plus susceptibles d'apporter des améliorations dans les domaines où elles sont nécessaires.

PRINCIPALES LACUNES ET INCOHÉRENCES

Les lacunes et les incohérences dans la mise en œuvre des directives pour le transport de matières radioactives à travers l'UE ont été évaluées. Les conclusions sont documentées à la section 5.3.1 du rapport. Une des conclusions importantes est qu'il y a des chevauchements dans les dispositions existantes plutôt que des lacunes. Il a été constaté que les exigences des réglementations sur le transport sont beaucoup plus précises que celles des réglementations sur la radioprotection. En outre, les réglementations sur le transport contiennent une certaine souplesse d'utilisation pour faciliter leur application (des exigences plus strictes peuvent ne pas être appliquées) qui n'est pas présente dans les réglementations sur la radioprotection. Le retrait de dispositions de facilitation pour la législation sur les transports ou l'ajout d'un objectif de facilitation aux réglementations sur la radioprotection n'est probablement pas viable, de sorte que cette différence sera probablement maintenue. La meilleure façon de gérer cela serait de procéder à une mise en œuvre guidée. Dans l'ensemble, il ne semble pas y avoir de lacunes dans la législation.

Néanmoins, il pourrait être nécessaire de régler le chevauchement des législations qui a donné lieu à des interprétations variables, ce qui pourrait potentiellement créer des lacunes. Les tableaux 37, 38 et 39 du rapport fournissent des détails sur les différences dans la mise en œuvre des exigences liées à la préparation et l'intervention en cas d'urgence.

L'analyse de la situation a permis d'identifier des lacunes dans la collecte et le report de données. Des améliorations dans ce domaine sont attendues pour aider à identifier les problèmes en développement. Il existe de bonnes pratiques dans certains États membres. Des améliorations volontaires de la part des États membres grâce à l'échange de bonnes pratiques seraient bénéfiques et pourraient être appuyées par l'action de la Communauté Européenne.

Il y avait peu d'information sur la question de savoir s'il y avait un niveau approprié de surveillance des colis qui ne nécessitent pas l'approbation de l'autorité compétente. Le niveau d'inspection des colis qui ne nécessitent pas d'approbation semble faible. Une plus grande transparence sur la façon dont les niveaux d'inspection sont calculés serait un avantage pour l'assurance du public.

La préparation et l'intervention en cas d'urgence pour le transport de matières radioactives est le seul domaine où des mesures urgentes sont suggérées.

Dans l'ensemble, l'étude a révélé qu'il est nécessaire d'améliorer la transparence grâce à la collecte de données et à l'échange d'informations, et que le niveau de sûreté pourrait être amélioré grâce à la production de documents guide ciblés.

UTILITÉ DES EXAMENS PAR LES PAIRS

L'utilité des examens par les pairs a été particulièrement abordée dans l'étude. Les données sur les examens par les pairs et les autres examens actuellement mis en œuvre sont disponibles dans la section 8 du rapport, alors que l'annexe 2 fournit des extraits des rapports des missions IRRS pour les États membres qui incluaient le transport de matières radioactives dans la portée de ces services AIEA de haut niveau d'examen par les pairs.

Pour le transport aérien, il existe un système international efficace d'examens portant également sur les marchandises dangereuses (c.-à-d. y compris les matières radioactives). Ce système est exploité par l'ICAO et couvre tous les États membres de l'ICAO (y compris les 28 États membres de l'UE). Un système similaire s'applique au transport maritime. Les examens dans les transports aériens et maritimes peuvent être utilisés comme données d'entrée pour l'examen du transport des matières radioactives. Cependant, peu d'États membres semblent être au courant de cette possibilité.

Pour le transport routier et ferroviaire, les missions IRRS de l'AIEA pourraient fournir des examens de base. Plus de la moitié des États membres de l'UE ont choisi d'inclure le transport dans leur mission IRRS. Ces examens portent sur des questions de réglementation et semblent donner lieu à des suggestions parfois contradictoires en ce qui concerne la mise en œuvre.

L'AIEA offre un service appelé TranSAS, qui est plus spécifique au transport et donc plus complet. Néanmoins, l'accueil d'une telle mission exige des ressources assez importantes. Seuls deux États membres de l'UE ont profité de cet examen par les pairs, et les missions associées ont été mis en œuvre il y a longtemps. L'AIEA a mis au point une version TranSAS moins exigeante en ressources (mini-TranSAS) pour l'application dans les régions en voie de développement. Jusqu'à présent, ce service n'a pas été déployé en Europe, bien qu'un tel style d'examen pourrait être utile dans les États membres de l'UE. L'avantage supplémentaire d'une mini-TranSAS est qu'elle encourage les États voisins à travailler ensemble. En tant que telle, elle serait efficace comme moteur pour l'amélioration de l'harmonisation.

Il y a des avantages évidents à utiliser les examens par les pairs en termes de transparence et d'assurance du public, et leur utilisation est recommandée.

PROPOSITIONS DE DOMAINES D'AMÉLIORATION

L'objectif de l'analyse entreprise dans le cadre de cette étude était d'identifier les domaines dans lesquels des améliorations dans les dispositions et/ou la réglementation pourraient conduire à un transport plus sûr et plus sécurisé des matières radioactives, offrant une meilleure protection de la population, mais aussi l'amélioration du commerce à travers l'UE. De plus, des domaines où la transparence pourrait favoriser une plus grande acceptation par le public ont été examinés. Un processus analytique a été utilisé pour déterminer les principales recommandations qui offriraient le maximum d'avantages dans une vaste gamme de domaines. Ce processus a porté sur les connaissances et l'expérience en matière de transport de matières radioactives à travers l'UE et a inclus les points de vue et les opinions du groupe des parties prenantes. L'annexe 7 fournit des renseignements sur le processus par lequel ces recommandations clés ont été élaborées et peaufinées avec la participation active des parties prenantes.

Les domaines d'amélioration proposés, en plus de diverses propositions spécifiques discutées ensuite, comprennent :

- L'harmonisation de l'évaluation des conteneurs de transport et/ou la reconnaissance mutuelle des certificats. Les organismes de réglementation se sont montrés prudents dans ce domaine, mais ils ont soutenu que le partage plus systématique de l'information est une étape importante. Le partage systématique de l'information peut réduire la pression sur les ressources réglementaires, ce qui est particulièrement pertinent pour les petits organismes de réglementation.
- La préparation et l'intervention en cas d'urgence. Bien qu'il n'y ait eu aucune défaillance manifeste à ce jour, il est important de noter que toute lacune dans ce domaine pourrait être révélée en cas d'urgence. Néanmoins, il est probable que différentes approches des plans de préparation et d'intervention en cas d'urgence seront mises au défi de façon critique, en particulier en cas d'urgence dans le domaine du transport transfrontalier. Ce domaine mérite des conseils et un examen plus approfondi à l'avenir.

RECOMMANDATIONS CLÉS

Les données recueillies au moyen de questionnaires et les informations recueillies lors d'entretiens et d'ateliers de travail avec les parties prenantes confirment que le transport de matières radioactives dans l'UE continue d'avoir un excellent bilan de sûreté. L'évaluation n'a identifié que deux événements liés au transport classés comme INES 2 ou au-dessus, qui ont été signalés dans l'UE au cours des cinq dernières années.

L'étude a examiné l'information fournie par chaque État membre et l'a analysée en détail afin d'identifier les domaines où des améliorations pourraient être apportées. Ceux-ci ont fait l'objet de discussions approfondies avec le groupe des parties prenantes, d'abord par courrier électronique, puis au cours de l'atelier de travail spécifiquement organisé dans le but d'évaluer et de convenir des recommandations clés de l'étude. Dans le cadre de cette interaction, les parties prenantes se sont entendues sur la liste des enjeux potentiels qui devraient être abordés activement.

Bien que la phase initiale de l'étude ait permis d'identifier un certain nombre de défis potentiels, il a été déterminé par la suite que la (grande) majorité d'entre eux étaient bien gérés par l'industrie et/ou les organismes de réglementation. Il s'agit peut-être là d'une des conclusions les plus importantes de l'étude, à savoir que des processus actifs sont en place dans l'industrie et dans les autorités compétentes des États membres de l'UE pour identifier tout problème lié au transport de matières radioactives, et il y a des preuves évidentes que des problèmes sont activement traités. Néanmoins, il reste quelques domaines où des actions sont encouragées ou même nécessaires.

Les défis potentiels identifiés dans l'étude ont été réduits à un certain nombre de questions prioritaires. Une « entité » (par exemple, Commission Européenne, autorité de l'État membre, etc.) qui est la mieux placée pour traiter de chacun de ces problèmes a été identifiée. Les problèmes prioritaires, tels qu'approuvés par le groupe des parties prenantes, comprennent les points suivants :

1. Examiner les différentes dispositions en matière de report, notamment la directive du Conseil 2006/117/Euratom et son document type unique, ainsi que le règlement 1493/93, qui traitent des reports d'information sur le transport :

    - Définir les objectifs pour la simplification des exigences de communication d'informations.

La Commission Européenne est la mieux placée pour diriger cette recommandation.

2. Établir une meilleure communication entre les autorités compétentes en se basant sur les meilleures pratiques existantes en ce qui concerne l'évaluation de la conception des colis, renforçant ainsi l'harmonisation et le calendrier de l'évaluation réglementaire :

    - Communiquer entre autorités compétentes sur l'évaluation des colis.

Les autorités compétentes des États membres sont les mieux placées pour diriger cette recommandation.

3. Mettre en place un système européen d'information sur les colis, en tenant compte de l'expérience acquise avec le système PACKTRAM de l'AIEA. L'étendue de l'information stockée et les colis enregistrés seraient établis dans le cadre de la phase de planification. La mesure dans laquelle cela pourrait permettre de simplifier l'échange d'informations sur les colis ne nécessitant pas l'approbation de l'autorité compétente mérite d'être examinée, en prenant en compte les éléments suivants :

    - Sur la base de l'expérience acquise avec PACKTRAM, identifier les informations utiles (et les informations qui créent une charge pour la collecte) ;
    - Déterminer si un système existant peut être adapté à l'objectif ;
    - Déterminer les spécifications du système, incluant au minimum les informations relatives à l'approbation du colis (par exemple, le type de colis, la date d'approbation, la date d'expiration, etc.) ;
    - Envisager l'hébergement/l'accueil et l'exploitation à long terme (par exemple, JRC)
    - Créer un système d'information et le renseigner à partir de données existantes ;
    - Définir un système durable pour la maintenance de la base de données.

La Commission Européenne et les autorités compétentes des États membres sont les mieux placées pour diriger cette recommandation, mais elles auront besoin d'une large participation et du soutien de l'industrie.

4. A court terme, améliorer le niveau de formation des organismes de réglementation, de l'industrie et des premiers intervenants ; à long terme, établir un système complet de renforcement des capacités, reflétant éventuellement les bonnes pratiques du Royaume-Uni.

A court terme :

- Développer la formation croisée des experts des transports et des experts en radioprotection.

A long terme :

- Rassembler les informations de manière coordonnée sur les exigences à court et à long terme ;
- Établir un programme coordonné (y compris des partenariats entre l'industrie et les régulateurs) pour développer les compétences adéquates en matière de transport.

Les États membres sont les mieux placés pour diriger cette recommandation.

5. Assurer une coordination efficace entre les groupes traitant des différents aspects de la sûreté des matières radioactives, en renforçant la communication entre experts via des technologies modernes :

- Partager les contacts des experts des États membres entre les trois groupes (radioprotection, déchets et transport) afin d'encourager la coordination au niveau national (en faisant appel à des groupes tels que l'EACA) ;
- Établir des points de contact de la Commission Européenne pour chaque groupe et veiller à ce que les informations sur les avis d'experts et les propositions soient partagées.

La Commission Européenne est la mieux placée pour diriger cette recommandation.

6. Attribuer la responsabilité de faciliter le transport des matières radioactives à un groupe d'organismes industriels de la Commission Européenne et des États membres, qui sont séparés des autorités compétentes. L'une des tâches initiales pour un tel groupe consiste à examiner tous les ports de l'Union Européenne afin d'établir leur capacité à traiter des matières radioactives, y compris des restrictions en termes de temps et de paperasse. En outre, la proposition consiste à effectuer un examen juridique des obstacles actuellement en place :

- Demander aux États Membres de désigner un organe directeur non réglementaire pour faciliter le transport de matières radioactives et veiller à ce que cela soit rendu public ;
- Mettre en œuvre des activités liées au refus d'expédition, selon les besoins, y compris :
  - Examen des coûts de toute nouvelle proposition de réglementation concernant le transport de matières radioactives ;
  - Examen de tous les ports de l'UE pour établir leur capacité à traiter des matières radioactives, y compris des restrictions en termes de temps et de paperasserie ;
  - Examen juridique des obstacles signalés comme étant actuellement en place en raison de mises en œuvre divergentes des directives.

La Commission Européenne et l'industrie sont les mieux placées pour diriger cette recommandation.

7. Assurer la transparence des rapports relatifs au transport de matières radioactives et encourager la publication d'autres renseignements pertinents. Envisager d'utiliser un simple rapport consolidé comme moyen efficace de diffuser l'information

S’assurer que le rapport reste simple, mais tenir compte des points suivants :

- Collecte de données consolidées sur les incidents ;
- Réalisation d’un examen par les pairs des données ;
- Évaluation des informations sur l'exposition du public (voir l'article 66 de la Directive BSS).

La Commission Européenne et les États membres sont les mieux placés pour diriger cette recommandation.

8. Poursuivre et coordonner les examens des besoins en améliorations nécessaires en matière de sûreté.

Envisager de s’appuyer sur les groupes existants (par exemple, EACA, MedNet) pour examiner les problèmes réglementaires. En outre, établir une liste priorisée de problèmes pouvant nécessiter des modifications importantes des réglementations, notamment :

- Exigences sur la séparation de l'air ;
- Exigences administratives applicables aux anciennes matières, exceptées les matières fissiles ;
- Définition des déchets : la Commission Européenne décidera si une activité est nécessaire ;
- Prise en compte de la gestion du vieillissement des fûts à double usage avant le chargement ;
- Examen des problèmes liés aux colis auto-approuvés, y compris les meilleures pratiques actuelles.

La Commission Européenne et les autorités compétentes des États membres sont les mieux placées pour diriger cette recommandation.

9. Envisager d'adopter le moyen le plus simple d'encourager une conformité harmonisée, principalement par la production de documents guide. Les aspects importants, tels que ceux énumérés ci-dessous, doivent être identifiés et hiérarchisés :

- Établir une liste prioritaire de documents guide, en tenant compte :
  - Des responsabilités de l'expéditeur et du transporteur (en tenant compte de l'ADR) ;
  - De l’application de l'approche graduée dans l’assurance de la conformité ;
  - De l’évaluation de l’expositions du public (voir la directive BSS, article 66).
- Produire les documents par ordre de priorité ;
- Créer un forum d’apprentissage opérationnel sur les transports à l’intention de l’industrie afin de fournir des conseils à partir des enseignements retenus.

Les autorités compétentes des États membres sont les mieux placées pour diriger cette recommandation.

Certains éléments supplémentaires, qui ont été jugés comme notables par le groupe des parties prenantes, sont présentés dans une annexe[12] au rapport.

[12] Dans le processus d'affiner le travail à effectuer pour produire une liste gérable, un certain nombre d'éléments ont été retirés lors du deuxième atelier de travail. Cependant, il a été demandé de conserver ces éléments pour référence future. Ces points sont également présentés dans l'annexe respective du rapport.

En conclusion, on peut affirmer que **la réponse des États Membres aux problèmes de transport des matières radioactives est efficace**, bien que des préoccupations spécifiques demeurent. Il semble plus approprié de répondre aux préoccupations de façon ciblée.

Cette approche ne nécessite pas d'efforts considérables, bien que l'amélioration du partage de l'information reste essentielle pour le secteur du transport de matières radioactives.

Ce projet a mis en lumière l'importance des nouveaux groupes régionaux EACA et MedNet. Des synergies seront clairement créées si la Commission Européenne décide de s'engager.

DISTRIBUTION LIST[13]

COMPETENT AUTHORITIES

Name	Country
Mr Friedrich KIRCHNAWY	Austria
Mr Guy LOURTIE	Belgium
Ms Lyudmila SIMEONOVA	Bulgaria
Mr Boris ILIJAŠ	Croatia
Ms Marina AVGOUSTI	Cyprus
Mr Vlastimil DUCHACEK	Czech Republic
Ms Marie LUNDGAARD DAVIDSDOTTIR	Denmark
Mr Rando PAURSON **Mr Teet KOITJÄRV**	Estonia
Mr Santtu HELLSTÉN	Finland
Mr Thierry CHRUPEK	France
Mr Helmut REIN **Ms Ina LENNARZ**	Germany
Ms Stavroula VOGIATZI	Greece
Mr Josef SAFAR	Hungary
Mr Jarlath DUFFY	Ireland
Mr Sandro TRIVELLONI	Italy
Mr Dace SATROVSKA	Latvia
Mr Vaidas STATKUS	Lithuania
Mr Patrick MAJERUS	Luxembourg
Mr Paul BREJZA	Malta
Mr Mathieu TER MORSHUIZEN	Netherlands
Mr Adrian JAKOWIUK	Poland
Ms Luisa COSTA	Portugal
Mr Tite FIERBINTU	Romania
Ms Alena BUJNOVÁ	Slovakia
Ms Polona TAVCAR	Slovenia
Mr Fernando ZAMORA MARTIN	Spain
Mr Helmuth ZIKA	Sweden
Mr Iain DAVIDSON **Mr Simon CLARK**	United Kingdom

REPRESENTATIVES OF INTEREST GROUPS

Name	Interest Group
Dr Ingo REICHE	BFE
Mr Tiberio CABIANCA	CRCE
Mr Rob DEKKERS	GE Healthcare
Mr Peter BANKS	Green Party
Mr Tim ELWELL	NDT LTD
Dr Adrian HALL	Royal Marsden Hospital
Mr Serge GORLIN	WNA
Mr Steven CRANE	AREVA
Mr Thomas SICKERT	ISSPA
Mr Roger SPAUTZ	Greenpeace

[13] Stakeholders Group members having contributed to the project from the beginning and during both Workshops.

Name	Interest Group
Ms Anne PRESTA	WTNI
Mr Olivier KERVELLA	UNECE
Mr Steve WHITTINGHAM	IAEA
Mr Florian SPIELMANN	URENCO
Mr Thomas KLUTH	SIEMPELKAMP
Mr Roland CHAVASSE	TIC

EUROPEAN COMMISSION[14]

Name	Department
Michael KUSKE	DG ENER D1
Ghislain PASCAL	DG ENER D1
Ildiko KOVACS	DG ENER D1
Simon MURPHY	DG ENER D2
Olivier COLLARD	DG ENER D3
Ferenc LIPCSEI	DG ENER E1
Marie France HAUPT	DG ENER E1
Niina PALOMÄKI	ESA
Monica STANCIU	DG MOVE
Roberto FERRAVANTE	DG MOVE
Manuel MARTIN RAMOS	JRC
Wiktor WOJTAS	DG HOME D2
Foivos MARIAS	DG RTD

CONSULTANT

Name	Company
James STEWART	ENCO
Bojan TOMIC	ENCO
Oana VELICU	ENCO
Erwin FRUEHWIRT	ENCO
Karin LEROCH	ENCO
Susanne CZERNY	ENCO
Madalina BUDU	ENCO
Ghandikota RAMESH (professional editor)	ENCO

[14] European Commission Task Force members having contributed to the project from the beginning and during both workshops.

COUNTRY ABBREVIATIONS

Code	Country
AT	Austria
BE	Belgium
BG	Bulgaria
HR	Croatia
CY	Cyprus
CZ	Czech Republic
DK	Denmark
EE	Estonia
FI	Finland
FR	France
DE	Germany
EL	Greece
HU	Hungary
IE	Ireland
IT	Italy
LV	Latvia
LT	Lithuania
LU	Luxembourg
MT	Malta
NL	Netherlands
PL	Poland
PT	Portugal
RO	Romania
SK	Slovakia
SI	Slovenia
ES	Spain
SE	Sweden
UK	United Kingdom

ABBREVIATIONS USED IN THIS REPORT

Abbreviation	Meaning
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IAEA BSS	IAEA Basic Safety Standards
BSSD, BSS Directive	Basic Safety Standards Directive
CA	Competent Authority
COTIF	Convention concerning International Carriage by Rail
CPPNMNF	Convention on the Physical Protection of Nuclear Materials and Nuclear Facilities
CRP	Coordinated Research Project (IAEA)
CSI	criticality safety index
CTF	Commission Task Force
DG ENER	Directorate-General for Energy
DGSA	Dangerous goods safety advisor
DPC	dual purpose cask
EACA	European Association of Competent Authorities[15]
EPR	Emergency preparedness and response
EURATOM	European Atomic Energy Community
HASS	high-activity sealed radioactive sources and orphan sources
IAEA	International Atomic Energy Agency
ICAO	International Civil Aviation Organization
ICAO TI	ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air
IMO	International Maritime Organization
IMO IMDG	International Maritime Dangerous Goods Code
INES	International Nuclear and Radiological Event Scale
INLEX	International Expert Group on Nuclear Liability
IRPA	International Radiation Protection Association
IRRS	Integrated Regulatory Review Service (IAEA)
MedNet	Mediterranean network for the safe transport of radioactive material
MS	European Union Member State. When an undefined State is referred to, possibly from outside the European Union (e.g. during mentions of cross-border shipments), 'State' is used.
nfi	N/A or No answer
NGO	non-governmental organisation
N/K	Not known
NSD	Nuclear Safety Directive
NORM	naturally occurring radioactive materials
ONR	Office of Nuclear Regulation (UK)
OECD/NEA	Organisation for Economic Co-operation and Development/Nuclear Energy Agency
OSJD	Organisation for Co-operation between Railways
OTIF	Intergovernmental Organisation for International Carriage by Rail
PHE	Public Health England
PPE	personal protective equipment
RID	Regulations concerning the international carriage of dangerous goods by rail
RAM	radioactive materials
RPP	radiation protection programme
RTF	radioactive traffic factor

[15] Includes MedNet

Abbreviation	Meaning
SG	Stakeholders Group
SMGS	Agreement on International Goods Transport by Rail
SOLAS	International Convention for the Safety of Life at Sea
SSR-6	Regulations for the Safe Transport of Radioactive Material (IAEA)
SWG	Standing Working Group
TECDOC	Technical Document (IAEA)
TFWG	Transport Facilitation Working Group
TI	Transport Index
TRAM	Transport of radioactive material
TranSAS	Transport Safety Appraisal Service (IAEA)
TRANSSC	Transport Safety Standards Committee (IAEA)
TSO	Technical Support Organisation
UNECE	United Nations Economic Commission for Europe
WASSC	Waste Safety Standards Committee (IAEA)
WNA	World Nuclear Association
WNTI	World Nuclear Transport Institute

1 INTRODUCTION

The adoption of several major directives (the Basic Safety Standards Directive, Nuclear Safety Directive, Shipment Directive[16]) that also impact the transport sector have made it appropriate to review the status and investigate the challenges related to the transport of radioactive materials in the European Union, and to determine whether the current arrangements are adequate in the light of new safety and security requirements.

This report relates to the DG ENER project "Comprehensive Examination and Analyses of the Situation of Transport of Nuclear Materials", which is aimed at studying the current situation regarding the transport of radioactive materials in EU Member States (MS). It reflects the requirements of the Terms of Reference of the project, the Contractor's tender documents, and the discussions and the agreement reached during the project's kick-off meeting held in Luxembourg on 5 May 2017.

The report is based on the results of a detailed questionnaire and follow up questions, along with the results of investigations by the Consultant, a first workshop held in Brussels and a second one held in Luxembourg, followed by final comments from the Commission Task Force (CTF). The Stakeholder Group (SG) and CTF were involved during this period through consultations, questionnaires, discussions during workshops, as well as the review of draft reports and individual inputs, as appropriate. Close involvement of all relevant stakeholders in the SG and their active participation were very important in obtaining the broadest view and consensus on the further steps to be undertaken in this area, as necessary.

During this study a number of issues were identified which have been analysed to produce conclusions and suggestions for a way forward. While these are addressed in the sections that follow in this report, important general findings were noted.

The data collected and the information obtained from interviews and workshops confirm that the transport of radioactive materials continues to have an excellent safety record. Although issues have been identified, there is clear evidence of effective regulatory and industry response, and no evidence of significant accidents.

Past studies, such as the 5th Report of the Standing Working Group on Safe Transport of Radioactive Materials in the European Union (2006), were also reviewed to avoid duplication. To the extent possible, the results of IAEA Integrated Regulatory Review Service (IRRS) missions and follow-up missions were used as inputs for this study. A description of earlier studies and information from IRRS missions are presented in Annexes A1 and A2 of this report.

Although the study found the situation to be generally positive, the main area that would seem to offer room for improvement was transparency (for example, information on exposures to workers and the public were not readily available).

[16] This is a reference to Council Directive 2006/117/EURATOM of 20 November 2006 on the 'Supervision and Control of Shipments of Radioactive Waste and Spent Fuel', commonly called the 'Shipment Directive'.

2 BACKGROUND

2.1 GENERAL

The transport of radioactive materials is essential to the nuclear industry, though even if nuclear energy is not included, radioactive materials such as medical radioisotopes are important to the economic, health and social well-being of the population.

Prior to the start of this project estimates suggested that around three million packages containing radioactive materials were transported in the EU every year. About 80% of those packages were transported by road, about 8% each by rail and air and the remainder by water (or were unspecified). The transport of sources, in particular medical radioisotopes, was dominant in terms of the number of shipments. With regard to radioactivity, fuel cycle materials —, in particular spent nuclear fuel — dominated, though the number of packages was very small. In the vast majority of cases, radioactive materials were produced at one place and then transported for use to another location. In many cases these transports crossed State borders, particularly radioactive sources, medical isotopes, ores and concentrates, radioactive waste, and fresh and spent fuel.

Regardless of whether the transport is national or across State borders, by its nature this movement gives rise to possible radiological hazards. Many organisations are typically involved, from those producing/generating substances and preparing packages, to shipping agents, carriers and consignees.

To allow smooth transportation, but even more importantly, to minimise the risks to workers, the public and the environment, the transport of radioactive materials is internationally regulated by means of international conventions, agreements and regulations, which also comprise modal conventions and regulations. These include ADR (for road transport), COTIF (RID) and SMGS (for rail transport), ADN (for inland waterways), the Chicago Convention (ICAO Technical Instructions) for air transport, SOLAS (IMDG code) for maritime transport, and most important the UN Model Regulations (the 'Orange Book', summing up all requirements for dangerous goods transport by all modes) and the IAEA Transport Regulations (SSR-6[17]) which cover safety requirements for the transport of radioactive materials. Throughout this report the term "Transport Regulations" is used to denote this collection of requirements.

At the EU level, some aspects of the transport of radioactive materials are covered under by the Treaty on European Union and some under EURATOM Treaty. Under these treaties, there are various Directives (or Regulations), including: Directive 2008/68/EC on the inland transport of dangerous goods; Council Directives laying down Basic Safety Standards (BSS Directive) (2013/59/EURATOM); supervision and control of shipments of radioactive waste and spent fuel (SD) (2006/117/EURATOM); establishing a Community framework for the nuclear safety of nuclear installations (NSD) (2009/71/EURATOM, including the 2014/87/EURATOM amendment); and for the responsible and safe management of radioactive waste and spent fuel (2011/70/EURATOM). These Directives establish important Community requirements for the: nuclear safety of installations and radiation protection; spent fuel and radioactive waste management and supervision and control of shipments; dangerous goods shipments; and creating a framework within which cross-border transport should be conducted without unnecessary hindrances. Further to the EU Directives, various national legal and regulatory documents implementing the international conventions, agreements, regulations and

[17] A new revision of SSR-6 was issued by the IAEA near the end of this study. The final draft of SSR-6 (Rev.1) was taken into account during the study, for consistency with latest applicable standards.

Directives mentioned above establish the framework for the safe and secure transport of radioactive materials in the EU, thereby ensuring that there are no harmful effects to the population or the environment.

A good practice noted at the Community level was the development of a Technical Guide on ‘Package Design Safety Reports for the Transport of Radioactive Material’ (European PDSR Guide Issue 3, December 2014), intended to be used to develop safety reports of package designs within European MS. This Technical Guide significantly minimizes the efforts of Competent Authorities in evaluating applications for certificates of package designs by harmonizing the content of safety reports submitted in support to those applications, and also imposes uniform safety requirements resulting from the preparation of such safety reports (including those for packages not requiring approval by a Competent Authority).

The advantages of the EU’s common area include not only enhancing economic output, but also ensuring that EU citizens, wherever they reside and/or travel, are protected against hazards. From this perspective, the transport of radioactive materials needs to meet the highest levels of safety and security, and the regulations must be harmonized across EU MS. This would assure safe and secure transport, reduce differences in commerce, and eliminate variations, however minor, between the regulations/legislation and practices in each MS.

At present, in addition to licensing issues (e.g. lack of mutual recognition of the approval of transport package/cask designs), there are differences among MS for example, in defining exemption and clearance levels, and in the consideration of naturally occurring radioactive materials. Current transport regulations include the concept of exemption and, to a certain extent, exclusion (where this exceeds exemption levels). As a result, radioactive materials in the activity range between clearance and exemption are not subject to transport regulations but are still often transported. With increased security concerns and portal monitoring this can lead to false alarms and problems. Particular problems are occurring where the clearance levels vary between MS.

Consistent application of rules throughout the EU MS presents a challenge in its own right. A slightly different interpretation of some rules and administrative issues in some MS has been found to impede legitimate transport activities, while not contributing to safety or the security of EU citizens.

2.2 EXPERT GROUPS

A Standing Working Group (SWG) was established by a resolution of the European Parliament (22/1/1982 (OJ C 40/42)). The SWG provided advice to the European Commission over several years on the funding of research including for the following research areas:

- Review of Community status;
- Assessment of risk;
- Harmonised documentation;
- Incident reporting;
- Leading development of international regulations;
- Radiation protection (in particular, contamination).

The SWG ceased operation in 2011. More information is presented in Annex A1.

Two groups of regulators supplied information for this study: the European Association of Competent Authorities (EACA) and the Mediterranean network for the safe transport of radioactive material (MedNet). These are informal groups of Competent Authorities for the transport of radioactive materials, ensuring that: “All activities under the responsibility of Competent Authorities are possible with work focused on the interpretation of the regulatory requirements and implementation of regulatory oversight/intervention, including:

(a) Exchange of information:

- Review of State variations;
    - Issues and initiatives in European countries;
    - Package design assessment issues.

(b) Development of good practice guidance, for example:

- Structure and content of Package Design Safety Reports;
- Radiation protection programme (reduction of doses);
- Packages not requiring competent authority approval;
- Compliance inspection programmes for Competent Authorities.

(c) Development of joint action plans (future intention):

- Joint audits/compliance inspections of duty holders;
- Exchange of staff for training.

(d) Discuss changes to the transport regulations (IAEA, European).

(e) Development of a website for public access."

The EACA was included in the SG and participated in both workshops organised in the framework of this study. It reviewed this report and its comments were implemented in the final version of this report.

3 OBJECTIVES

This study establishes the 'state of the EU' in terms of activities, infrastructure, regulation and application of regulations. It examines these elements to assist in guiding future Union/Community policy and actions. Consequently, the study identifies areas where the Union/Community influence could be most effective.

The objectives of this study are:

- To identify areas where enhancements of transport safety and security are possible and justified, considering the latest scientific and technological advances and reflecting the future scope (i.e. type of radioactive materials and their quantities) and current practices and processes for the transport of radioactive materials, as well as to enable conclusions to be drawn in relation to (potential) areas for improvement.

- To identify areas where transparency could be enhanced and to propose possible solutions in this respect. Such measures should help increase public confidence and 'demystify' the transport of radioactive materials.

This study analyses the current situation in the EU and in each individual MS with regard to the transport of radioactive materials by means of questionnaires and follow-up interviews, and by creating a discussion forum with all involved stakeholders during two workshops. The study identifies gaps with regard to international standards and differences in MS approaches or regulations which make the transport of radioactive materials across MS difficult by creating discontinuity. The outcome of the analysis, after being assessed and discussed by the stakeholders, establishes a basis for improvement, both at the national and Community levels. The recommendations were developed to ensure greater harmonization, considering current and future developments of radioactive material transport, and aim at justified safety and security enhancements.

The study also assesses the level of transparency in MS. Transparency is closely linked to accountability and can be related to the right to understand the decisions made by Competent Authorities. Transparency has several goals, including improvement in the efficiency of public communication and in combating corruption. Of particular relevance for this study was that an acceptable level of transparency was considered to be achieved if pertinent information presented by the MS was:

- Comprehensive;
- Clearly understandable to the audience;
- Open;
- Accessible.

In order to assess transparency, the questionnaires allowed the use of "Not known" as a response. The logic behind this was that responders were chosen with the widest experience on the subject and had the greatest interest in the information requested. Thus, if these responders could not address the questions easily, the answers were unlikely to be open and accessible. In some cases, during the workshops, concern was expressed over the exact meaning of the data and gaps, which questions were valid related to the clarity and understandability of information, and whether comprehensive self-explanatory information was available.

The conclusions drawn on transparency were based on all of these aspects, having been treated as a measure of the ease with which a member of the public could become informed about the activities of the State/Competent Authority in order to hold them accountable.

4 SCOPE

To achieve the objectives of the study, data were collected from all EU MS[18], both on issues dealing with the transport of radioactive materials within and across MS, as well as with national regulations and practices related to the safety and security of the transport of radioactive materials.

The scope of this study covers industry and regulatory infrastructures for the transport of radioactive materials by road, rail, waterways, and air/seaborne transport where most relevant (e.g. for short lived radiopharmaceuticals and fuel cycle material, respectively) and where these modes of transport have practices that would be of use in other modes. For a full-scope analysis of the current situation at the EU level, the data collected covered all areas of interest for the transport of radioactive materials. Specifically, the materials transported, transport enterprises, development and implementation of regulations, emergency planning and exercises, enforcement and investigation, inspection of transport operations, witnessing of manufacture, witnessing of testing, examination of maintenance and servicing arrangements, assessment, audits of management systems, liaison and cooperation, issuing of approvals, training and information distribution, capacity (regulator and industry), effectiveness measures, accidents, images, reports, international participation, specific issues, approvals, notifications and information requirements, costs, guidance needs, public perception, open market, policy for review and revision of regulations.

Specific issues relevant for the transport of radioactive materials and encountering the most challenges were part of the scope of this study and are presented in this report.

For some issues, the approach of collecting the data through a questionnaire needed to be supplemented with case studies, mainly because of the specificity of the issue and the fact that not all MS had experience and/or interest in the subject area. For those issues, case studies were developed for which targeted data collection and subsequent analyses proved to be more effective in addressing the subject. These case studies are also presented in this report.

The scope of application of the BSS Directive for the transport of radioactive materials was also assessed in detail in this report, since it is of particular importance in defining gaps and overlaps in EU legislation that could be addressed at the EU level.

The scope of the work focused on the development of recommendations to enhance the safety and security of the transport of radioactive materials and the harmonization of approaches across the EU. In light of this, the Consultant assessed the status and identified gaps, which were discussed at two workshops established within this project. The first workshop was devoted to a discussion of the findings of the study and the identification of potential gaps in other areas of interest. In the second workshop, the SG assessed the resulting draft recommendations. Close interaction and consultation with the CTF on every element of the study was maintained throughout the implementation of the project.

The scope of work included the preparation of reports, including summaries (e.g. for publishing on the web), in the format and style required by the EC.

The Consultant ensured that all project objectives have been addressed and that the results have been delivered with the required level of rigour.

[18] A total of 25 MS participated in the study (Portugal and Cyprus did not respond, while Hungary submitted information after this study was concluded).

5 THE APPROACH

5.1 GENERAL APPROACH

The project was implemented through one preliminary task and four main tasks:

- *Task 0: Project Inception Period.* The methodology to be used was agreed with the CTF, the SG was defined, an Inception Report was prepared and the kick-off meeting was organized.

- *Task 1: Collection and Compilation of Data.* The complex questionnaire for collecting data from EU MS was drafted and agreed upon, after which it was distributed to the established contact points in MS. The responses were recorded in an Excel file and the need for additional information was defined in an another questionnaire.

- *Task 2: Data Analysis and Identification of Best Practices and Gaps.* These were the core tasks of the project. They involved evaluations and comparisons of MS data to: derive best practices and areas for improvement; determine how the arrangements could be further harmonised to enhance the safety and security of transport; optimise the use of resources, including avoiding duplications; and also remove unnecessary barriers that might exist. An Interim Report was prepared and shared with the SG and CTF before a workshop was organised to discuss the achievements of this study and possible areas where more information and analysis are required. Based on the discussions held during this workshop, a Draft Final Report was prepared to document the work, but also to clearly structure the findings and recommendations for the improvement of safety and security. The Draft Final Report was discussed at a second workshop and the suggestions of participants were used in the development of this Final Report.

- *Task 3: Organisation of Two Workshops*. The first workshop was held to discuss the interim results of the project, while the second was convened to discuss the final findings and disseminate the information obtained in the study.

- *Task 4: Preparation of the Final Report.* The Final Report of this project was prepared in compliance with SG and CTF proposals and the project requirements.

There were three key actors whose interaction was essential for the successful implementation of this project: the CTF, the SG and the Consultant’s team. Thorough, open and collaborative interaction ensured the achievement of the project objectives and the drafting of realistic, implementable recommendations.

The Consultant's team took the lead in the practical implementation of the activities, from data collection and analysis to drawing preliminary conclusions.

DG ENER, representing the European Commission, managed the project and, as appropriate, assessed and provided approval of the major steps in project implementation. DG ENER also acted as the secretariat to the SG.

The CTF, consisting of representatives of various EC services, directed the project to ensure that all views and interests were adequately reflected. It also provided opinion and feedback from the EC's services on relevant aspects of the project.

The SG was the indispensable actor in this project, providing its views on all key project matters and, in particular, on the relevance and applicability of the conclusions and recommendations. The composition of the SG was critical to ensure consensus and provide sound advice. It included all interested parties: national regulators (on transport, as well as on nuclear safety/radiation protection and members of EACA); industry, including manufacturers of sources and radiopharmaceuticals; distributors; nuclear research and industry organisations, including radioactive waste management organisations; radioactive material carriers and consignees; local authorities; and, to the extent appropriate, NGOs. The preliminary proposal for the composition and operation of the SG was successfully introduced at the project's kick-off meeting.

The key interactions were the two workshops, the first of which took place in Brussels ten months after initiation of the project, The second was held in Luxembourg, 15 months after project initiation. The Consultant provided the CTF and SG with relevant input (the draft Interim Report and draft Final Report) within the specified time frame (i.e. at least 15 days before the events), proposed the work agendas and recorded the outcomes in the minutes of each workshop.

It must be emphasised that, based on the agreement of DG ENER, the Consultant engaged the SG early in the project well in advance of the first workshop. The SG members were asked (in accordance with their positions and responsibilities) to support data collection in their countries by answering the questionnaire and providing insights through interviews, along with the provision of advice on the criteria used in the analysis. Once drafted by the Consultant, and after agreement with CTF, the recommendations were communicated to the SG for consideration of criteria such as plausibility, appropriateness, feasibility of implementation, etc. Other pre-workshop interactions aimed at ensuring that SG members were fully informed and had a thorough understanding of the required steps and of the basis for the recommendations. This facilitated a smooth transition to topical discussions as well as maximization of the range of discussion topics during the workshops, leading to effective and efficient consensus in the areas of interest, and thus ensuring accurate input to the EC on further actions.

The outcome of the first workshop was incorporated into the analysis and recommendations documented in a draft Final Report, which, in turn, constituted the basis for further discussions at the second workshop. This report incorporates the final conclusions of the study which resulted from the joint efforts of the SG; it was discussed thoroughly with the CTF and was subject to the approval by the DG ENER before being issued.

One of the fundamental elements for the project's success was the interaction between the CTF and the SG. The SG members were proposed by the Consultant's team and agreed to by DG ENER. The Consultant maintained contact with the members of the SG. According to the implementation strategy, the ultimate users of the SG are the EC and the CTF, with the SG being the 'validation key' for the findings/gaps and areas for possible harmonisation. Therefore, it was important that the Consultant's team 'take a back seat' in this process rather than 'guide' the discussions. This ensured that the basis for discussions were set, while the SG was able to look into every element in the study, and accurately determine its importance and potential solutions and future steps.

The CTF presence at the two workshops ensured first hand insights into the SG thinking process and deliberations. The Consultant's team, in close coordination with the CTF, 'canvassed' the main pillars of the study well in advance before the first workshop to facilitate a complete picture of the individual positions, and for future work.

The Consultant was the 'service provider' tasked with collecting and analysing information, and identifying gaps, as well as serving as an 'adviser' and 'enabler' in the decision making process, facilitating SG discussions and decision making by the EC.

5.2 DATA COLLECTION

The questionnaire and the follow-up questionnaire are presented in Annex A3.

A key principle of the data gathering for this study was to focus on information that was readily available. There were several gaps in the information provided (suggesting that, since the Competent Authority was unable to provide the information, the information was not readily available). In addition, there were some inconsistencies in information where multiple sources were involved (although the trends were consistent).

Thus, the data obtained were not treated as being completely accurate. Rather, the methodology employed expert judgement, interpreting the results based on trends emerging from multiple sets (over 20) of similar data.

The following is an example of this methodology

- Where a significant number of MS did not provide any data, the areas identified as areas where data collection needed to be improved.
- Trends were identified, i.e. areas where all data sets showed similar changes over time.

However, the methodology does not provide a means for the identification of a precise rate for compliance activities.

Information on the situation regarding the transport of radioactive material (TRAM) in EU MS was collected by means of an extensive questionnaire (see Annex A3) comprising more than one hundred questions with some seven hundred data fields. The questionnaire was divided into five sub-sections addressing aspects of TRAM:

(1) Industry and Transport Infrastructure: 4 sub-groups, 14 questions;

(2) Regulatory Infrastructure (regulations and oversight): 13 sub-groups, 71 questions;

(3) Effectiveness Measures: 5 sub-groups, 16 questions;

(4) General Background: 4 questions;

(5) Specific Issues: 6 sub-groups, 25 questions.

Up to 50% of the questions required text entry, 25% required numerical values, Yes/No choices or ‘multiple choice’ answers.

The questionnaire was directed to a single contact point in each Member State, targeting the national Competent Authority responsible for the transport of radioactive materials. The format of the questionnaire was based on Compliance Assurance for the Safe Transport of Radioactive Material (IAEA Safety Standards Series No. TS-G-1.5), issued by the IAEA in 2009.

It was decided that the official contact list produced by UNECE as a result of notifications under 1.8.4 of ADR would be used for distributing the questionnaire. ADR 1.8.4 requires States to inform the UNECE of the address of the authorities designated as competent to implement ADR. In addition, ADR notes that any query concerning its application should be directed to the relevant Competent Authority. Directive 2008/68/EC requires Member States to comply with ADR 1.8.4.

One error was noted on the list and notified to UNECE, which corrected the error within a day of being notified. This indicates that UNECE maintains the list effectively, even though the list is based solely on information provided to it: several of the contacts were not successful, several State notifications were over ten years old, etc. As such, an early flag emerged that States may not be complying with the requirement to provide information on the identity of their competent authorities.

A backup process was employed to supplement the required contact information, consisting of the membership list of the EACA, the IAEA TRANSSC attendance lists and personal contacts. To minimize effort, the questionnaire for each MS was partially pre-filled by the Consultant using publicly-available information (official publications and websites, etc). The extent to which questionnaires could be pre-filled varied greatly between countries, depending on how much information was in the public domain. Typically, up to a third of the information was pre-filled in the questionnaire.

The questionnaire was sent to the Competent Authority in each country responsible for the transport of radioactive material and for validating the pre-fill and completing of the questionnaire. Upon return of the completed questionnaires, the Consultant sought clarifications from the Competent Authorities for responses which were unclear, inconsistent or incomplete. Finally, the responses were compiled in an Excel database which was used for benchmarking and mapping.

The response rate was satisfactory, with questionnaires received from 25 countries (plus Hungary which responded after the second workshop; Cyprus and Portugal did not respond. While the database has been frozen in order to complete this draft Final Report, a version remains open for further inputs until final delivery to the CTF.

Based on the compilation of data, the identification of key trends, the actions agreed at the first workshop, and the conclusions and action plans discussed at the second workshop, this report documents the process and incorporates the results of the comprehensive examination and analyses of the situation of transport of nuclear materials.

5.3 ANALYSIS

Prior to the work carried out under this study, during the starting phase of this project, the existing legal structure and the level of legal and technical competence were reviewed. The results of this analysis (see Chapters 5.3.1 and 5.3.2) were considered in identifying issues and deriving conclusions in the rest of the report. Also, in the initial phase, the results of IRRS missions in participating MS were analysed and taken into consideration.

The analysis in this study focused on the store of knowledge readily available to States on the industry infrastructure for the transport of radioactive materials, and built on this knowledge by looking at the regulatory infrastructure that oversees the safety of this transport structure. Following this, a number of issues were addressed, including the concept of health indicators, which could provide guidance on the overall effectiveness of the regulatory system. An additional area was added to the study following the first workshop: examining how the BSS Directive was being applied in transport. The situation in each MS, consolidated from the individual answers, was analysed to provide a simple representation of the overall picture. Finally, a number of typical transport operations were examined as case studies.

The data collected during this study are contained in Annexes A4 and A5 in this report and the analysis of the results is presented in the following chapters. Other analyses are presented in each chapter as introductions to the work performed in this project.

Before the first workshop, a number of issues were identified based on the answers provided by MS. During the second workshop these issues were analysed by the SG and CFT and revised to form a shorter list of 25 issues (action areas), which were included in this Report. Furthermore, based on these action areas, the SG and the CFT prepared a summary of all recommendations, along with the action plans where appropriate, which are presented in Chapter 11.

5.3.1 ANALYSIS OF THE EXISTING LEGAL STRUCTURE

5.3.1.1 POTENTIAL FOR COMPETING REQUIREMENTS

A crucial part of international commerce is the ability to trade freely, which requires the ability to transport goods freely between States. A significant portion of these goods are defined as 'dangerous' or 'hazardous', and consequently a harmonised set of legislation has been developed internationally to establish a common safety framework for the transport of dangerous goods, including radioactive material as Class 7 of dangerous goods. This common safety framework has been established for different modes of transport through a number of treaties or conventions (see Chapter 2.1), many of them covering a wide range of issues of relevance to transport other than dangerous goods. The European Union values freedom of trade between MS and has, in one form or another, encouraged the adoption of these conventions in the EU for the purpose of assuring trade. The requirements in these treaties or conventions applicable to the transport of radioactive materials are drawn up from IAEA 'Regulations for the Safe Transport of Radioactive Material' (IAEA-Safety Standards Series No. SSR-6) according to the review procedure of these documents.

At the European level, the range of legislation covering the transport of radioactive material is wide and not homogeneous, being partially specific to the activity, supporting and/or of a peripheral nature. This chapter lists the main legal framework applicable to this area. Of note is the overlapping of legislation applicable to the transport of radioactive materials, which is caused by the application of different treaties regulating separate modes of transport (see Chapter 2.1). The scope and character of requirements from different international conventions implemented in MS either jointly as the European Union entered into them, or separately as each MS entered into them, were analysed for completeness and potential conflicts. The appropriate conclusions given below were drawn from this process.

Of particular legal relevance is the 'Agreement between the European Union and the Intergovernmental Organisation for International Carriage by Rail on the Accession of the European Union to the Convention concerning International Carriage by Rail (COTIF) of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999', where the European Union, rather than the individual States, acceded to one of these conventions. This is the first of the conventions governing the transport of radioactive materials that has become binding on the EU (as opposed to the individual States).

According to the European Union Treaties Office Database, "The Uniform Rules' created by OTIF are applicable to international rail transport on railway infrastructure of about 250,000 km, and to complementary carriage on 17,000 km of shipping lines and inland waterways, as well as prior or subsequent domestic carriage by road. The main tasks of OTIF are as follows:

- International rail transport law (passenger and freight traffic);
- Carriage of dangerous goods;
- Contracts for the use of vehicles;
- Contracts for the use of railway infrastructure;
    - Validation of technical standards and adoption of uniform technical specifications for railway equipment;
    - Removal of obstacles to the crossing of frontiers in international rail transport;
    - Participation in the preparation of other international conventions concerning rail transport."[19]

European Union competence is either shared with MS or is exclusive. There are 46 countries in OTIF. As a result, the technical requirements for the safe transport of radioactive materials by rail is a small part of a convention that involves more States than are part of the EU. There are similarities with other modes. A combination of the

[19] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:tr0051

breadth, benefits and geographical coverage of the modal conventions means that MS are effectively bound to them for the transport of radioactive materials.

Directive 2008/68/EC as modified by Commission Directive 2016/2309, sets requirements for the transport of dangerous goods (including radioactive material) by road, rail and inland waterway. This includes reference to the technical requirements set out under the Convention concerning International Carriage by Rail. Since the EU is a signatory of COTIF, there is a need for this directive to align with the COTIF requirements (for road transport all MS are signatories of the relevant treaty).

Article 3 of this Directive is particularly important, in that it states, "the transport of dangerous goods shall be authorised, subject to compliance". In effect, this Directive has a facilitation focus. It defines safety provisions deemed to be acceptable for international shipments. Conversely, for air transport the requirements are seen as a minimum level. The complexity of the international structure means that, for radioactive materials, these technical requirements flow from IAEA Safety Standards No. SSR-6, almost in a word for word form. The ability to change the technical safety requirements needs to be carried out consistently across all modes in order to prevent blockages to transport. As a result, changes to EU safety rules for the transport of radioactive materials are best made at the IAEA level.

IAEA Safety Standards Series No. SSR-6 has the goal of implementing the IAEA Basic Safety Standards (IAEA BSS) for transport. The EURATOM Basic Safety Standards (EURATOM BSS) are also related to the IAEA BSS. However, there is no issue that prevents the adjustment and improvement of these requirements to better match the needs of the Community. They also apply to transport. The EURATOM BSS set a minimum level of safety.

This leads to the situation that one aspect of Community legislation sets a maximum level of safety for the transport of radioactive materials, while another sets a minimum level of safety for the same matter. Given that for rail transport the maximum level of safety is binding on the EU, a difficult situation is created if the Community sets a higher level of safety. Effectively, the MS could face an incompatible set of directives. With the introduction of the new BSS Directive this report assists by confirming that any differences between the IAEA BSS and the EURATOM BSS do not lead to any issues for MS.

5.3.1.2 RELEVANT TRANSPORT LEGISLATION (EU AND EURATOM)

As mentioned in Chapter 2.1, at the EU level, some aspects of the transport of radioactive materials are covered under the Treaty on European Union and some under the EURATOM Treaty.

The primary legislation under the Treaty on European Union covering the transport of radioactive material in the Community is Directive 2008/68/EC, as modified by Commission Directive 2016/2309. This covers the transport of all dangerous goods by road, rail and inland waterway.

Extract from 2008/68/EC

1. Without prejudice to Article 6, dangerous goods shall not be transported in so far as this is prohibited by Annex I, Section I.1, Annex II, Section II.1, or Annex III, Section III.1.

2. Without prejudice to the general rules on market access or the rules generally applicable to the transport of goods, the transport of dangerous goods shall be authorised, subject to compliance with the conditions laid down in Annex I, Section I.1, Annex II, Section II.1, and Annex III, Section III.1.

Article 4

Third countries

The transport of dangerous goods between Member States and third countries shall be authorised in so far as it complies with the requirements of the ADR, RID or ADN, unless otherwise indicated in the Annexes.

Restrictions on grounds of transport safety

1. Member States may on grounds of transport safety apply more stringent provisions, with the exception of construction requirements, concerning the national transport of dangerous goods by vehicles, wagons and inland waterway vessels registered or put into circulation within their territory.

2. If, in the event of an accident or incident within its territory, a Member State considers that the safety provisions applicable have been found to be insufficient to limit the hazards involved in transport operations and if there is an urgent need to take action, that Member State shall, at the planning stage, notify the Commission of the measures which it proposes to take.

Acting in accordance with the procedure referred to in Article 9(2), the Commission shall decide whether to authorise the implementation of the measures in question and the duration of that authorisation.

This Directive includes security requirements to the extent permitted by European competence. Thus, when MS identify differences, they request approval and, if accepted, derogations applicable at the level of the requesting MS are issued. Derogations are listed in Commission Implementing Decision 2017/695.

Amendments to the requirements are also considered at the Community level, with Council Decision (EU) 2016/179 providing an example of the Community view on recent amendments.

Directive 95/50/EC provides a Community based inspection and non-compliance reporting regime.

EU Regulations 965/2012 and 376/2014 provide a basis for the regulation of transport of radioactive materials by air.

Between them, these requirements specify regulatory systems covering almost all radioactive materials transported within the Community (whether intra-community or extra-community shipments, but excluding some areas such as military transport). The packaging, marking, labelling, placarding, approval and consignment requirements are supported by requirements for training, radiation protection, emergency preparedness and response.

For carriers of radioactive materials in the European Union, Regulation (EC) No 1072/2009 and Regulation (EC) No 1071/2009 result in an effective European licencing system for hauliers involved in the carriage of radioactive materials.

Along with the above, a number of transport-related regulations and directives relate to the collection of statistical data: Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009; Regulation (EC) No 1072/2009 of the European Parliament and of the Council of 21 October 2009; and Directive 2003/59/EC of the European Parliament and of the Council of 15 July 2003.[20]

The EU legislation on transport is extensive and very specific in setting duties and actions for employees, employers and regulators.

A number of ‘import/export’ related directives under the EURATOM Treaty effectively create a standard documentation system for the transfer of material between MS. These include:

- COUNCIL DIRECTIVE 2006/117/EURATOM of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel;
- COMMISSION DECISION of 5 March 2008 establishing the standard document for the supervision and control of shipments of radioactive waste and spent fuel referred to in Council Directive 2006/117/Euratom (notified under document number C(2008) 793) (2008/312/Euratom);
- COUNCIL DIRECTIVE 2013/59/EURATOM of 5 December 2013 (chapter IX Section 2 on HASS after February 2018 – prior to this Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources);

[20] In March 2018, the European Parliament decided an update was necessary.

- COUNCIL REGULATION (EURATOM) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States.

These only apply to cross-boundary shipments of a small fraction of the radioactive materials shipped; in effect, they only cover import/export operations and relate to a very small percentage of Community shipments.

Council Directive 2013/59/EURATOM of 5 December 2013, laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (the BSS Directive), has a much wider scope. It deals with all aspects of radiation protection related to radioactive materials, including during transport. This Directive is primarily focused on operations in facilities within a State. Certain requirements are difficult to implement if an activity takes place in multiple States, some potentially outside the Community. In order to address this difficulty, the requirements set out in the various modal requirements have the goal of supporting the BSS Directive in a manner that is effective for transport.

The difficulty in applying the BSS Directive to transport can be clearly seen when considering issues such as dose constraints for journeys that transit a number of States, including States outside the Community. Article 6 of the BSS Directive requires the establishment of dose constraints. The Transport Regulations incorporate constraints by establishing segregation distances for the separation of materials from workers and the public during transport. A second requirement related to this aspect is the responsibility of the Competent Authority: assessing exposures to persons. These two requirements establish a system of constraints that are effective in implementing Article 6 requirements for transport.

Nevertheless, there are requirements in the BSS Directive that can be easily applied for transport in MS, such as the requirements establishing dose limits, and these are not included in modal transport requirements. A more detailed assessment dedicated to the requirements of the BSS Directive applicable to the transport of radioactive material is presented in Chapter 9.

5.3.1.3 EFFECTIVE COMPLIANCE

A difficulty in the transport of radioactive material is the large number of participants involved, including package designers, package testers, packaging manufacturers, packers, consignors, carriers and consignees. This is further complicated by the fact that packages that do not require Competent Authority approval can be of general use, not specially designed to carry radioactive materials (for example, a cardboard box that is the main component of an excepted package). It can be hard to inspect the manufacture of these packages under this legislation since the manufacturer has no knowledge or intention of the package use in the carriage of radioactive material (this is not the case for other dangerous goods). Evidence presented during the workshops suggested that a comprehensive list of all transport participants is not available in MS, with reliance on an inspection regime to identify the packages being used in a certain State.

If it is known that a specific package is being carried in a particular Member State, it is possible to identify all the participants involved in the consignment. However, it can be very difficult to confirm the suitability of packaging during carriage, since opening a package at a roadside check is unlikely to be safe.

It is therefore possible that all or some of the other transport participants are in another State (e.g. the manufacturer). The Competent Authority can ask for evidence of the acceptability of the manufacturer, but since the manufacturing activity has taken place in another State it can be difficult to confirm. In such cases, reliance needs to be placed on the Competent Authority in the manufacturer’s State, who may not be aware that the manufacturing activity is taking place.

Packages that do not require Competent Authority approval make up the vast majority of radioactive material packages transported in Europe. The compliance regime involves inspection and provision of information by the consignor. Often this inspection will be prompted by roadside checks. However, other compliance activities, such as source holder inspections, can lead to transport packaging considerations.

As a result, there is an overlap in compliance assurance, where compliance checks on a source producer in one State are essential for verification of the safety requirements for transport in another State. The primary compliance checks on facilities are clearly related to the BSS Directive, and this produces a link between the regulatory activities for radiological protection and regulatory activities for transport both within and between states.

The conclusion is that in order to facilitate appropriate levels of inspection of all the participants involved in a transport in each MS, it is of utmost importance for MS to share information on the activities they are aware of and for effective liaison between all Competent Authorities.

5.3.1.4 SUMMARY OF THE ANALYSIS OF THE EXISTING LEGAL STRUCTURE

As a result of the complexity of the regulatory system and the overlap between radiation protection and transport requirements, a number of issues have been identified in this study. There are a range of options for addressing these issues. The simplest option for dealing with regulatory issues is likely to be MS simply agreeing on how to operate. This is likely to also be the most cost-effective option.

Transport requirements are much more specific than radiation protection regulations (which can be seen as goal setting in many areas). As a result, if a potentially inconsistent position is identified, the easiest option is an interpretation that links the two requirements.

There are limited options for changing legislation. The main targets would be an amendment to the EURATOM BSS or the IAEA Transport Regulations. However, the possibility of changing these regulatory documents as a result of anything identified in this study is likely to be low given the current review and revision cycle for international provisions. Other directives are also likely to be changed only through their respective review and revision process.

In conclusion, this study is unlikely to result in regulatory changes in the short term. Any short term changes are more likely to focus on improved implementation, harmonisation and transparency.

5.3.2 ANALYSIS OF EXISTING LEGAL AND TECHNICAL COMPETENCE, MEMBERSHIP

5.3.2.1 GROUPS, COMMITTEES, ASSOCIATIONS

Safety provisions for the transport of radioactive materials are mainly contained in EU Directive 2008/68/EC and in EU Regulations 965/2012 and 376/2014. In order to provide expert opinion, the expert transport group must have adequate legal and technical competence covering these areas. Currently, the alternatives are:

A. *The SWG* (see Chapter 2.2). Legally and technically competent body to deal with issues related to the transport of radioactive materials in the Community. Membership covers most interest groups, except perhaps civil society, but it has not been active since 2011.

(1) *The EURATOM Expert Group.* Limited to providing advice on the safety standards. Thus, their legal competence with regard to the transport of radioactive materials is limited. No information was available when this study was performed on this group's technical competence or the appropriateness of its membership.

(2) *The Shipment Directive Advisory Committee (2006/117/EURATOM).* Technical competence covering the appropriate areas and covering regulatory aspects of the transport of radioactive materials. This committee does not appear to have legal competence in the relevant areas.

(3) *EACA* (see Chapter 2.2). Association with no legal competence. In terms of technical competence, EACA covers all regulatory aspects of the transport of radioactive materials. However, the membership is limited to regulators of most MS, plus some additional States.

5.3.2.2 SUMMARY OF ANALYSIS OF EXISTING LEGAL AND TECHNICAL COMPETENCE, MEMBERSHIP

Based on the activities discussed in this report, it is recommended that a new group of transport experts be formed. However, none of the above options are fully suitable and some would require significant changes in legislation. The SWG still appears to be the most appropriate body, though its membership is not wide enough to include all interested parties. To meet all of the goals, an 'updated SWG' might be more appropriate.

Other aspects to take into account in the establishment of the expert transport group include:

- Use of modern collaboration software could enable the expert transport group to be established at minimal cost;
- Making use of the members of existing expert groups could simplify the establishment of this group (EACA, including MedNet, WNTI, WNA, etc.);
- Defining the expert transport group's activities based on desired outcomes to ensure effectiveness;
- Areas other than transport.

6 INDUSTRY INFRASTRUCTURE REVIEW

This chapter sets out the industry infrastructure for each MS. A number of areas were investigated through a questionnaire, and then examined further with a follow up questionnaire (see Annex A3). As previously emphasized by SWG members, in order for an MS to understand its compliance assurance needs, it must understand the activities carried out by the industry within its borders. As such, the first section of the questionnaire was aimed at collecting information from each MS that was readily available to those responsible for compliance assurance. The information requested was consistent with the IAEA recommendations for initial information to develop compliance assurance systems. The amount of readily available information doubled as a performance indicator for the transparency of the Competent Authority.

The concept behind the survey was to gather a broad range of information to provide a bigger picture. During the review of this report by the SG, concern was expressed that the results should not be interpreted as an accurate statistical analysis. This was consistent with the intent of the study.

Table 1 provides an overview of the responses received. The outcome was marked as:

Red — information not readily-available;

Green — information readily-available.

Some MS were either unable to respond to many of the questions or chose not to respond. The average response rate was slightly higher than 50%, which was below expectations since much of the data should be readily available, not just to Competent Authorities but also to the public. During the workshops the respondents explained that it had taken considerable effort to provide the information, suggesting that even the information they provided was not readily available to them.

Table 1: Overview of responses

	AT	BE	BG	HR	CY	CZ	DK	EE	FI	FR	DE	EL	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SK	SI	ES	SE	UK
How many packages were consigned in your country in 2016																												
How many packages were consigned in your country in 2026																												
How many packages were consigned in your country in 2036																												
How many consignments took place in your country in 2016																												
How many consignments took place in your country in 2026																												
How many consignments took place in your country in 2036																												
Which areas do you see the major change occurring in?																												
Breakdown of the package types consigned in 2016																												
Breakdown of the modes of transport used for packages in 2016																												
Breakdown of the carrier types for packages in 2016 (%)																												
Breakdown of the end use of material for packages in 2016																												
Transboundary shipments																												
How many Consignors, Consignees, Owners, Users were involved in radioactive material transport in the state in 2016?																												
What is your best estimate of the change in industry experience?																												
Transport Enterprises																												
Route Restrictions, air, sea, inland waterway																												
Any restrictions on road routes for transport of radioactive material																												
Any restrictions on rail routes for transport of radioactive material																												
Allowable Border Crossing Points																												

Detailed MS responses are provided in Annex A4, and the following analysis provides an overview of the lessons learned from the data collection.

6.1 BASIC DATA COLLECTION

One of the simplest measures of the transport industry is the number of items shipped, the number of consignments, or the number of conveyances. These are often multiplied by the distance travelled. For the purpose of this study, two measures were requested: the number of packages consigned, and the number of consignments made. Considering the gaps in reporting, this study estimates that around 3,000,000 packages were consigned in the Community in 2016. Figures for the number of consignments in 2016 totalled around 1,000,000 in the community. Taking information from MS that reported both the number of packages as well as the number of consignments provides an average of around two packages per consignment. Changes are expected over the next 10–20 years, but they are expected to be relatively limited.

6.2 POTENTIAL FOR ERRORS IN DATA

The existing requirements for data collection are consolidated into the Eurostat transport database.

Regulation (EU) No. 70/2012 of the European Parliament and of the Council of 18 January 2012 on statistical returns with respect to the carriage of goods by road sets out requirements for MS to gather information on a number of issues, including the transport of radioactive materials by road on conveyances that are registered in their State in a fair amount of detail. This information needs to be transmitted to Eurostat.

Regulation (EU) 2018/643 provides for data collection for rail, while Directive 2010/65/EU that provides for the collection of information on radioactive materials on ships.

Eurostat's transport database (file road_go_ta_dg) for 2016 reported 44,000 shipments for the road transport of radioactive materials in the EU (this study was primarily related to the Community, while the Eurostat data are related to the EU; these are the same in relation to statistics on shipments).

The difference in the number of shipments/consignments reported voluntarily in this study and as a result of European legislation to Eurostat is significant. It is clear that the official reports providing statistical information to the EU are significantly in error.

A further guide to data accuracy is the estimate of the number of packages per consignment. The Consultant's knowledge of the industry indicates that many consignments are larger than this, with consignments in the tens and hundreds of packages being commonplace. This does not seem consistent with the data collected. The larger consignments tend to have smaller quantities in each package, which may make them harder for Competent Authorities to identify. It is possible that the collection of data on consignments/packages is resulting in an underestimate.

Overall, based on the figures recorded in EU statistics, the number of MS which failed to report data, and the Consultant's knowledge of the industry, the conclusion is that the data collected in the Community and the Union could benefit from greater coordination. In particular, the purpose of data collection should be clearly identified to ensure that its value is understood by the MS who can benefit from the activity.

6.2.1 SUITABILITY OF EXISTING REPORTING SYSTEMS

The following requirements deal with the provision of information related to the transport of radioactive materials:

- Registration of Competent Authorities, Directive 2008/68/EC and ADR 1.8.4 for each ADR requirement:
    - Details of the national Competent Authority;
    - Updated as required.
- Roadside checks, Council Directive 95/50/EC:
    - Number of checks;
    - Place of vehicle registration;
    - Number/category of infringements;
    - Number and type of penalties;
    - Annual reporting of totals.
- Road transport statistical return, Regulation (EU) No 70/2012:
    - Vehicle details, journey details (must not take place at frontiers);
    - Details of goods (for radioactive materials, including type, weight, type of freight, place of loading, place of unloading, distance travelled);
    - Quarterly reporting of statistics.
- Rail transport statistical return, Regulation (EU) 2018/643:
    - Permits compulsory surveys;
    - Annual and quarterly reporting;
    - Similar data to road transport.

- Inland waterway Regulation (EU) 2018/974:
    - General data on goods — does not cover radioactive materials specifically.
- Sea transport statistical return, Directive 2009/42/EC:
    - Annual and quarterly reporting;
    - Main ports general data;
    - General data on goods — does not cover radioactive materials specifically;
    - Does not seem suitable for reporting data on radioactive materials.
- Air transport statistical return, Regulation (EC) No 437/2003:
    - Annual and quarterly reporting;
    - Main airports general data;
    - General data on goods — does not cover radioactive materials specifically;
    - Units specified do not appear to be appropriate for the collection of data on the transport of radioactive materials.

Information obtained as a result of these requirements is available publicly and is of benefit in ensuring that the graded approach to compliance assurance is implemented effectively.

Further examination of the statistical reporting required by legislation indicated that some data are currently collected in tonne– km units. The use of these units is questionable. For example, a massive package weighing several tonnes can be holding less material than a small cardboard box weighing less than a kg. There are three facts that feed into the potential problem with these units. Radioactive materials can have a very high level of hazard compared with the mass, or vice versa (this is also the case for some other dangerous goods). Radioactive packages need to be classified as dangerous goods even when shipped empty after use. Radioactive packages can be very heavy because of the need for shielding. As a result, some legislative requirements specify data that can be hard to collect and can have limited use as a result of the units used.

In addition, the transport of excepted packages is intended to be consistent with the transport of normal freight, requiring little or no operational controls other than those appropriate to normal freight transport. This makes the collection of shipment data difficult to achieve without adding undue regulatory burden.

In the framework of this study there was a good response rate regarding the modes of transport, package types and future trends in the industry. There were also good responses in relation to knowledge of transport restrictions. However, there were a number of areas where data collection was sparse.

A methodology for recording information has been in operation in Italy for a number of years and has provided valuable information to the State authorities and to Community studies. The methodology involves limited overhead for both the State and industry. This demonstrates that a system of data collection can be implemented without introducing undue administrative burden. The Italian data collection system is presented in Annex A10 (Improved Data Collection). A system such as this would be of benefit for both MS and the EU/Community in determining the resource requirements for their compliance assurance regimes.

It is clear that sufficient legal basis exists to require collection of statistical data. However, the data collected may need review to ensure that the information collected is suitable for the purpose of reviewing compliance assurance needs for the transport of radioactive materials in the Union/Community.

6.3 OTHER SOURCES OF INFORMATION – SHIPMENT DIRECTIVE REPORTS

There are other sources of information available and several were reviewed, in particular two reports that provided additional data on some transboundary shipments:

- REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE on Member States implementation of the Council

Directive 2006/117/EURATOM on the supervision and control of shipments of radioactive waste and spent fuel, Second Report, {SWD(2018) 4 final};

- COMMISSION STAFF WORKING DOCUMENT Accompanying the document: Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee on the implementation by the Member States of Council Directive 2006/117/EURATOM on the supervision and control of shipments of radioactive waste and spent fuel, Second Report, {COM(2018) 6 final}.

These reports were prepared following the second three-year period of implementation of Council Directive 2006/117/EURATOM of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel, and they provide details of the number of shipments covered by this Directive. The reports identify less than 30 packages per year as falling under the Directive. Compared with the 3,000,000 packages reported as part of this study, this is a very small proportion of the packages consigned in the Community (0.001%) out of which waste packages represent around 0.1% of the numbers reported in this study. This is due mainly to the fact that Council Directive 2006/117/EURATOM covers only spent fuel and radioactive waste, with the majority of industry shipments comprising radioisotopes; other shipments, such as uranium, fresh fuel, etc., are outside the scope of this report. At the same time, Council Directive 2006/117/EURATOM covers only cross-border shipments (i.e. transboundary).

As a result, the data from these reports are statistically insignificant in terms of the number of packages. This does not mean they are unimportant, since they identify some specific issues. In particular, there is a need for definitions (such as radioactive waste) to be consistent both in wording and in interpretation between MS.

6.4 IMPORTANCE OF AIRPORTS AND PORTS

In terms of consistency the number of packages consigned varied by several orders of magnitude between MS. This disparity requires a form of normalisation to be carried out, though there is no standardised method agreed between MS. For the purpose of this study, the data were normalised by dividing the number of packages by the population of each State (although options, such as GDP, might be appropriate in other circumstances). This method helped to set a few packages per 1,000 of the population as the norm. Belgium was a significant outlier with a few tens of packages per 1,000 of the population. The fact that Belgium is one of the main sources of medical isotopes in the world explains this difference. While this State predicts that there will be a reduction in consignments in the future, this is open to question since the world market continues to grow and the industry continues to consolidate. Similarly, neighbouring Netherlands has a key role in the radiopharmaceutical industry. These two MS are responsible for around 50% of the world's supply of molybdenum-99 (Mo 99).

The data suggest that 60% of consignments are for medical purposes and 25% for industrial uses. The key role of Belgium and Netherlands in medical shipments means that airports in these MS are particularly important for shipments of radioactive materials in the Community.

Of the five major airports in Belgium, only two were reported to allow shipments of radioactive materials. In the Netherlands only two of the five major airports were reported to allow such shipments. Monitoring these key transport hubs to ensure that there are no problems with denial is important not only for Europe but also globally.

While the data suggest that around two-thirds of airports and three-quarters of sea ports in the Community do not accept radioactive materials, which could be interpreted as an equally weighted problem, the importance of ports accepting radioactive materials needs to be emphasised because of the greater sensitivity. Air transport is normally point to point, while sea transport relies on multiple stops during journeys.

For instance, the current data show that for any air journey within the Community, a simple probabilistic approach suggests that there is a 10% chance that the route is available.

For sea transport, the probability that a journey cannot be made depends on the number of ports that a ship might call at on a route. Where the service is direct from port of loading to the port of dispatch with no intermediate calls, the simplistic assessment of probability that the journey can be made is around 6%. With one intermediate port this falls to around 1%.

While this is an overly simplistic approach, the situation could in fact be much worse if a major port refuses radioactive materials. The effect could be that a single port refusing the transit of radioactive materials could create a total barrier to sea shipment to other MS.

Further to this, some ports that do accept radioactive materials have specific administrative barriers that impede free shipment. One port has recently started to accept the transit of radioactive materials, but subject to additional requirements. Similarly, key ports have implemented requirements related to security.

The information presented here has been taken into account in the discussions and details found in Chapter 8.6, Denial of Shipments, Chapter 10, Case Studies, and the corresponding Annex A6.

6.5 REGULATORY OVERSIGHT

Another issue looked at in the basic data/industry infrastructure section of the study was the extent of regulatory oversight. There are a number of regulatory functions expected of a Competent Authority, and most Competent Authorities appeared to have difficulty identifying the appropriate resource allocations to each of these functions. For example, one of the highest resource allocations was for testing, and yet only five tests were reported. Similarly, a number of MS indicated that no resources had been allocated to areas they later identified as being important.

At the same time the information collected indicated that over 95% of the packages shipped did not require any approvals by the Competent Authority. As a result, the vast majority of packages rely on a graded approach to inspections. Typically, there are around 50 regulated entities per inspector in MS, which would appear to be manageable. However, it should be noted that there was a low response rate to the question asking for data on the number of consignors, consignees, users and owners in each MS (this represents the industry being regulated). During discussions in the workshops some States identified this as a problem they were dealing with. Particularly good information was available from Italy which has a long-standing national reporting system.

Overall, MS could improve their estimates of resource requirements for a regulatory infrastructure. This, in turn, would suggest a need for improved data collection and reporting systems on the transport of radioactive materials in MS, as discussed in Chapter 6.2.1.

6.6 SUMMARY OF THE REVIEW OF INDUSTRY INFRASTRUCTURE

In terms of the basic data that was collected, there was a reasonable, but variable, response from MS. Discussions in the workshops with stakeholders identified some good practices, and some MS mentioned their efforts to improve data availability. There are insufficient data to demonstrate that the compliance assurance regime in most MS is functioning at an appropriate level. However, no information was collected that suggested there are particular issues. The importance of improving data collection and reporting systems is that it allows MS to demonstrate in a transparent manner about how they are ensuring compliance.

Additionally, improvements in the quality of the data as required by legislation, along with improved reporting would be beneficial in identifying adverse trends in advance of any critical concerns, for example the availability of airports or sea ports.

Positive examples of data collection methods in Italy, and the new efforts in Belgium related to roadside checks provide options for future action by MS. Ensuring that competent authorities are aware of all relevant data collection activities in the EU and in the Community could be beneficial.

7 REGULATORY INFRASTRUCTURE REVIEW

This chapter examines the regulatory infrastructure for each State. A review of the infrastructure was primarily performed with regard to ADR, with due account of guidance provided in the IAEA's 'Compliance Assurance for the Safe Transport of Radioactive Material' (IAEA Safety Standards Series No. TS-G-1.5) on the application of the IAEA Transport Regulations to the transport of radioactive materials. Together these create a best practice framework for a State Competent Authority dealing with the transport of radioactive materials.

In order to structure the review, a 'compliance circle' (Fig. 1-1 from IAEA Safety Standards Series No. TS-G-1.5) is used. This splits compliance into 12 areas that are relevant to transport. States were asked questions designed to elicit information that would demonstrate that compliance was being achieved in each area.

The compliance circle is shown in **Figure 1**.

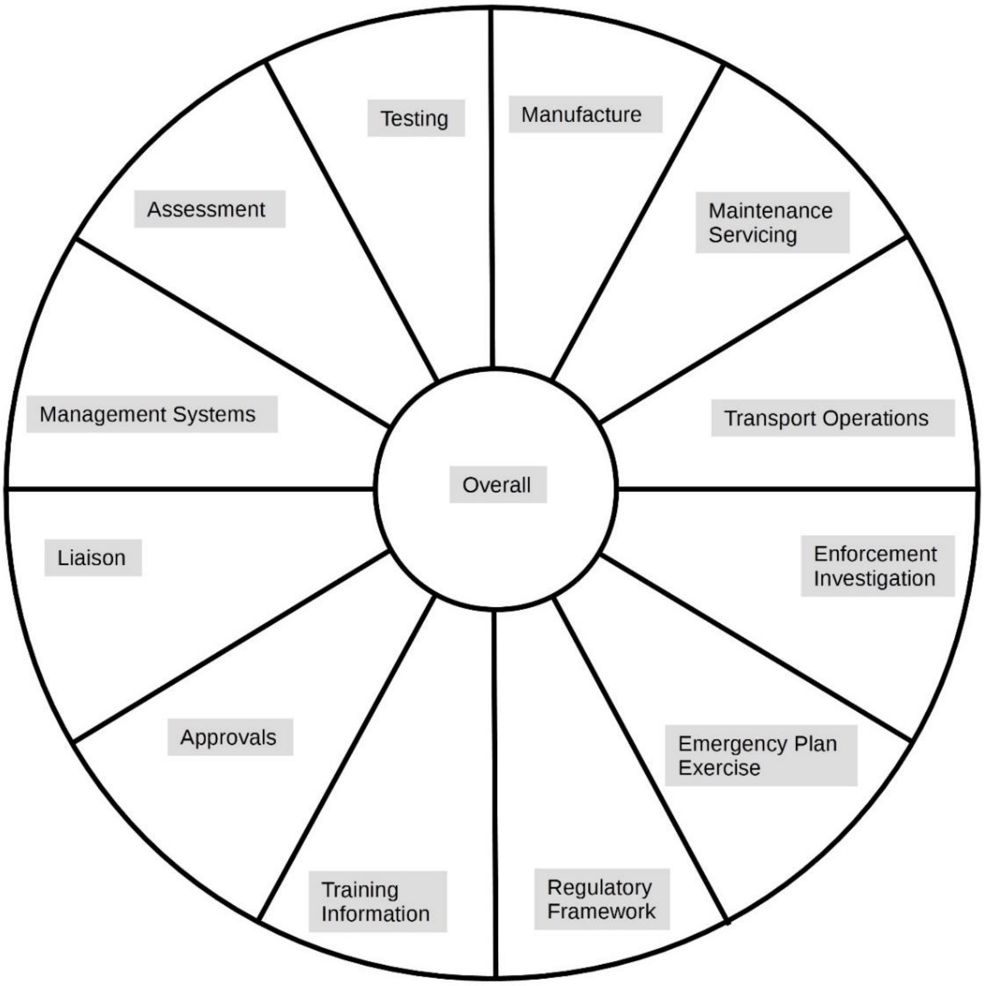


Figure 1: Compliance circle.

The responses of each MS were reviewed by the Consultant to determine whether there was enough evidence provided to satisfy a knowledgeable person that compliance was being demonstrated. Again, a nil response was permitted in order to test transparency; the concept being tested was transparent demonstration of compliance.

The outcome was marked as follows:

Red: Compliance not demonstrated;

Amber: Compliance partly demonstrated;

Green: Compliance demonstrated.

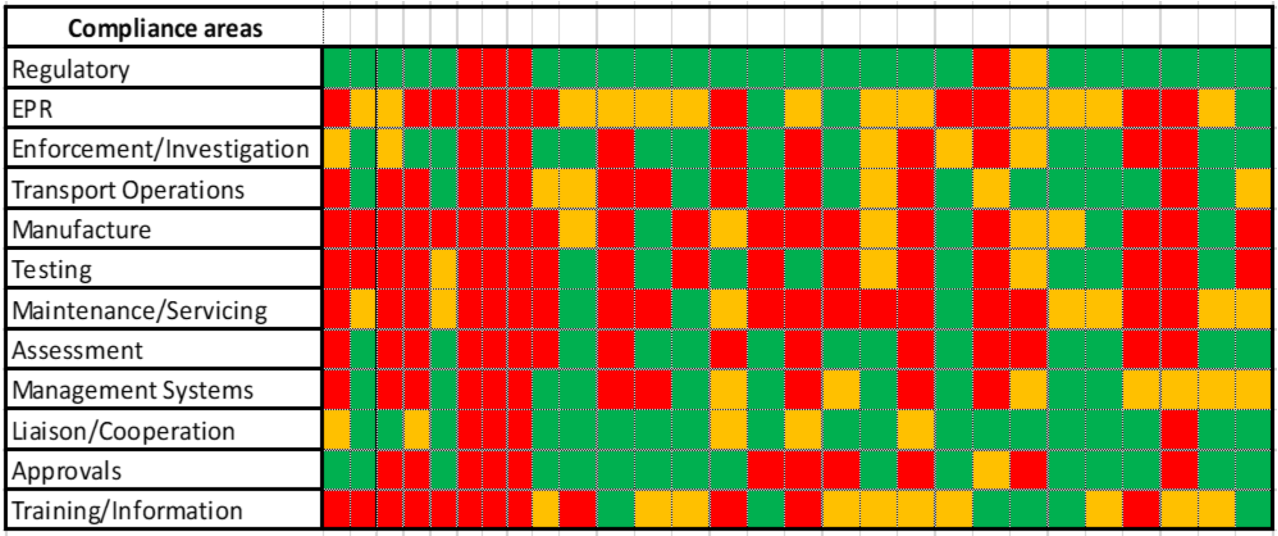
In some areas, MS reported the number of inspections — a low number was not considered negative in itself. The Consultant was aware that a graded approach was essential in many areas, and this was the more important issue — did the information presented demonstrate that a graded approach was being applied in arriving at the low number. The acceptability of the number of inspections was not questioned unless it was significantly out of step with other MS.

Each of the 12 areas had multiple questions that were reviewed separately and an overall judgement was applied to the entire area of compliance. The fact that the majority of questions were not answered by a MS in one area of compliance would not result in a red ranking. Indeed, in some cases MS answered less than half of the questions and the overall rating for the area was green.

It is important that the information is not treated as precise scientific data. As stated before, the methodology used was to gather information in a manner that would provide an indication of the state of compliance in the 28 MS. So, it would be appropriate to interpret an area of compliance as being 'generally red', but not '66% red' as this would suggest a level of accuracy that does not exist.

Table 2 gives MS results without disclosing the identity of the States, making the MS order aleatory. Further updates have been obtained since this review was carried out.

Table 2: Review summary by Member State



Some of the information in other sections fed into the analysis. If the area of 'Monitoring and Inspection of Transport Operations' is considered, then there are a number of items that are needed or can assist in demonstrating compliance.

It is necessary to rely on a random inspection regime unless a Competent Authority is aware of who is transporting radioactive materials.. Such a regime is set out in Directive 95/50/EC, which describes a standard system for roadside checks for dangerous goods (including radioactive materials). The background to this directive suggests that a rate of around 2% checks is considered as a target for some MS.

However, it is difficult to demonstrate that a random regime is acceptable unless a suitable 'denominator' is defined. For example, if a Competent Authority is unaware of the total number of consignments (or as a minimum of its order of magnitude) made in its State, destined for its State or passing through the State, then it is difficult to determine the appropriate level of inspections. Similarly, the number of carriers operating in the State can be an important factor in determining the number of transport operations that should be inspected.

In addition, the ability to adjust inspection rates based on intelligence is necessary. A good example is the repetition of incidents involving contamination on the nuclear fuel packages. This unacceptable level of non-compliance should (and did) trigger inspections for such contamination.

As a result, the Consultant looked at a wide range of information in considering whether an MS was demonstrating it had an acceptable transport inspection programme. A similar approach was used in reviewing other areas. **Figure 2** summarises MS results by compliance area.

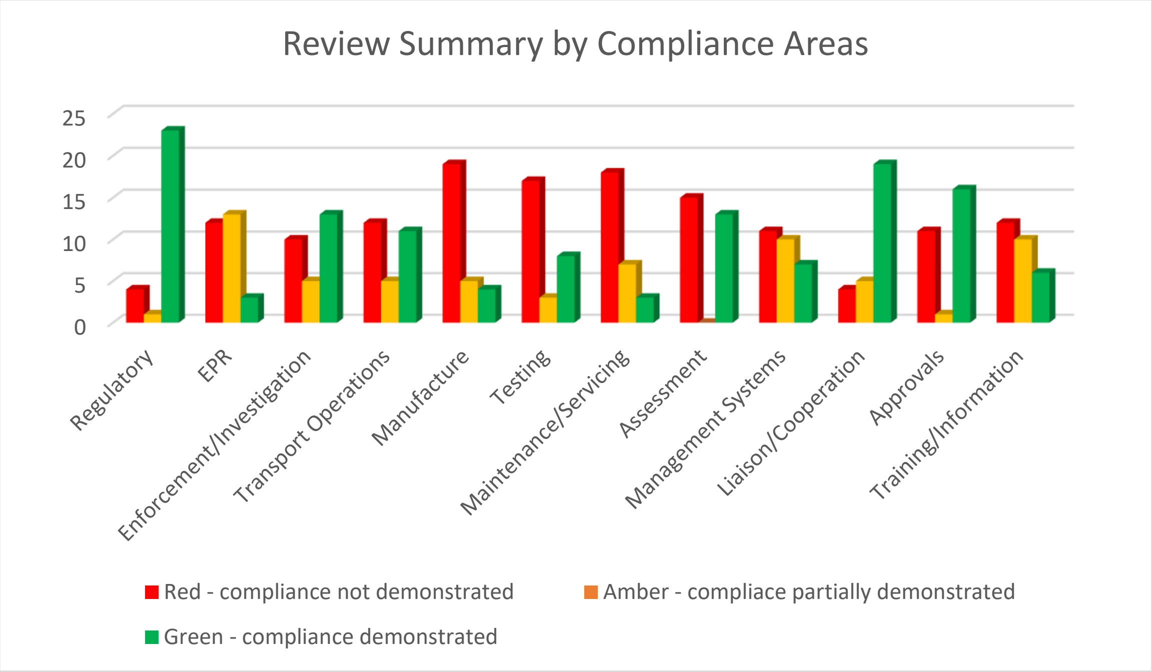


Figure 2: Review summary by compliance area

The areas where good response was obtained were those involving Competent Authority operations (regulatory, liaison, approvals and assessments). Areas of physical operations on the packaging (manufacture, testing, maintenance/servicing) and EPR registered particularly poor results. There was little demonstration that there was knowledge of the testing of emergency plans for air and sea modes. The national response systems for transport accidents seemed to be poorly understood in relation to radioactive material.

Annex A5 discusses each area in detail. The main issues are drawn together in the following sections of this chapter.

7.1 MAINTAINING AN EFFECTIVE REGULATORY FRAMEWORK

The responses showed that in general regulatory systems in MS were in good order. Most were up to date, and there were effective systems in place to manage the necessary updates. Any suggested improvements are minor, and as a result this area is considered a low priority for action. Three issues were identified in this area, from which Issue I-3 is potentially the most important in that it relates to threats to free trade.

Some States reported a different status for the legislation in the implementation record. The extent of communication between regulatory bodies may not be as advanced as it should be, particularly between Competent Authorities, for the transport of radioactive material and dangerous goods and for modal transport.

RELEVANT INTERNATIONAL PROVISIONS

IAEA GSR Part 1 (Rev.1) Requirement 7

"Requirement 7: Coordination of different authorities with responsibilities for safety within the regulatory framework for safety

Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties.

2.18. Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as:

…(11) Safety in the transport of dangerous goods, including nuclear material and radioactive material;

This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience."

IAEA TS-G-1.5 2.7.

More than one organization may be responsible for the regulatory control of the transport of radioactive material in a State…Where there are several responsible authorities, they should cooperate closely and there should be legal or formal agreements between them covering the responsibilities of each authority. Each competent authority is required to communicate with and provide information to other governmental and non-governmental organizations that have related responsibilities.

There are many international provisions providing guidance on the need for effective liaison within a State. There are more than ten government bodies with a direct role in the safe transport of radioactive materials in an MS, and as a result effective liaison is particularly important.

During the second workshop, the particular relevance of the Slovenian example was highlighted by the SG and CTF: "learn from incidents within the community…, as well as sharing good practices with the aim at improving both safety and security during different modal transports; this group would deal also with occasional concerns of industry on denial of shipment".

Issue I-1. A comprehensive set of interested parties should be developed by MS, and more extensive sharing of information between regulators should be assured.

The EU has competence in the area of rail regulation and is involved in a limited number of MS on the development of the SMGS. However, with the development of new rail links between Europe and Asia, the potential for shipments under the SMGS to become relevant to other States seems to be more likely. Once an SMGS shipment enters the EU, there is limited border control to prevent it from carrying on to a non-SMGS State.

While it has been reported that there is difficulty in maintaining an active group of EU SMGS States, it may be appropriate to widen the participation in SMGS discussions. At present there are no significant differences between SMGS and RID, so this is unlikely to be a short-term issue. However, with the development of long-distance rail links it may become more important. UNECE has an interest in the SMGS, RID and the new rail links and is likely to be the most appropriate body to oversee the matter.

Issue I-2. The EU may wish to consider to extending its involvement in the SMGS.

The ADR and RID are aimed at the facilitation of transport. In other words, they set a maximum level of safety to be applied. At least one MS has no measures listed for implementation, and others have reported variations that would not appear to be consistent with the facilitative nature of ADR and Directive 2003/68/EC.

__RELEVANT INTERNATIONAL PROVISIONS__

DIRECTIVE 2008/68/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Article 3 General provisions

1. Without prejudice to Article 6, dangerous goods shall not be transported in so far as this is prohibited by Annex I, Section I.1, Annex II, Section II.1, or Annex III, Section III.1.

2. Without prejudice to the general rules on market access or the rules generally applicable to the transport of goods, the transport of dangerous goods shall be authorised, subject to compliance with the conditions laid down in Annex I, Section I.1, Annex II, Section II.1, and Annex III, Section III.1.

International provisions provide guidance and do not support general obstacles to transport. However, the potential exists for one MS to block legal commercial activities in neighbouring States. An example is the radiopharmaceutical business, which depends on the transport infrastructure, not only in Belgium and Netherlands but also in neighbouring States, due to the flight options from different airports. In addition, there is a need to deliver nuclear material to these MS to ensure the continued operation of reactors. At least one neighbouring MS already prohibits the transport of nuclear materials, and one more has significant political issues surrounding the transport of such materials. During the second workshop, the SG and CTF noted that clarity of all applicable legislation was considered a suitable first step before identifying the administrative burden related to variations in the application of radioactive material transport legislation between MS.

Issue I-3. Identify all legislation applying to the transport of radioactive materials.

7.2 MONITORING AND INSPECTION OF TRANSPORT OPERATIONS

Carrier operations are inspected and reported routinely to the European Commission. This compliance action was one of the areas where the perception was a balance between clarity and gaps in the responses. One of the issues in this area appeared to be related to liaison within States. The Consultant identified examples that were not included in the responses. Improved liaison would have a positive effect.

As mentioned previously, an important aspect of this compliance area is knowing whom to inspect. In transport there are two key groups of people: the consignor and the carrier. The responses indicated a varied system of registration of carriers/consignors. In addition, the responses did not appear to be fully consistent with the operation of the transport industry (for example, registration of carriers of dangerous goods is almost universal for air transport, but registration of consignors is not).

The patchwork nature of registration means that in some cases multiple people need to register, while in other cases no one has to register. This is of particular concern in terms of trade in that the need (and cost) of registration for a delivery between two locations can depend on the direction of travel. Clarity over the responsibility for safety is important and this normally is directed at the registrant or licensee. The varied focus on the consignor/carrier could potentially lead to a situation where the direction of travel could also affect the level of regulatory oversight.

The European Parliament identified the need for clarity in this area some 35 years ago. With the introduction of the updated BSS Directive, this may be a good opportunity to harmonise registration requirements in the Community. Unlike in the case of facilities, transport that requires enterprises to operate in more than one MS introduces the essential need for harmonisation, particularly to ensure that the primary responsibility for safety is assigned and safety is maintained at all times.

Relevant international provisions exist that can provide guidance on this matter, pointing to consignors having primary responsibility for safety.

RELEVANT INTERNATIONAL PROVISIONS

2013/59/EURATOM

Article 4

(7) "authorisation" means the registration or licensing of a practice;

(98) "undertaking" means a natural or legal person who has legal responsibility under national law for carrying out a practice, or for a radiation source (including cases where the owner or holder of a radiation source does not conduct related human activities);

Article 31

Member States shall ensure that the undertaking is responsible for assessing and implementing arrangements for the radiation protection of exposed workers.

Member States shall arrange for a clear allocation of responsibilities for the protection of workers in any exposure situation, to an undertaking

> *(45) The IAEA together with … have revised the International Basic Safety Standards in the light of the ICRP's new Publication 103, and the Commission has informed the IAEA of its decision of 6 August 2012 to co-sponsor that document on behalf of the European Atomic Energy Community IAEA BSS*
>
> *Footnote 18 With regard to material being transported in accordance with the IAEA Transport Regulations, the requirements of these Standards for notification and authorization are fulfilled by means of compliance with the requirements of the IAEA Transport Regulations.*

2008/68/EC

ADR 1.4.2 sets out the obligations of the main participants. "The consignor of dangerous goods is required to hand over for carriage only consignments which conform to the requirements of ADR."

IAEA SSG-26

104.1 … By placing primary reliance on the package design and preparation, the need for any special actions during carriage (i.e. by the carrier) is minimized. Nevertheless, some operational controls are required for safety purposes.

IAEA TS-G-1.5

4.71 "The consignor is required to comply with the Transport Regulations both at the point of dispatch and during the subsequent transport of the package. The consignor may delegate some of the actions needed to achieve this compliance but is required to retain overall responsibility for these actions and for their completion."

4.73 According to the Transport Regulations, the consignor has the primary responsibility for transport safety; .... Each carrier … should ensure that its contribution to transport safety is complementary to the efforts of the consignor"

Issue I-4. Guidance on carrier and consignor responsibilities should be developed for radioactive materials.

The responsibility of carriers and consignors has been an outstanding issue for 30 years but was identified as being relatively simple to solve by some participants at the second workshop. In terms of inspection rates the responses (supplemented by returns on roadside checks) indicate that both carrier and consignor inspections are performed at around the 1% rate (1% of consignors per year and 1% of shipments per year). It is clear from guidance that this is a major area of compliance assurance and that all of industry needs to be covered by inspections. The data reported indicate patchy, low-level inspections. Given that over 95% of packages are not subject to approval by a Competent Authority, the low rate reported raises questions on the effective targeting of inspections. Primary responsibility for safety lies with the consignor and current inspection rates indicate that these parties will only be inspected once every 100 years. At the same time, many consignors will have inspections related to their business, which is where liaison could help in reducing the need for inspections for transport purposes.

One issue identified at the first workshop was that some MS have a demarcation issue for regulatory bodies related to the inspection of consignors and carriers. The focus on roadside checks, while important, does not provide oversight of the key areas affecting the safety of radioactive material transport where safety is primarily affected by activities up to the consignment stage.

The limited data available infer an infringement rate of 1 in 3 from roadside inspections based on a standardised system. While a significant portion of these will not be in the highest risk category of the standardised inspection system, the figures suggest inspection of transport operations is important. Inspections in one MS can have an influence on safety in another MS, and this suggests the need to have a coordinated approach. There are international provisions that support the importance of this area.

RELEVANT INTERNATIONAL PROVISIONS
Text extracted from IAEA TS-G-1.5 4.63-4.70; 4.71-4.75
"A major feature of the compliance assurance programme of a competent authority will be the performance of inspections of transport operations"
"All types and aspects of transport should be periodically inspected, in accordance with the size of the industry for the transport of radioactive material in the State."

At the second workshop it was noted that the guidance document on the application of compliance assurance in each of the 12 areas of the compliance circle was being updated by the IAEA and might include guidance on how to apply the graded approach to determine a suitable sampling regime.

Issue I-5. Facilitate compliance assurance that involves the inter-dependency between State regulators, particularly in the areas of design, testing, manufacture and servicing.

During the second workshop, the SG and CTF suggested that this could be taken up by one of the regulatory associations (e.g. EACA). The standard roadside check system is set out in Council Directive 95/50/EC. This establishes checks that seem appropriate to a carrier. However, they are certainly not enough to ensure the safety of aspects controlled by the consignor. Given that the safety of radioactive material transport is primarily in the correct consigning of packages meeting the regulatory standards, there is some question as to whether focusing on roadside checks is the correct approach for Class 7; and certainly the units (e.g. mass) for transport reported to the EU seem to be inappropriate. International provisions set out a purpose for checks, and there remains a question as to whether the current practice under this Directive is appropriate for radioactive material transport.

RELEVANT INTERNATIONAL PROVISIONS
COUNCIL DIRECTIVE 95/50/EC
whereas the respective procedures for checking and the definitions relating to this type of transport should accordingly be harmonized in order for compliance with the safety standards laid down therein to be verified more effectively;
Whereas the Member States should ensure a sufficient level of checks on the vehicles concerned throughout their territory while, where possible, avoiding the proliferation of such checks;
Whereas checks should be carried out using a list of common items applicable to such transport throughout the Community;
Whereas it is necessary to draw up a list of infringements deemed sufficiently serious by all Member States to result in the application to the vehicles concerned of appropriate measures depending on the circumstances

or the requirements of safety, including, where appropriate, refusal to admit the vehicles concerned to the Community;

IAEA SSG-26

545.1. The consignor should take appropriate actions according to its management system to ensure that compliance with the requirements can be demonstrated. This does not mean that actions such as placarding the vehicle have to be carried out by the consignor.

IAEA TS-G-1.5

4.10. … In all cases, the Transport Regulations place the primary responsibility for compliance on the consignor.

4.71. Regulations for the transport of dangerous goods require the consignor to dispatch a package safely and in a manner that complies with the regulations. The consignor may be the owner or manufacturer of the package, or the user or operator of a package owned by a third party. The consignor is required to comply with the Transport Regulations both at the point of dispatch and during the subsequent transport of the package. The consignor may delegate some of the actions needed to achieve this compliance but is required to retain overall responsibility for these actions and for their completion. The declaration on the transport documents signed by the consignor attests to this responsibility.

The SG placed strong emphasis on the use of a graded approach. A key part of this approach is focused inspection based on intelligence (such as information on high rates of non-compliance in specific areas). One area that has caused significant issues in the past is surface contamination on spent fuel and waste packages from nuclear sites. The responses identified only a few MS monitoring this area and at a relatively low level in most MS. The balance between the random nature of roadside checks and the focused nature of intelligence-based inspection is important. Thus, it was thought to be beneficial to provide additional guidance for information on radioactive material checks at the roadside, and also guidance that can be used to support consignor-based inspections.

Issue I-6. Review the need for additional information requirements for roadside checks for radioactive materials and guidance for consignor checks.

7.3 AUDITS OF MANAGEMENT SYSTEMS

Management systems are an extension of regulatory inspections in that they provide a means for the Competent Authority to assure compliance with regulations. As a result, the auditing of management systems is one of the most effective means of assisting industries wishing to comply with regulations. This compliance was demonstrated to a low to moderate level in the responses.

There are indications that compliance checking has improved over the past few years, which may be attributable to the work of the regulatory networks established recently. Extending the influence of these networks might enhance compliance assurance while reducing the burden faced by industry and the State.

International provisions support States working together, and the ADR clearly requires this cooperation.

RELEVANT INTERNATIONAL PROVISIONS

ADR 1.8.2.1

The [Member States] shall agree on mutual administrative support for the implementation of ADR.

IAEA TS-G-1.5

International cooperation

“National competent authorities meet regularly under the auspices of the IAEA …. The common aim of such meetings is related to the uniformity of the application of the Transport Regulations in all Member States. International cooperation in the field of compliance assurance is clearly a powerful tool that can help to achieve that aim.”

Management systems

“Through its compliance assurance programme, the competent authority should ensure that the requirements have been met, for example, by requesting information on and inspecting the radiation protection programmes in use in the industry.”

“The competent authority should put in place an auditing programme to verify that the user’s management system is implemented and followed correctly.”

“The competent authority should also ensure by means of an ongoing audit or inspection programme that suitable management systems are implemented in the transport of packages of other types”

Although audits are being carried out, the majority of MS did not have a national programme. Such a programme is an indication of the intelligence led application of the graded approach. A key area of radiological safety is the active use of radiation protection programmes. There is evidence that these are audited, but the responses do not provide evidence that radiation protection specialists are involved in the audit.

Issue I-7. Consideration should be given as to how the existing grouping of MS for Europe and the Mediterranean region can be linked to Community initiatives. The SG and CTF inputs from the second workshop indicated that steps are already being taken to address this issue.

7.4 DESIGN ASSESSMENT

Assessment is one of the activities of the Competent Authority that is carried out in a home office setting. The responses tended to show transparency in carrying out compliance assurance. One of the issues is consideration of the stability of regulations that govern such assessments, given that the regulations are very specific in nature. Assessments were identified as taking several years to complete.

At the time of writing, changes were being considered to the IAEA Transport Regulations. These changes may be incorporated into the next edition of the UNECE model regulations, and then find their way into the modal regulations, becoming binding at different dates for different modes (according to a well-established process). Ultimately this process could lead to new European legislation in 2021. Other changes occur on a two-year cycle for all dangerous goods. While there are issues which require urgent treatment (such as the carriage of lithium batteries), there is also a lack of stability caused by automatic changes to regulations on such a routine basis.

The accident at the Fukushima Daiichi nuclear power plant led to changes to air transport legislation worldwide through a process more appropriate for urgent safety changes. This raises the question as to whether the current system can responds sufficiently rapidly to address important safety issues in a timely manner. In other words, the current process may not be fast enough for urgent issues and may be too frequent for routine changes.

The IAEA estimates that the cost of making changes to the Transport Regulations will be around €10 million up to the point of publication. This includes consultations on the changes by States represented on six international committees which are required to review any changes). The costs of familiarisation and implementation are much greater.

Given that the approval of some packages can take up to ten years, it is impossible for the industry to gain an approval against the regulations in force at the time of application. There are a number of potential solutions to this issue, such as allowing approval against older editions of regulations or reducing the frequency of regulatory updates. There are no international provisions that provide guidance on the best way to examine this issue.

A common theme for peer reviews related to transport for nuclear States is the frequency of compliance checks applied to non-CA approved packages. This issue is noted in several sections of this report. Only nine package designs that do not require approval by Competent Authorities were subject to an independent review by a Competent Authority over a five-year period, while a further 24 were subject to a review of the original assessment. Even taking into consideration the application of the graded approach, this seems to be a very low number. There are international provisions that provide direction.

In conclusion, demonstrating the safety of the design of packages that did not require Competent Authority approval through the compliance regime does not appear to take place in a transparent manner. Issue I-5 also applies to the review of non-CA approved packages. At the same time, MS carried out assessments of shipments, the majority of which were limited to Europe. This suggests that there is scope for a European initiative to release assessment resources through a more integrated work process.

<u>*RELEVANT INTERNATIONAL PROVISIONS*</u>

IAEA TS-G-1.5

"the Transport Regulations establish requirements for all packagings, packages…; the designs of such ..., packagings and packages can be assessed in respect of their compliance with the regulatory requirements."

"It is the responsibility of the competent authority to ensure that the designs of packages are assessed against all the relevant parts of the Transport Regulations. Therefore, the competent authority … should also ensure that similar assessments of package designs that do not require approval by the competent authority (such as Type A packages or industrial packages) are carried out by the appropriate organizations and that the necessary evidence of such assessments is made available to the competent authority, if requested."

"Reviews and assessments by competent authorities of applications for approval are usually demanding with regard to the necessary resources, skills and expertise."

7.5 ISSUING OF APPROVALS

The issuing of approvals is another area where the responses were clear and positive, following the assessment and remaining closely related to it. There are two types of approval, one where an MS is the first to approve (State of origin approval) and the other where an approval is given after State of origin approval as part of a chain (multilateral approval, which can be by validation). The responses showed that the majority of the 100 State of origin approvals are issued by only two MS. The majority of multilateral approvals relate to package designs originally approved in another MS.

This leads to a situation where MS which have no experience in State of origin approvals are re-approving the work of MS that issue approvals on a weekly basis. The number of Competent Authorities with experience in assessing packages and approving them is limited. The capacity of many of these Competent Authorities is also a matter of concern.

Some EU MS have agreements of certificate recognition in place with States outside the EU (even where regulations may differ). Based on this, it would seem likely that recognition of approvals from other States in the Union could be acceptable (EU recognition system).

An alternative to this could be the establishment of a central assessment body (potentially comprising one or more technical support organisations (TSOs) working for a regulatory oversight body), which would produce either European certificates or certificates that could be issued by a national authority. International provisions are clear concerning the need for approvals by each Competent Authority.

RELEVANT INTERNATIONAL PROVISIONS

IAEA TS-G-1.5

5.1. One of the responsibilities of the competent authority is to issue approvals. The decision to grant an approval is based upon the competent authority's evaluation of the applicant's demonstration of compliance with the relevant requirements of the Transport Regulations. Depending on the type of approval, the corresponding application should contain at least the information as described in Section VIII of the Transport Regulations (paras 803, 805(c), 807, 810, 813, 822 and 825).

5.6. In accordance with para. 802 of the Transport Regulations, competent authority approval is required for the following:

(a) Special form radioactive material;

(b) Low dispersible radioactive material;

(c) Packages containing 0.1 kg or more of uranium hexafluoride;

(d) All packages containing fissile material unless excepted by para. 672 of the Transport Regulations;

(e) Type B(U) and Type B(M) packages;

(f) Type C packages;

(g) Special arrangements;

(h) The radiation protection programme for special use vessels;

(i) The calculation of radionuclide values that are not listed in Table 1 of the Transport Regulations.

Given the number of options, and the evidence of this combined approval system functioning in other areas of industry, there seems to be good reason to investigate this issue further.

Issue I-8. Encourage cooperation between Competent Authorities in the assessment of packages.

7.6 WITNESSING OF TESTING

This is one of the areas where a transparent demonstration of compliance assurance was not provided by the MS responses. Non-CA approved packages may be developed without the intention of using them in transporting radioactive materials, so it is difficult to identify them for testing in advance.

The number of test facilities is limited in the Community, and the potential for activities related to testing taking place in facilities in different States (including States far from Europe) is significant. There are limited facilities where packages can be tested to regulatory standards, particularly large packages. It is usual for parts of the compliance regime to require interface with other States. Few MS identified a strong legal basis for working with other States in this area.

To be clear, it is possible for testing in support of approval to be completed in a State which has no State of origin approval experience (which may or may not have an interest in witnessing the tests), and the results presented to another State for approval. This is particularly the case for packages that do not require Competent Authority approval.

This could extend to a number of other areas where compliance assurance is related. Examining the extent to which this is the case would assist in determining the benefits of a formal permanent agreement on compliance between MS. There are clear international provisions that encourage this cooperation. Thus, Issue I-5 also applies here.

RELEVANT INTERNATIONAL PROVISIONS
ADR 1.8.2.1
The [Member States] shall agree on mutual administrative support for the implementation of ADR.
IAEA TS-G-1.5
International cooperation
"National competent authorities meet regularly under the auspices of the IAEA …. The common aim of such meetings is related to the uniformity of the application of the Transport Regulations in all Member States. International cooperation in the field of compliance assurance is clearly a powerful tool that can help to achieve that aim."
"Testing may be carried out by the designer, the applicant, a third party testing organization, or the competent authority or its nominated independent agent. Irrespective of the organization that actually performs the testing, testing should be carried out to the satisfaction of the competent authority and in a quality assured manner."
"The competent authority (or other approving body) should reserve the right to vary the test programmes in the course of testing in the light of the experience gained."
"Test programmes are important for demonstrating that the performance of packages complies with the applicable regulations; the competent authority should therefore consider the need to witness the actual tests periodically."

The number of tests reported for packages that did not require Competent Authority approval was fairly small. During the workshops, the SG suggested this might be a result of there being a small number of tests carried out, and the graded approach suggesting a need for very few tests to be witnessed. Follow-up information was gathered directly from industry sources that identified a significant rate of testing taking place over the past five years of both Competent Authority approved packages and packages not requiring such approval.

The higher testing rate in two MS suggests variable standards being applied in the Community. The principles established in the preambular text to Council Directive 95/50/EC set out the goal to establish a consistent level of checks of a consistent set of items with a consistent enforcement policy which is reported to the Commission on a regular basis. Issue I-5 also applies in this area.

RELEVANT INTERNATIONAL PROVISIONS

IAEA SSR-6

307. The competent authority shall assure compliance with these Regulations.

IAEA TS-G-1.5

4.63. A major feature of the compliance assurance programme of a competent authority will be the performance of inspections of transport operations… their frequency should be determined in accordance with the scope and activities of the organization being inspected, as well as with the complexity and radiological significance of the activities.

DIRECTIVE 95/50/EC

Whereas the Member States should ensure a sufficient level of checks on the vehicles concerned throughout their territory while, where possible, avoiding the proliferation of such checks;

Whereas, in the light of the principle of subsidiarity, Community action is therefore necessary to improve the level of safety of the transport of dangerous goods;

Whereas checks should be carried out using a list of common items applicable to such transport throughout the Community;

Whereas it is necessary to draw up a list of infringements deemed sufficiently serious by all Member States to result in the application to the vehicles concerned of appropriate measures depending on the circumstances or the requirements of safety, including, where appropriate, refusal to admit the vehicles concerned to the Community;

Whereas the application of this Directive should be monitored on the basis of a report to be submitted by the Commission

7.7 WITNESSING OF MANUFACTURE

The responses to this area of compliance assurance was particularly poor in terms of demonstration of compliance. Given the number of packages that do not require Competent Authority approval, many of which are single use, the number of manufacturing operations witnessed by Competent Authorities was small. As such, this is similar to the issues discussed previously regarding appropriate inspection and package testing sampling rates. It remains possible that the sampling rate of manufacturing operations witnessed is adequate. However it does not appear to be so and there is no clear evidence of why the reported rate should be acceptable. International provisions provide guidance on the need for these inspections. Issue I-5 also applies in this area.

RELEVANT INTERNATIONAL PROVISIONS
IAEA TS-G-1.5 *4.86 "Packagings should be manufactured in a controlled manner and in accordance with the design specifications and the management system. In order to confirm this, the competent authority may request sufficient information to carry out such inspections of the manufacturing as it deems necessary to obtain assurance of compliance with the Transport Regulations."* *4.87 "Manufacturing facilities and subcontractors may be subject to inspections by the competent authority. The frequency and extent of such inspections should be determined by the level of confidence that the competent authority has in the manufacturing arrangements and by the importance to safety of the package features concerned."* *4.91 "The competent authority should ensure that, before the first shipment of a packaging, the manufacturer has fulfilled the requirements of para. 501 of the Transport Regulations…"*

ADR 6.4.23.19 requires the notification of serial numbers to the Competent Authority that approved the design. MS do not appear to be managing serial number registers effectively. However, given the EU-wide transport of radioactive materials and the potential for fraudulent activities to occur internationally, it may be more appropriate for the EU to hold a single register available to all MS. This is the type of activity suited for centralisation. There are relevant international provisions advising on the need for the Competent Authority to maintain this register.

RELEVANT INTERNATIONAL PROVISION
TS-G-1.5 *"For packages approved by the competent authority, the competent authority is required to be informed of the serial number of each accepted packaging"*

Issue I-9. It is suggested that the EU develop a packaging information system that is focused on the needs of the EU, including a register of packages and valid serial numbers. This could be extended if required.

7.8 EXAMINATION OF MAINTENANCE AND SERVICING

Maintenance and servicing are another area where the lack of transparent demonstration of compliance assurance was noted. A few MS carry out checks on paperwork. Checks of actual operations were much more limited, with only three MS indicating they carried them out.

One of the most significant transport incidents in the community involved maintenance responsibility in a different MS from where the package was consigned. To investigate the potential interdependency between MS, a follow up study was carried out. While only three States actually inspected maintenance operations, it was reported that maintenance and servicing took place in 16 MS. A number of cases was identified where maintenance took place in an MS other than the MS of use.

The importance of MS working together to identify and inspect facilities important to each other with an appropriate frequency was noted in this area. There are international provisions on the need for witnessing maintenance and servicing operations. Issue I-5 also applies to this area.

RELEVANT INTERNATIONAL PROVISIONS

IAEA TS-G-1.5

"The competent authority should witness the maintenance and servicing operations carried out by the user (this should be planned but perhaps not announced)."

"For packages approved by the competent authority, the user should be required to record all safety related deviations from and modifications to the specifications, as well as any significant damage noted during the use of the packages. The competent authority should be informed of these deviations before the packages are returned to service, within a certain time period (e.g. 30 days), in accordance with the requirements of the competent authority."

7.9 EMERGENCY PLANNING AND EXERCISES

This is perhaps the area of compliance assurance that was weakest in terms of transparent demonstration of compliance. It also revealed some conflicting approaches, both within and between MS. In terms of regulations, there are three primary aspects of planning for emergency arrangements, exercising (including witnessing of tests) and reviewing. These three areas are consistent with the BSS Directive Article 98.

The modal regulations for roads spell out the responsibilities for planning fairly well. The end result is that there is a structure which involves drivers, carriers, consignors and Competent Authorities in the development of emergency response plans that is established in directive backed requirements. The response that represents this best is that of the Netherlands. Similar clarity is found in other modal regulations.

The initial responses pointed to a complex and varied situation, and as a result a detailed follow up was carried out. MS were asked who should review plans, witness exercises, test plans and respond to emergencies. The situation reported was particularly varied, even within MS. In some places the responses suggested discontinuities within MS as well as between MS.

The new BSS Directive repeats the existing requirement for MS to ensure that emergency response plans are established, tested, reviewed and, if necessary, revised. There is a lack of clarity over which of these aspects are being applied to transport in each MS, and over allocation of responsibilities for each area.

The lack of clarity and harmonisation in the area of emergency preparedness and response (EPR) is significant across the Community and requirements do not appear to be demonstrated as fully implemented. For the time being, it is recommended that the three tables of responsibilities collected as part of this study should be promulgated to raise awareness of the situation in each MS.

There are a number of international provisions in addition to those mentioned above, and there is an overlap that needs to be managed. It is important to ensure that the national interpretation of the goal sought by the BSS Directive remains consistent with the requirements in the binding provisions of international modal requirements, and, in particular, that there are no gaps within and between MS.

RELEVANT INTERNATIONAL PROVISIONS

IAEA TS-G-1.5

4.99. The competent authority should periodically assess the risk of an accident involving the transport of radioactive material and its potential consequences. Emergency planning by the competent authority and other responsible authorities, usually organizations with responsibility for public health and safety, should be based on these and other relevant assessments.

4.100. Detailed recommendations on emergency planning and preparedness are provided in Ref. [6].

4.101. International cooperation may be needed in the case of a transport accident, as discussed in paras 3.15 and 6.10.

2013/59/EURATOM

Article 17 Prior information and training for emergency workers

Article 69 Emergency response

Article 70 Information to the members of the public likely to be affected in the event of an emergency

Article 71 Information to the members of the public actually affected in the event of an emergency

Article 97 Emergency management system

Article 98 Emergency preparedness

1. Member States shall ensure that emergency response plans are established in advance for the various types of emergencies identified by an assessment of potential emergency exposure situations.

…

4. Member States shall ensure that emergency response plans are tested, reviewed and, as appropriate, revised at regular intervals, taking into account lessons learned from past emergency exposure situations and taking into account the results of the participation in emergency exercises at national and international level.

Article 99 International cooperation

7.10 ENFORCEMENT ACTIONS AND INVESTIGATION OF INCIDENTS

This area of compliance is particularly difficult to assess. While other areas have a 'denominator' in the hundreds, thousands or even millions, the safety record for the transport of radioactive material is particularly good. That is, it is not unusual for there to be no need for enforcement or incident investigation in many MS for a number of years. As a result, a lack of response is not necessarily an indication of a lack of transparency. In addition, the lack of incidents is a key source of information in determining how to allocate resources in line with the graded approach.

The majority of enforcement actions and investigation of incidents take place in a small number of MS. There was good evidence provided that this area is effectively regulated, although it may not be employed in many cases (because it is not required). The penalties employed covered a wide range in each State, allowing the penalty to be varied according to the severity of non-compliance.

While relevant international provisions appear to be implemented effectively, there seems little need for change in this area even though a high transparency rating was not demonstrated.

RELEVANT INTERNATIONAL PROVISIONS

IAEA TS-G-1.5

"Every system for compliance assurance should include provisions for enforcement. In this context, enforcement means any formal actions by the competent authority against the user of the regulations when cases of violation or non-compliance by that user have been observed."

"A range of enforcement actions may be applied, depending on the safety significance of the violation or non-compliance."

"A system for the reporting of all significant incidents, including accidents, or of deviations from the Transport Regulations, should be developed, and the competent authority or its authorized representatives should investigate any reported occurrences."

"The competent authority should also liaise with other groups concerning enforcement to obtain a clear understanding of the respective responsibilities and operating methods of each of the departments or agencies involved. When the competent authority has such an understanding, it can consider the completeness of the inspection and enforcement arrangements and identify any areas of overlap between the arrangements of different agencies, or, more importantly, it can identify where there are gaps between the operations of one agency and those of another agency."

7.11 TRAINING AND DISTRIBUTION OF INFORMATION

A common issue would appear to be the availability of trained persons to work in industry and Competent Authorities. This places a focus on this area of compliance assurance. The responses failed to demonstrate that this area of compliance was being delivered effectively.

Training of different groups occurs in various MS, but is patchy at best. Understanding the training needs and focusing on capacity building in the EU may be beneficial, in particular for State officials. Different MS appear to focus on different aspects of training, indicating the benefit of an EU based approach to developing competence.

RELEVANT INTERNATIONAL PROVISIONS

IAEA TS-G-1.5

"Preparation and issuing of information and guidance by the competent authority are needed for the implementation and functioning of a compliance assurance programme…. it may involve the development and sponsoring of seminars, conferences or training courses for personnel of regulatory bodies, consignors, carriers and other groups, to explain the correct application of the Transport Regulations."

"The duties and responsibilities of other personnel, such as employees of the competent authority, independent inspectors and emergency personnel, should also be specified so that the necessary training can be determined and provided."

"In addition to providing for the training of its own personnel, the competent authority should, as appropriate, specify and participate in the training of other persons involved in the transport of radioactive material. Furthermore, the competent authority should ensure through its compliance assurance programme and its monitoring of management systems that all the training needs of the organizations involved in transport are recognized and implemented."

While some Competent Authorities have limited involvement in this area of compliance assurance, there is some international guidance available.

Issue I-10. Develop an EU capacity building model based on the UK national system.

During follow-up meetings it was suggested that those Competent Authorities that originate in the radiation protection area might benefit from training in practical transport infrastructure, while those that originate in transport might benefit from radiological protection training. Cross-regulatory familiarisation between radiation protection and transport regulators should be improved where necessary (taking the example of France).

The IAEA has a suitable training programme, which has not been operating in Europe for several years since it is normally funded by IAEA Technical Cooperation funds (much of which are supplied by the EU). This training is now available on-line. There is a possibility of partnerships outside of the EU, such as the modal agencies, modal industry bodies and the IAEA (for example, by supporting enhancement of their technical basis document which describes how transport safety is ensured).

Based on the results of this study the following areas should be given specific consideration:

- Competent Authorities;
- Transport nodes (airports, sea ports, border crossings).

One area that appeared to be lacking was a coordinated programme for training/capacity building. The SG was introduced to the capacity building system in place in the UK and the possibility of adopting this at the European level was considered.

The key steps to be considered would be:

- Establishing Community needs for capacity building;
- Establishing guiding groups, partnerships and sponsorships;
- Establishing industry and Competent Authority supported training and development activities;
- Establishing and promulgating the basis of the safe transport of radioactive material;
- Developing transport expertise within the radiation protection specialty, including:
    - Radiation protection (and nuclear safety) Competent Authority employees;
    - Radioactive material industry (including spent nuclear fuel and radioactive waste);
- Development of radioactive material transport knowledge within the transport industry.

Issue I-11. The EU should encourage training, and potentially the IAEA on-line training platform. Consideration of the need for harmonised tests is appropriate.

> The UK regulator (ONR) identified a UK-wide capacity building process, a collaborative approach between the UK Government (including the regulatory body) and the industry. This involved the establishment of the Nuclear Skills Strategy Group (NSSG) with support from the industry.
>
> The NSSG initiated research into the future needs for nuclear specialists nationally and the results are available in the report **Nuclear Workforce Assessment 2015**
>
> http://www.cogentskills.com/media/59769/nuclear-workforce-assessment-2015_r1.pdf
>
> This research indicated that in the next five years, an average of 8,200 new recruits would be required in the field.
>
> Following this assessment, the NSSG in partnership with the UK Government, regulators, and trade unions have developed the Nuclear Skills Strategic Plan, (http://www.cogentskills.com/media/76258/national-nuclear-skills-strategic-plan.pdf), which covers national development of skills from schools through to experts. A number of new postgraduate nuclear courses have been set up with an increasing number of participating students. The strategy covers specialists suitable for work in the industry and the regulatory bodies.

In order to achieve this, it will be necessary to identify a responsible entity.

Issue I-12. It is proposed that an EU body is established incorporating non-regulatory governmental representatives which are responsible for facilitation of the transport of radioactive materials.

It was noted during the second workshop that the IAEA was hosting a special event during its annual General Conference on this subject, and may be identifying such a body at the international level. This was identified as an area where work was currently ongoing.

As part of this area, the SG identified the provision of guidance as one of the most cost-effective means of improving overall compliance. It was proposed, therefore, that initial guidance could be developed that identifies MS responsibilities for carriers and consignors covering both the safety and security of the transport of radioactive materials. Suggestions for guidance include the following:

- Guidance should be specific to the types of transport packages;
- Guidance should be specific to the target audience;
- Guidance should take into account the graded approach;
- Overviews of the situation in each MS to support understanding.

Overall, this area of compliance seems to be targeted for improvement globally and, as a result, there are potential benefits from joining in the global efforts. In addition to the provision of useful information, appropriate training is an important aspect of transparency. This is potentially the area of compliance that would be easiest to improve, and the SG's input suggests it may have the greatest effect in improving overall compliance.

7.12 INTERDEPARTMENTAL LIAISON AND COOPERATION

A number of MS identified formal arrangements for the interface with other Competent Authorities, but most did not. When examining responses in other areas it is clear that communication within a MS could be improved. The response option 'N/K' was intended to allow this particular aspect to be identified. There are international provisions that guide the need for effective liaison.

RELEVANT INTERNATIONAL PROVISIONS
IAEA TS-G-1.5 *"more than one organization may be responsible for the regulatory control of transport in a State"* *"The competent authority should arrange regular meetings for all parties within this complex network of agencies and persons in order to ensure:* *(a) An exchange of information regarding existing regulations for the transport of radioactive material;* *(b) An exchange of information on changes to national laws and regulations as well as changes to the Transport Regulations;* *(c) A complete programme of training for personnel at all levels;* *(d) Consistent application of inspection and enforcement relating to compliance assurance;* *(e) A regular review of all measures for emergency response, including the responsibilities of the competent authority, the industry for the transport of radioactive material and other relevant agencies;* *(f) A suitable forum for the discussion and resolution of issues relating to the Transport Regulations and compliance assurance."* *"The competent authority should put in place formal agreements with agencies responsible for national regulations that are only indirectly linked with the Transport Regulations."* *"The competent authority should agree to an adaptation of the emergency procedures of such agencies to the particular case of accidents in the transport of radioactive material. Although the solution to such problems may be relatively simple, the competent authority should agree to the procedures for emergency response and should initiate a system of periodic review of any such procedures."*

The first step to improve the effectiveness of liaison is to identify the organisations with which the liaison should take place. Some responses indicated the detailed advantages of working together. The overall area, although not having formal arrangements, is working effectively internationally, but could improve nationally. Issue I-1 applies in this case.

7.13 SUMMARY OF REGULATORY INFRASTRUCTURE REVIEW

Overall, the areas where the responses demonstrated effective compliance in a transparent way are office based Competent Authority activities. There is no evidence that there are significant failures in compliance assurance (with one exception), but there is a lack of readily available information that may imply the effective application of the graded approach.

As far as the application of the graded approach is concerned, there were limited responses that would justify the balance of regulatory effort between packages requiring Competent Authority approval and packages that do not require Competent Authority approval. While the balance may be correct, the level of oversight of packages that do not require Competent Authority approval is at a level that would appear low to the public. As a result, greater transparency in relation to the choice of inspection level is important.

There are a number of areas where improvements can be made, such as the provision of guidance and capacity building, but urgent action would not appear to be warranted in most areas. The one exception is the area of emergency preparedness and response, where the overlapping regulations appear to have resulted in a complex mixture of arrangements that have potential gaps. This could resolve itself in the near future, though it is an area where ongoing monitoring of the situation would be beneficial.

8 SPECIFIC ISSUES

Specific issues were identified by the Consultant and the CTF and were explored as part of this study. The SG identified the graded approach as a potential reason for the low number of inspections in several areas. The first two items in this chapter look at the information that could justify low inspection rates, namely internal and external reviews of the regulatory system as a whole.

Specific questions concerning waste, ageing (packages used for long term storage), and denial of shipments were required by the contract and were reviewed here. The SG tended to be cautious about any responses that went beyond transport safety.

Three sections were added, one to allow respondents to provide examples of good practices that they felt should be considered, and two others that resulted from SG inputs during the project — the administrative and financial costs of making applications.

8.1 EFFECTIVENESS REVIEWS

One of the specific issues examined was how the Competent Authority becomes aware of its effectiveness. This feeds directly into the understanding of which areas of compliance assurance the Competent Authority should focus on improving. Annex 1 of IAEA Safety Standards Series No. TS-G-1.5 sets out the means for establishing a compliance assurance programme.

IAEA TS-G-1.5 Annex 1

(12) Implementation of the initial compliance assurance programme;

(13) Collection of initial evidence of compliance with the Transport Regulations by means of the activities shown in Fig. I–1;

(14) Accumulation and review of evidence of compliance on a continual basis;

(15) Conduct of periodic reviews of all aspects of the compliance assurance programme; adjustment of the input or effort deployed by the competent authority in addressing the various segments of the compliance assurance circle shown in Fig. I–1

The compliance assurance circle consists of the areas covered in Chapter 7 of this report. Given that several Competent Authorities were unable to answer the full set of questions 2.1 to 2.12 and taking into account the effort needed for each aspect, the effectiveness of compliance assurance was hard to estimate. Based on answers to question 2.13, it appears that the information expected to be provided by Competent Authorities to demonstrate that compliance assurance is evidence-driven is not being routinely collected in the Community. There are several items that the questionnaire identified as particularly relevant; these were the areas set out in question 3.

8.1.1 NORMAL TRANSPORT

The safety record of the transport of radioactive materials is very good. As a result, one of the key measures of safety trends is the radiation exposure of workers and the public when no accidents occur.

8.1.1.1 WORKER EXPOSURES

The majority of MS reported on the means of assessing worker exposure, many MS noting that results came from individual monitoring. The upper exposures mentioned were around 5 mSv in a year. Some MS recognised that exposures might be assessed through workplace monitoring.

Some MS indicated that very short-lived radionuclides could lead to higher exposures, and Spain identified that package design issues could be improved to reduce worker exposure, especially of carriers of urgent medical products. It is clear that worker exposure is being reviewed widely in the Community and does not appear to be a significant concern.

8.1.1.2 PUBLIC EXPOSURES

Some MS reported on the use of radiation monitoring networks to assess public exposure. The effectiveness of this method is not obvious. Several MS reported the use of carriers/licensees to assess public exposure. Around one-third of responders reported programmes of public exposure assessment by the Competent Authority. However some of the suggested methodologies appear to be inappropriate for the transport of radioactive materials.

Several studies carried out by the UK are of particular relevance:

- PHE-CRCE-035 - Survey into the Radiological Impact of the Normal Transport of Radioactive Material in the UK by Road and Rail, March 2017;
- PHE-CRCE-006 - Survey into the Radiological Impact of the Normal Transport of Radioactive Material by Air, 2012 study, published in January 2014;
- HPA-RPD-050 - A Survey into the Radiological Impact of the Normal Transport of Radioactive Material by Sea - Final Report February 2009;
- NRPB-W66 - Survey into the Radiological Impact of the Normal Transport of Radioactive Material in the UK by Road and Rail - Final Report March 2005;
- NRPB-W39 - Survey into the Radiological Impact of the Normal Transport of Radioactive Material by Air - Final Report 2003;
- NRPB-M749 - Radiological Impact of the Normal Transport of Radioactive Material by Sea - Final Report 1996;
- NRPB-R255 - Radiation Exposure from the Normal Transport of Radioactive Materials within the United Kingdom –1991 Review - Final Report 1992;
- NRPB-M219 - Radiological Impact of the Normal Transport of Radioactive Materials by Air - Final report 1990;
- Radiological Impact of the Normal Transport of Radioactive Material by Sea - Final Report 1988;
- NRPB-R115 - Radiation Exposure Resulting from the Normal Transport of Radioactive Materials within the United Kingdom - Final Report 1984.

In addition, a Community-wide study from 2003, 'Statistics on the Transport of Radioactive Materials and Statistical Analyses', is accessible online and can be downloaded at https://ec.europa.eu/energy/sites/ener/files/documents/20131018_trm_statistics.pdf

The study includes the finding that "Occupational and public exposure data are generally not being collected, reported and published by transport operators and Competent Authorities on a routine basis". This is consistent with the findings of this study.

There are a number of relevant international provisions that cover this area.

RELEVANT INTERNATIONAL PROVISIONS

IAEA SSR-6

308. The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the Basic Safety Standards.

IAEA SSG 26

308.2. In order to comply with para. 308 of the Transport Regulations, information on the radiation doses to workers and to members of the public should be collected and reviewed, as appropriate.

IAEA TS-G-1.5

4.51. The competent authority is required to arrange for periodic assessments to evaluate the radiation doses to workers and to members of the public due to the transport of radioactive material (para. 308 of the Transport Regulations). Data from consignors and carriers that need to assess the doses arising from their transport operations may be used in such assessments of radiation doses by the competent authority. However, the competent authority should independently verify the data received from consignors and carriers. Questionnaires, analyses, site visits and measurements may be used to assess doses.

IAEA GSR Part 3

3.135 The regulatory body shall be responsible, as appropriate, for:

(c) Making provision for an independent monitoring programme.

(d) Assessment of the total public exposure due to authorized sources and practices in the State on the basis of monitoring data provided by registrants and licensees and with the use of data from independent monitoring and assessments.

BSS Directive

Article 66 Estimation of doses to the members of the public

1. Member States shall ensure that arrangements are made for the estimation of doses to members of the public from authorised practices. The extent of such arrangements shall be proportionate to the exposure risk involved.

2. Member States shall ensure the identification of practices for which an assessment of doses to members of the public shall be carried out. Member States shall specify those practices for which this assessment needs to be carried out in a realistic way and those for which a screening assessment is sufficient.

3. For the realistic assessment of doses to the members of the public, the competent authority shall:

(a) decide on a reasonable extent of surveys to be conducted and information to be taken into account in order to identify the representative person, taking into account the effective pathways for transmission of the radioactive substances;

(b) decide on a reasonable frequency of monitoring of the relevant parameters as determined in point (a);

(c) ensure that the estimates of doses to the representative person include:

i) assessment of the doses due to external radiation, indicating, where appropriate, the type of the radiation in question;

ii) assessment of the intake of radionuclides, indicating the nature of the radionuclides and, where necessary, their physical and chemical states, and determination of the activity concentrations of these radionuclides in food and drinking water or other relevant environmental media;

iii) assessment of the doses that the representative person, as identified in point (a), is liable to receive;

(d) require records to be kept and be made available on request to all stakeholders relating to measurements of external exposure and contamination, estimates of intakes of radionuclides, and the results of the assessment of the doses received by the representative person.

It appears that some MS may be limiting the term 'persons' to workers, and that the Community is not assessing doses to the public effectively. This would seem to be a significant gap in the justification of the low levels of inspection. If there is no assurance that the system of protection is achieving its goal, then the inspection rates cannot be demonstrated to be acceptable.

8.1.2 ACCIDENTS

The low accident rate will naturally limit the information that can be gathered, but the information on enforcement and investigation in the previous chapter suggests that the Competent Authorities are aware of the accidents that occur.

8.1.2.1 RECORDS OF ACCIDENTS

Most MS require reports of incidents (as set out in the ADR), record them centrally and use the INES system. The INES system for transport was initially developed under the supervision of the EC and supplied to the IAEA for inclusion in the INES manual. Its wide adoption in the Community must be seen as a positive influence of the work of the former SWG.

MS were able to provide statistics on incidents. Only two events rated as INES 2 or above were reported in the Community for the last five years. However, only five MS were able to identify public reports that made this information available. This suggests a lack of transparency. Along with the low quality of information provided to the EU on radioactive material transport statistics, the poor availability of information demonstrated in the responses for this study suggested the need to improve transparency.

8.1.2.2 REVIEWS OF ACCIDENTS

Although most MS have a process of learning from accidents, some of them did not provide responses and several reported that learning did not take place. Again, the availability of public reports was limited.

8.1.2.3 HISTORICAL DOCUMENTATION

The availability of historical documentation was investigated in order to identify the frequency with which MS made information available. Again, the number of reports was limited. Some MS explained the lack of items to report. However, they did not expand on whether they were making this piece of information known publicly.

The European Parliament originally suggested annual reports should be made at Community level.

8.1.3 IMAGE

A review of the image perceived by the Competent Authority indicated that the most positive view was considered to be with workers, while the public had a slightly negative view. This may be the actual perception of the public, or the degree to which the Competent Authority addresses the concerns of the public, but in both cases better communication between the Competent Authorities and the public is necessary.

As part of the follow-up, a list of items was prepared that could be shared for the purpose of improving public perception. These items were reviewed by the Consultant for relevance. It was found that some were more appropriate than others. However, it was considered beneficial to keep full list in this report for further reference since some of the items that were not considered appropriate could provide guidance to other more important areas.

One general conclusion though is that the level of reporting by the Competent Authorities was considered overly technical for public consumption.

Belgium

- The FANC in collaboration with CGCCR and the Police has written an information document for the public, which is available on the FANC website (in French and Dutch). See:

- http://afcn.fgov.be/fr/dossiers-dinformation/transport-de-matieres-radioactives
- http://afcn.fgov.be/fr/system/files/dossier_dinformation_transport_de_matieres_radioactives.pdf

- For specific shipment (media, like transport of spent fuel, waste issued from reprocessing), after each transport the FANC publish a press release. For example (transport of spent fuel from the Netherlands to France through Belgium), see: http://afcn.fgov.be/fr/actualites/sixieme-transport-de-combustible-irradie-des-pays-bas-vers-la-france.

Bulgaria

- The Act on the Safe Use of Nuclear Energy
- Regulations on the Conditions and Procedure for Shipment of RAM
- Guide "Implementation of requirements for the safe transport of radioactive materials"
- Regulations for the procedure for issuing licenses and permits for safe use of nuclear energy
- Regulations on the conditions and order for the carriage of dangerous goods by road

Czech Republic

- In the Czech Republic there is no problem with public understanding concerning the transport of radioactive material. The State Office for Nuclear Safety as the competent authority provides information within fields of its competence, including the transport of the radioactive materials on the website, see: https://www.sujb.cz/en/

Denmark

- SIS publishes a publication each year, called "Transportorienteringen". It gives an overview of the transportation of radioactive material in Denmark. It addresses the previous year, and can be downloaded from ww.sis.dk. The publication is only available in Danish.

Estonia

- In KeA Homepage (www.keskkonnaamet.ee) are guidelines for Radiation Practice Licence applications.

Finland

- The new directive is still being implemented. The draft legislation is subject to public consultation.

France

- Nearly ten years after enacting the Act of 13th June 2006 relative to Transparency and Security in the Nuclear field (TSN Act), the Act of 17th August 2015 relative to Energy Transition for Green Growth (TECV Act) reinforces the legal provisions in terms of transparency and public information. In this context, the French nuclear authority (ASN) and IRSN, the technical support organization of ASN, conduct different actions to inform the public about nuclear and radiation risks. Concerning the transport of radioactive materials:
  - ASN consults the public by Internet on the synthesis of safety analysis reports for new package designs and their renewal and publishes after the consultation theses certificates;
  - IRSN publishes, on its website, all the technical assessments performed for ASN;
  - ASN publishes on its website all the inspection follow-up letters;
  - In the case of an incident ranked at level 1 or more on the INES scale, ASN publishes an informative communication;
  - IRSN also publishes every two years a review of all events involving a transport of radioactive materials;
  - ASN consults the public by Internet on the projects of guidelines and regulatory texts;

- ASN and IRSN present on their websites general information about transport and the regulatory provisions. In addition, ASN publishes every year an annual report that presents the state of nuclear safety and radiation protection in France, which includes transport activities.

- Article 7 of the Environment Charter embodies the right of participation of any citizen in the framing of public decisions having an impact on the environment. In addition, article L. 123-19 of the Environment Code provides a procedure of consultation of the public via Internet on draft regulatory texts having an impact on the environment. ASN has decided to apply this widely. Consequently, most important ASN draft statutory resolutions including transport of radioactive materials are considered as having an impact on the environment and are therefore subject to public participation. The public participation procedure consists in posting the draft statutory resolution, corresponding to the draft approval certificate in the field of transport, on www.asn.fr for about 15-21 days in order to give people time to make their comments. A synthesis of the remarks made, indicating those taken into account, and a document setting out the reasons for the resolution can be published on www.asn.fr at the latest on the date of publication of the resolution. Furthermore, in a volunteer approach as it is not required by the French legal system, ASN published guidelines to inform and consult the public. This approach allows to answer to the public's growing needs to understand and take part in decision-making on issues relating to health or environmental risks.

Greece

- https://eeae.gr/en/radiation-protection/transport-of-radioactive-materials

Ireland

- http://www.epa.ie/radiation/lic/needtoknow/transport/
- http://www.epa.ie/radiation/lic/irrs/ (see sections on transport)
- The EPA has a Business Support Team / Inspectorate which can assist the public / applicants / licensees with queries relating to the transport of radioactive material (Monday-Friday 09:00- 17:00). Additionally, the EPA in association with the Garda Síochána (National Police) have a dedicated phone number for out of hours incidents or emergencies, with an on-call Duty Officer assigned from the EPA.
- http://www.hsa.ie/eng/Your_Industry/ADR_-_Carriage_of_Dangerous_Goods_by_Road/ADR_General_Information/Legislation/
- http://www.hsa.ie/eng/Your_Industry/ADR_-_Carriage_of_Dangerous_Goods_by_Road/ADR_General_Information/ADR_Main_Changes_Reports/
- http://www.hsa.ie/eng/Your_Industry/ADR_-_Carriage_of_Dangerous_Goods_by_Road/ADR_General_Information/Useful_Websites/
- http://www.hsa.ie/eng/Your_Industry/ADR_-_Carriage_of_Dangerous_Goods_by_Road/ADR_General_Information/Transportable_Pressure_Equipment_Directive/http://www.hsa.ie/eng/Your_Industry/ADR_-_Carriage_of_Dangerous_Goods_by_Road/ADR_Files/ADR_driver_training_information.pdf

Latvia

- Guidelines for the content of radiation safety quality assurance programme were developed by RSC SES in 2017 and published on SES website. General requirements for applicant`s management system, radiation protection officer and radiation workers, protection of workers and public are covered by these guidelines and are applicable to transport operators as well.
- Guidance prepared by radiation safety expert on safe transport of radioactive materials

Lithuania

- IAEA, ADR, RID, IMDG-Code, ICAO-TI are implemented in their original form
- Law on Radiation Protection
- Law on Nuclear Safety; Law on Nuclear Energy
- Rules on Import, Export, Transit and Transport of Radioactive Material, Radioactive Waste and Spent Nuclear Fuel, approved by the Order No. V-1271/22.3-139 of the Minister of Health of the Republic of Lithuania and Head of State Nuclear Power Safety Inspectorate on 24 December 2008.
- Requirements for Recognition of Certificate of Compliance of Transportation Package for Radioactive Materials and Radioactive Waste, approved by the Order No.73 of the Director of Radiation Protection Centre on 7 November 2008;
- Nuclear Safety Requirements „BSR-4.1.1-2017 „Rules on issuing transportation certificates of Nuclear Fuel Cycle, Nuclear and Fissile Materials.

Luxembourg

- http://www.sante.public.lu/fr/espace-professionnel/radioprotection-etablissement-autorisation/transport/index.html

Netherlands

- The main source is the ANVS website (https://www.autoriteitnvs.nl/). ANVS has active transparent communication about, among other things:
- Publication of all issued transport licenses (https://www.rvo.nl/vergunningen-online, search for company or 'transport'). Note that: 1. They are open for objection by stakeholders/the public after publication. 2. For security reasons, only licenses concerning the transport of fissile material cat I,II and III are not actively made public. However, they are announced on the website and the public may require ANVS to send a public version where specific security related details have been removed.
- Transparent justification of practises: this is clearly regulated (see regulation: http://wetten.overheid.nl/BWBR0040509/2018-02-06, look for 'rechtvaardiging'). The regulation contains a list of practices that are justified and a negative list of those applications that are not justified (annex 2 of the regulation). This is called 'generic' justification. The applicant may apply for justification in case of new application and always has to explain the specific use to enable the ANVS to decide on the 'specific' justification. Once justified, the motivation can be found in the license (both for transport and other use of RAM/radiation)

Poland

- Through access to public information in accordance with Polish law (Act of 6 September 2001. On access to public information).

Romania

- The list of the authorized carriers for transport of radioactive material
- The specific norms on protection against ionizing radiations for transport of radioactive material
- The ADR questionnaire for training of the personnel involved in transport of radioactive material with their answers

Slovenia

- Sevalne novice (Engl. Radiation News) in Slovenian language

Spain

- El transporte de materiales radiactivos (Actualización 2015) Publicaciones - Serie divulgativa - SDB-06.01. Published by CSN (www.csn.es)
- FDE-02.12 - 12 Preguntas frecuentes sobre el transporte de material radiactivo. Published by the CSN: www.csn.es
- El transporte de material radiactivo. Transporte de residuos radiactivos y de combustible nuclear irradiado.
- Monografía Comité Asesor. Published by the CSN (www.csn.es)

Sweden

- SSM home page (ssm.se)
- TiB
- SSM press hotline
- Transparency is a key value at SSM

United Kingdom

- ONR regards transparency as one of the key principles of enforcement as set out in our Enforcement Policy Statement - http://www.onr.org.uk/documents/2014/enforcement-policy-statement.pdf
- ONR therefore publish as much as practicable on the ONR website. The key documents relating to radioactive material transport can be found in:
  - http://www.onr.org.uk/transport/index.htm
  - http://www.onr.org.uk/transport/guidance.htm

  ONR decisions in relation to package approvals and inspections can be found in:

  - http://www.onr.org.uk/pars/index.htm and http://www.onr.org.uk/intervention-records/index.htm respectively.

- There is also some further Technical Assessment Guides (TAGs) which can be found at http://www.onr.org.uk/operational/tech_asst_guides/index.htm. These primarily provide guidance to ONR inspectors on the interpretation and application of regulations. TAGs also provide information to dutyholders regarding ONR's expectations of the nature and content of relevant technical elements of safety cases and security plans. Of particular significance are:
  - NS-TAST-GD-097 (Rev 0) - Criticality Safety Assessment of Transport Packages
  - NS-TAST-GD-099 (Rev 0) - Transport Engineering Assessment
  - NS-TAST-GD-100 (Rev 0) - Shielding and Dose Rate Safety Assessment of Transport Packages
- Some other useful documents include:
  - http://www.onr.org.uk/documents/a-guide-to-nuclear-regulation-in-the-uk.pdf (see page 28)
  - http://www.onr.org.uk/licensing-nuclear-installations.pdf (see pages 23 & 24)
  - http://www.onr.org.uk/documents/2014/enforcement-policy-statement.pdf (see pages 2 & 3)

The ability to provide a non-technical synthesis of the technical information available is considered to be a key aspect of transparency. Communicating in a language that the listener does not understand is not effective communication, and in this respect 'technical' is effectively another language used in the majority of these reports.

While technical communication is an important part of transparency in relation to other experts, it is not the appropriate language for the public. The development of the INES system is a good example of a tool that can be used to 'translate' the technical aspects of communication for the public. The background to determinations of the INES level for events (particularly for levels 3 and below) can involve complex technical decision making, which is of little interest to public perception of the severity of incidents.

8.1.4 REPORTS

8.1.4.1 COMPETENT AUTHORITY REPORTS ON NON-COMPLIANCE

Very few MS make information on non-compliance available to the public. There are clear international provisions on this matter, which recommend reporting only "outlines" and "main findings".

RELEVANT INTERNATIONAL PROVISIONS
2013/59/EURATOM *Article 104* *4. Member States shall ensure that outlines of the inspection programmes and the main findings from their implementation are available to the public.*

Issue I-13. Information should be made public on the outcome of inspections in line with BSS Directive requirements.

8.1.4.2 RADIOACTIVE INDUSTRY REPORTS

Few MS were able to identify reports by industry on compliance issues. Several MS gather this information and publish it in the form of a regulatory report. The prime responsibility for safety always lies with the industry, and this question was intended to identify whether there were any industry collaborations aimed at reviewing issues to improve safety. Only the UK identified an industry group carrying out this activity.

Issue I-14. Industry should cooperate with each other to learn from significant events (through the Competent Authority).

8.1.4.3 CARRIER REPORTS (e.g. DGSA REPORTS)

A significant source of information on safety performance is the DGSA (Dangerous Goods Safety Advisor) report. Only eight MS demonstrated knowledge of these reports. ADR 1.8.3.3 requires that a DGSA should produce an annual report on the carriage of dangerous goods; ADR 1.8.3.6 requires a report to be made by the DGSA in the event of an accident. The fact that the majority of class 7 Competent Authorities did not have a simple response to this question indicates that there may be a knowledge gap of the Competent Authorities related to this requirement, and several MS supported this assumption in follow-up meetings.

8.1.5 HISTORICAL DOCUMENTS/TECHNICAL BASIS — THE IAEA REVIEW PROCESS

The majority of MS were involved in the IAEA review process, which provides access to the technical basis of the regulations and to a significant amount of supporting historical information. As a result, it is expected that the Competent Authorities will have the information readily available to review the basis of regulatory requirements when needed.

8.2 STATE REVIEWS

MS were asked to provide information on international State audits or peer reviews that related to the transport of radioactive materials. Around two-thirds of the MS indicated that they had been subject to the transport module of the IAEA IRRS peer review.

Common issues identified include:

- Policy and procedure for regulatory review;
- Competence building/training;
- Authorisation clarification and consistency.

There was almost complete lack of awareness among MS of the International Civil Aviation Organization (ICAO) and International Maritime Organization (IMO) audit systems. These could provide feedback on the transport of dangerous goods, including radioactive materials.

Two MS reported that they were subject to audits with respect to land transport (**Figure 3**).

Data from the ICAO Universal Safety Oversight Audit Programme (USOAP) for Member States is presented in **Table 3** for a range of areas that may provide information relevant to the transport of radioactive materials. For example, the area of legislation covers the regulation of radioactive material transport by air and is of direct relevance, while the area of accident investigation has little direct relevance but may indicate a State-wide failure to learn from accidents. The numbers in the table are a measure of the State's safety oversight capability, called effective implementation (EI — %). A higher EI indicates greater maturity of the State's safety oversight system.

Table 3: Relevant ICAO audit results

	Legislation	Organisation	Licencing	Operations	Accident Investigation	Overall
Austria	90.91	67.42/81.82*	100	94.21	69.57	92.55
Belgium	81.82	77.78	92.31	86.89	87.78	87.01
Bulgaria	76.19	70	92	87.7	76.09	82.59
Croatia	59.09	72.73	94.05	89.17	55.56	75.33
Cyprus	63.64	81.82	76.71	90.83	78.26	75.34
Czech Republic	90.91	50	86.84	85.12	72.83	86.63

	Legislation	Organisation	Licencing	Operations	Accident Investigation	Overall
Denmark	81.82	66.67	94.81	82.91	89.13	86.15
Estonia	71.43	62.5	82.28	60.98	32.22	63.54
Finland	66.67	75	72.15	71.54	76.09	76.93
France	100	100	100	98.32	96.77	96.06
Germany	81.82	100	91.58	82.99	94.57	87.02
Greece	72.73	27.27	71.43	68.85	79.35	68.22
Hungary	57.89	66.67	83.95	85.47	90	70.56
Ireland	91.3	100	100	97.6	100	94.76
Italy	86.36	91.67	89.02	90.32	91.3	89.22
Latvia	77.27	87.5	94.74	91.87	80	86.91
Lithuania	73.91	55.56	91.36	82.26	22.58	72.68
Luxembourg	57.14	90.91	93.06	85.48	42.39	70.01
Malta	54.55	72.73	80.77	76.42	47.83	70.6
Netherlands	80.95	100	95	93.55	73.33	87.99
Poland	95.45	81.82	90.12	88	66.67	87.59
Portugal	86.36	63.64	95.06	91.2	75.56	72.56
Romania	95.45	90.91	100	96.75	69.57	91.95
Slovakia	86.36	63.64	86.42	60.66	43.01	75.2
Slovenia	43.48	45.45	83.95	69.35	31.11	63.38
Spain	72.73	75	91.36	89.34	73.91	85.21
Sweden	95.45	100	98.72	96.72	74.44	90.23
United Kingdom	95.45	83.33	94.87	85.25	83.33	93.5
EU 28 Average	71.03	67.42	72.72	67.72	54.77	

*There are two different results quoted for Austria in different tables.

The review shows that some MS are performing well below the global average in certain areas. Whether this reflects on the transport of radioactive materials in these MS is worth considering by the Competent Authorities. At a minimum it is suggested that Competent Authorities make themselves aware of their State's modal audit results.

For both the air and sea modes there are mandatory audit schemes, including follow-up, while the only system used that covers land transport of radioactive material is the IRRS peer review, and then only on a voluntary basis (missions are requested by MS). Some MS had chosen to include transport in the scope of their IRRS. The Nuclear Safety Directive in Article 8e calls for Member States to have peer reviews at regular intervals; however, the Directive is clearly focused on facilities and not activities such as transport.

The IAEA system provides a focus on whether the legislation has been implemented, but does not look at harmonisation of implementation. The IRRS reviews regulatory systems based on the IAEA safety standards, and with due account of national circumstances. However, given that the legislation on the transport of radioactive materials by land is set at EU level and is detailed in its requirements, it can be argued that, for effectiveness, the transport of radioactive materials should be reviewed at a level different from other activities involving the use of radioactive materials in that the aspect of harmonisation of implementation should also be reviewed.

The text in different IRRS reports can be conflicting in terms of implementation. For example, in some cases the focus of the IRRS can be toward consignors, in other cases toward carriers. One issue where contradictory suggestions were noted was related to the acceptance of the work of other States in the assessment process:

- "Good Practice: SSM assessment of packages takes account of work done by other Competent Authorities. This approach is novel, not widely used elsewhere, helps where resources are limited and maintains safety levels.

- After the first assessments carried out several years ago, the assessments for these approvals have been limited to an endorsement of the assessment made by the Competent Authority of the country of origin of the package designs. TS-G-1.1 (Rev. 1) however states that such assessments should be made independently, primarily because of the nature of the criticality hazard and the importance of maintaining sub-criticality at all times during transport."

A mandatory audit system is in place for air and sea modes and has proved feasible for implementation. Given the EU's involvement in setting requirements for land mode, and the fact that reviews are not audits and are voluntary in nature, criticism could be raised on the lack of oversight.

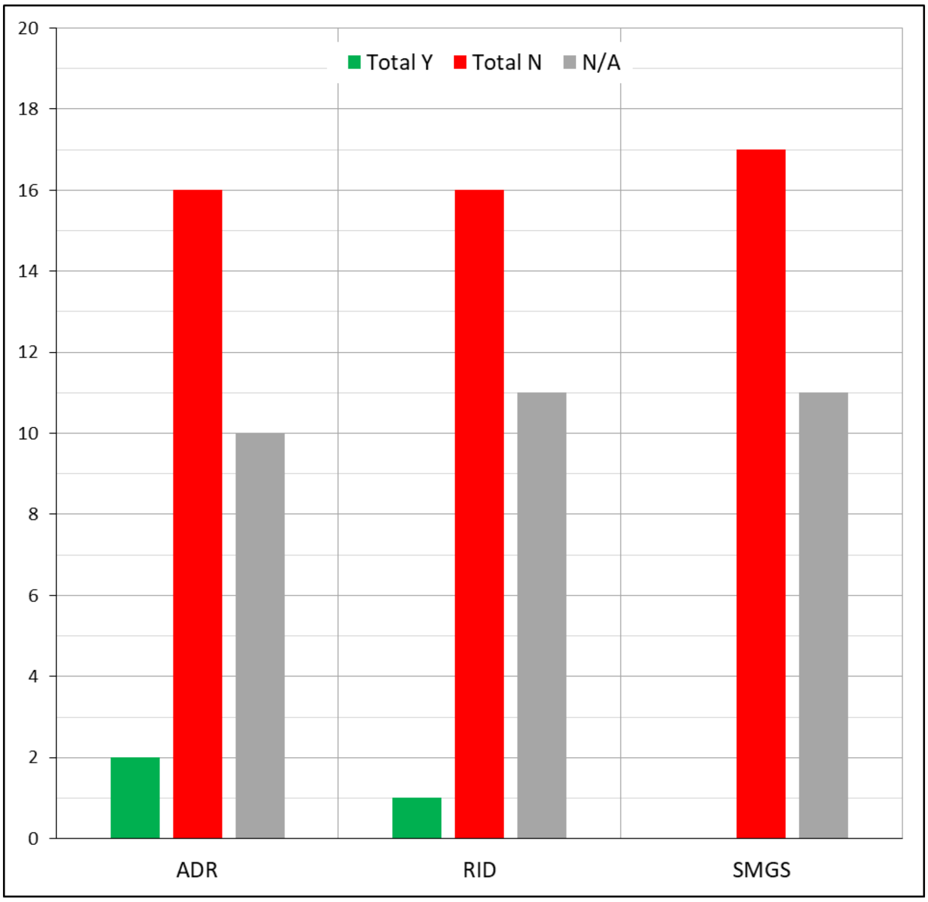


Figure 3: Audits under the auspices of organisations

Issue I-15. Consideration should be given to publishing information based on self-review or peer review based on a system such as the IAEA mini-TranSAS if the IRRS does not cover transport.

8.3 PEER REVIEWS

The use of peer reviews is suggested in this report. Several options are available, namely:

- IAEA IRRS including the transport module;
- IAEA TranSAS;
- IAEA mini-TranSAS;
- Modal authority system;
- Individual arrangements.

Peer reviews have several significant benefits, such as:

- Assistance for governments on appropriate resource allocation;
- Identification of areas where compliance assurance requires improving;
- Provision of confidence to the public that the Competent Authority is providing assurance of safety.

Many MS have requested an IRRS mission, including the transport module. The MS IRRS results are presented in Annex A2. The advantage of this is that transport is part of the integrated review, but the shortcoming is the possible limitation to Competent Authorities dealing with radioactive materials. In the time available for the mission, and given the integrated nature of the scope, it would be difficult to cover in detail all transport regulatory bodies. The IRRS is also limited by its high level of review, which can incur a significant overhead. However, the IRRS is internationally known and transparent. Given the number of recommendations and suggestions typically found in reports, it is likely that the main benefit for transport will be in the preparation for the mission.

TranSAS is another IAEA service, compatible with the transport module of the IRRS but extending beyond regulatory infrastructure and reviewing the entire transport safety infrastructure. It can be conducted as a follow-up to an IRRS, or as a stand-alone mission. The benefit is that it reviews the implementation of the transport regulations in detail and can be extended to cover all regulatory bodies dealing with transport. The disadvantage is that these missions are not always requested by the MS. It can be time consuming, but is comprehensive in nature and reports are published, ensuring transparency. The use of this IAEA service is likely to provide comprehensive information on potential areas for improvement for regulating the transport of radioactive materials.

The concept of the ‘mini-TranSAS’ was also developed to involve less overhead but still provide valuable recommendations on regulating the transport of radioactive materials. It has been used extensively in regions such as Africa. A mini-TranSAS involve groups of three or four (mainly neighbouring) States working in a group, each performing a self-assessment followed by a short review by the other States. It has the added advantage that it encourages neighbouring States to work together, while it can also be carried out without a central infrastructure.

The mini-TranSAS concept is based on a methodology employed by the IMO. Both IMO and ICAO have systems in place to examine transport, though not including close scrutiny of the transport of radioactive materials (dangerous goods transport may be looked at superficially).

The outcomes of IMO/ICAO reviews can be used, and they can be extrapolated to cover the transport of radioactive materials. For example, the need to improve accident root cause investigations may be worth examining in relation to the transport of radioactive materials, since modal transport accidents can be treated as initiating events for accidents involving the transport of radioactive materials. Such use of data has the advantage of requiring very little overhead.

Another possibility is to make individual arrangements to carry out peer reviews, which can be drawn from the ideas and concepts in the above systems. Specific issues could be reviewed in a very cost-effective manner. The disadvantage is that a self-defined process always involves a potential bias in terms of areas where improvements may be required.

8.4 WASTE AND EXCLUSION

8.4.1 WASTE DEFINITION

Several MS quote Directive text or follow it closely in their definition of radioactive waste. However, MS quoted different directives, indicating that there was a lack of clarity on a core definition of radioactive waste. Around two-thirds of MS believed that this was related to the transport of radioactive materials. The Directive on shipment of spent fuel and radioactive waste was identified as being relevant in linking transport to the definition of radioactive waste. The concept of the Directive on shipment of wastes (and on sources) is related primarily to the transfer of wastes from the jurisdiction of one Competent Authority to another. However, this does not apply within MS, even where there are regional Competent Authorities dealing with these wastes.

Issue I-16. Review the various directives, including Directive 2006/117/Euratom and the single standard document, with the consideration of simplifying requirements for notification.

8.4.2 EXCLUSION, EXEMPTION AND CLEARANCE VALUES

Exclusion is the concept that the regulatory system should not attempt to cover items which are not amenable to control.

Exemption can apply to total or partial exemption from regulation and can relate to situations where there is an assurance of the low risk of radiation exposure, or situations where regulatory control would not create any effective benefit.

The concepts of exemption and exclusion are widely applied in the transport of radioactive materials through the exclusions listed in paragraph 107 and the exemptions given in paragraph 236 of the IAEA Transport Regulations. Most MS apply the levels from international requirements.

Clearance levels are not normally used in transport, since all of these levels fall at or below the level of regulatory concern for the activities being carried out.

The BSS Directive defines clearance levels as "values established by the Competent Authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive".

Thus, the Directive sets default values, but permits MS to establish higher levels based on specific requirements. The potential of different clearance levels in different States has an effect on transport. This is particularly relevant to what the Directive states: "Human activities involving radioactively contaminated materials resulting from authorised releases or materials cleared in accordance with Article 30 shall not be managed as a planned exposure situation and, hence, are not required to be notified".

MS have applied different clearance levels in some cases. The potential is that State A could have a level higher than a neighbouring State B. This could lead to the application of the BSS Directive for parts of a transport journey. The potential exists for a carrier to transport cleared material without anyone's knowledge to a neighbouring state with clearance levels that are lower than those in its State. Whether material cleared in one MS remains cleared in another MS with different clearance levels is not clear, nor is it clear how the origin of material on a transport conveyance which was cleared can have its source easily identified.

Clearance levels are levels at the lowest level of concern, but the variation in values between MS could lead to administrative problems for the transport industry (as the industry responsible for moving the material from one jurisdiction to another). Several MS reported using specific practices, and providing for related transport to be partially exempted, including specific wastes. The potential for unmarked consignments of this State-level exempt material to cross borders is low if there is no cross-border transfer of wastes. However, the EEA report 'Movements of Waste Across the EU's Internal and External Borders' provides evidence of trade in wastes in Europe (EEA Report No 7/2012 (ISSN 1725-9177)).

While such exemptions are permissible within the terms of the directives, the potential for issues related to transport and differences in clearance levels between MS might in principle result in significant obstacles.

8.4.2.1 DETAILED REVIEW OF CLEARANCE LEVEL VARIABILITY

The Consultant carried out extensive research into this area to determine if the theoretical problem could become reality. There are some obvious radionuclides to consider as key examples, such as H-3, C-14 and Cs-137. The initial work on clearance levels was related to the use of Norwegian wood products following the accident at the Chernobyl Nuclear Power Plant. As a result, the Consultant based the examination on the various levels for Cs-137.

Preambular paragraph (37) of the BSS Directive states that: "There is a benefit in having the same activity concentration values both for the exemption of practices from regulatory control and for the clearance of materials from authorised practices". However, the details of the Directive allow for States to create variations to the levels.

> BSS Directive
>
> Article 4 includes relevant definitions:
>
> (11) "clearance levels" means values established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive;
>
> (34) "exemption level" means a value established by a competent authority or in legislation and expressed in terms of activity concentration or total activity at or below which a radiation source is not subject to notification or authorisation;

Particular attention should be paid to the following aspects:

- The clearance levels are only related to a practice subject to notification or authorisation;
- The clearance removes the materials from ALL of the requirements of the Directive;
- The exemption is only from notification and authorisation;
- Exemption relates to a radiation source rather than a practice.

It is not clear that MS have understood that all aspects of the Directive other than notification apply between the clearance and exemption levels.

> BSS Directive
>
> Article 25(4) extends the exemption from notification to say:
>
> Human activities involving radioactively contaminated materials resulting from authorised releases or materials cleared in accordance with Article 30 shall not be managed as a planned exposure situation and, hence, are not required to be notified.
>
> Article 26 provides amplification on the concept of exemption:
>
> Member States may decide that justified practices involving the following do not need to be notified

Reading the definitions, it seems that Article 25(4) is in fact applying exemption to human activities with material which has been cleared because it only disapplies notification, not the entire Directive. For example, further articles make it clear that registration can be required for existing exposure situations.

For moderate amounts of material (often considered to be less than 1000kg), Article 24 provides for an *exemption from authorisation* for Cs-137 where:

- The activity concentration does not exceed 10 Bq/g; or
- A level set by the competent authority based on Annex VII.

Since the Transport Regulations exempt material from any safety regulation (including documentation), the concern is that the material could be transported without knowledge of the existence of radioactive materials. However, as long as the material is subject to notification there would seem to be no reason for worry. The exception comes in the form of the clause that allows MS to apply higher levels in Article 25. Thus, if an MS applies an exemption from notification between concentrations of 0.1 Bq/g and 10 Bq/g for Cs-137, there is the possibility of material not subject to notification in an MS or notification in transport being moved to an MS where only the default values apply. The Consultant identified cases where MS applied different levels for Cs-137 (different levels even within an MS).

Environmental levels of Cs-137 in recent years have recorded levels between 0.1 Bq/g and 10 Bq/g. A recent shipment of mushrooms from Bulgaria indicated levels in excess of 1 Bq/g. Generally, MS applied an acceptable (safe) level in foodstuffs between 0.1 Bq/g and 1 Bq/g for Cs-137. Levels of Cs-137 in Scottish deer have been measured above 0.1 Bq/g in recent years.

If the levels in foods can exceed the default concentration, then the levels in the environment (particularly near Ukraine) are likely to be higher. Thus, it is possible that MS will take this into account when considering exemption from notification. The potential for movement from one MS to another of material that exceeds the notification level in the recipient MS is very likely.

A concern is that Article 30 only applies to authorised practices. As a result, any practice dealing with Cs-137 with a level less than 10 Bq/g is not subject to this article (which applies a clearance level of 0.1 Bq/g and prevents dilution). Thus, an authorised practice dealing with Cs-137 must apply 0.1 Bq/g to clearance. However, the Directive appears to permit the transfer of material below 10 Bq/g to a separate practice which could then dispose of it without applying Article 30.

8.4.2.2 SAFETY REGULATION AND OWNERSHIP

The fact that material is exempted from the application of the Transport Regulations does not mean that the original owner of the waste is exempted from responsibility. The means by which this responsibility is transferred is not transport-related, but rather a matter for waste regulation. In effect, if a MS chose to exempt material from the Transport Regulations, the material being subject to a transboundary or cross-border Directive, then the transboundary or cross-border Directive would still apply.

Given that there are examples of variable limits even within MS, and that the BSS Directive requirements still apply, it would seem reasonable to have a methodology in place for the notification of radioactive material transfer which applies more generally. This supports the Consultant's suggestion that these directives should apply within MS to ensure effective control of material. During the second workshop, MS have clearly stated that they are not supporting this proposal. Issue I-16 also applies in this case.

8.4.2.3 ARTICLE 23 OF THE BSS DIRECTIVE

One concern was the potential for material to be developed in such a manner that it came within the regulatory system. Article 23 of the BSS Directive is relevant to this issue. MS identified a number of activities that could lead to this:

- Pipes from the paper and pulp industry;
- Fertilizer;
- Oil industry;
- Geothermal energy;
- Coal burning;

- Chemical industry;
- Metallurgical industry;
- Ore extraction;
- Air and water filters (radium);
  - Scrap metal recycling.

It should be noted that this list extends beyond the industries listed in Annex VI of the BSS Directive. There are additional areas that were noted in follow-up meetings where items exempted from regulation could fall under regulation, such as depleted uranium residues on military equipment under civilian regulation. The potential for other areas, such as gas storage, is being investigated by the industry.

The means of identifying these activities were defined, including port monitors and inspection. One MS (Ireland) provided information on a systematic approach which appears to deal with the issue, and which is set out in the report 'Radiological assessment of NORM Industries in Ireland – Radiation doses to workers and members of the public' (https://www.epa.ie/pubs/reports/radiation/RPII_NORM_Report_08.pdf)

Overall, there appears to be a number of reviews at the national level. However, comprehensive collection and sharing of this information might prove beneficial.

Issue I-17. Guidance would be beneficial, including examples of a process that could be adopted by MS, to manage the review of activities that can bring material within the BSS Directive (e.g. based on the process in Ireland). Current activities are under way that cover this matter.

8.4.3 ARRANGEMENTS RELATED TO RADIOACTIVE WASTE, DECOMMISSIONING WASTE

Generally, the same regulations apply for the transport of radioactive waste as for the transport of other radioactive materials. MS generally also noted the requirements of Directive 2006/117/EURATOM, while a limited number of MS also quoted national requirements (but mostly they simply referred to the Directive). One thing is clear: unless there is effective control within MS as a starting point, an effective control between MS is unlikely. Issue I-16 also applies in this case.

8.4.4 RECYCLING ACTIVITIES

There is a limited number of recycling facilities that deal with the transport of radioactive materials in the Community, and as a result it is essential that transport be able to take place between MS. One issue that may affect this transfer is whether material destined for recycling is defined as radioactive waste. Four MS noted that this was the case, while other States did not answer. The Consultant's understanding is that even within MS this definition can vary between regulators and regions. Greater clarity on whether material destined for recycling should be considered as radioactive waste would be beneficial. Reports on the implementation of the Shipment Directive indicate that the different views on whether material is waste, particularly with respect to recycling, have caused difficulties in the Community.

Issue I-18. Clear interpretation on the classification of material destined for recycling.

8.5 AGEING

The issue of ageing was addressed in an IAEA Coordinated Research Project (CRP) on dual purpose casks which was completed several years ago, the results of which have not been published to date. A follow-up project is in place, but it is not clear whether it has been started.

Dual purpose casks are transport packages (approved in the country of design) and storage packages (approved in the country of storage). The multilateral nature of transport approval and the potential for delay before any transport takes place in an MS are two additional issues in this area.

Transport approvals by the Competent Authority are based on current regulations and typically last for five years. At the end of approval, a renewal takes place against the regulations in place at that time, which may permit the use of earlier regulations. Generally, the regulations recognise that changes should only be imposed on existing packages if there is a significant safety need. However, the regulations apply a transition system that currently limits packages to around 45 years in age, applying additional restrictions to older packages.

The transport regulatory system based on the IAEA Transport Regulations has been in existence for around 50 years, and dual purpose casks are intended to be transported over the next 50 years. It is not realistic to assume that any guarantee can be given regarding the regulatory infrastructure at that time based on the current range of experience of the stability of regulations.

These packages tend to be multilateral in nature, and as a result transport approval needs to be reviewed and accepted in every State through which, or into which, the package is transported. This means that the package will need to be approved for transport and storage in every State it is used. The storage approvals are State based and, although they may have a common safety case, are not dependant on each other. Should the originating State stop using the packages for transport and the primary transport approval lapses, then all associated transport approvals will cease to have effect.

Dual purpose packages are at times loaded for storage purposes at facilities with no transport taking place. As a result, the State is not being asked for multilateral approval. The issue in this scenario is that the transport approval normally incorporates the aspects of ageing management required to ensure that the package remains acceptable for transport in the future. As a result, there is a risk that approval will not be possible for transport later because of a lack of 'life-long' transport regulatory oversight.

Follow-up questions investigated this issue and identified at least one case in the Community where a dual purpose cask was used for storage in an MS where there was no transport approval. Since transport approval is required to bring the requirements for long-term monitoring of transport packages into effect, this means that the requirements for control are not applied. Should this continue, the pressure on Competent Authorities to allow transport of a sub-standard transport package after tens of years of storage could be unacceptably high. As a result, a means of ensuring that dual purpose casks are not used for storage without transport approval should be considered.

Issue I-19. Approvals of dual purpose casks are being administratively managed in the EU by ensuring transport approval prior to loading.

8.6 DENIAL OF SHIPMENTS

Only five MS indicated that denial of shipments was an issue of concern. Data indicate that some MS may not be aware of problem areas, or do not consider restrictions unreasonable. There are MS which have blanket restrictions on some radioactive material transports (indicated in the questionnaire) and do not consider denial of shipments to be an issue. The issue appears to be multi-layered. First, are there cases where radioactive material transport is not allowed or is made difficult? Second, is this justified? There can be no doubt that if the answer to the first question is yes, such cases do exist, as can be seen in the number of major air and sea ports that accept radioactive material (**Figure 4**). However, the second question should be the focus because the analysis of answers to it may hint at key issues behind denial of shipments.

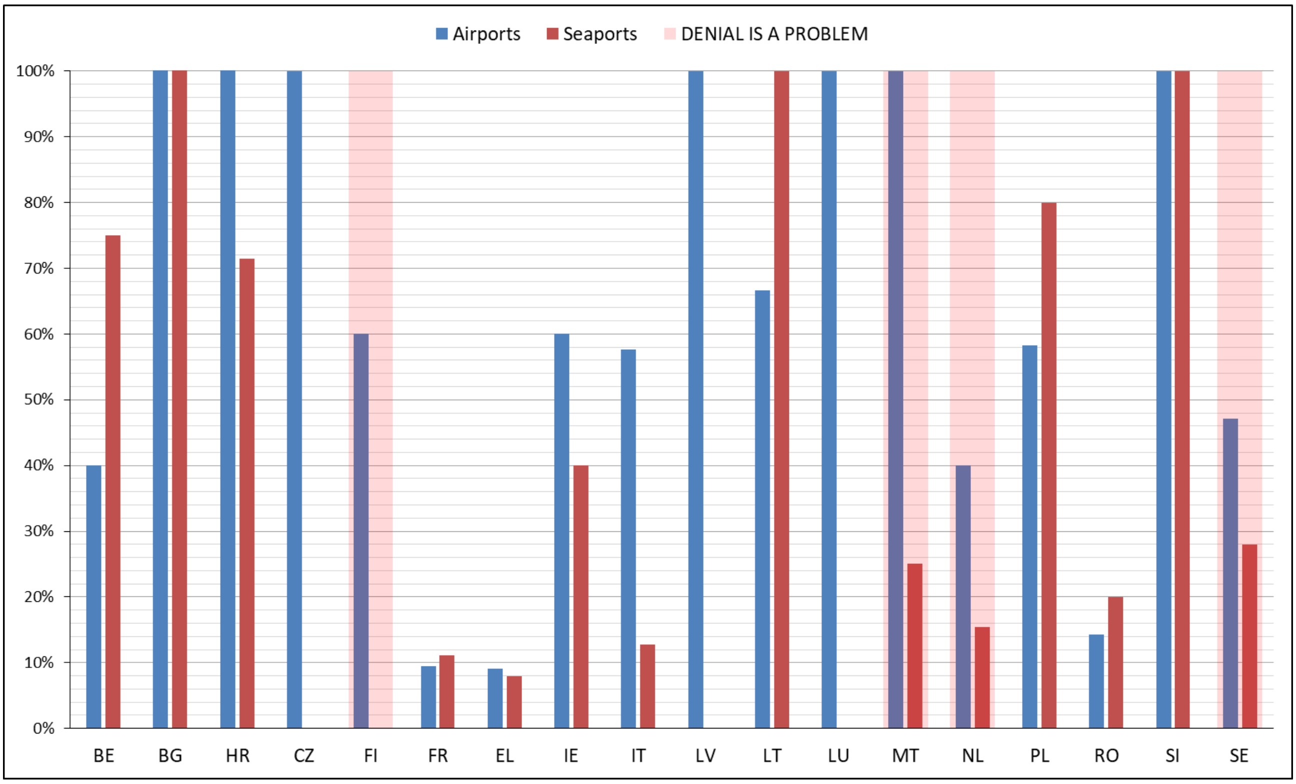


Figure 4: Percentage of major ports reported as willing to carry radioactive material

The Consultant reviewed shipment documentation over a specific period of time and found that at times the error rate was as high as 50%. However, the errors were not very significant and the shipments were carried out. Nevertheless, errors in documentation can lead to justified denial of shipments.

Issue I-20. Simple guidance with examples of how to complete the standard transport document could provide valuable support to industry compliance efforts.

During the workshop it was concluded that an organisation like the World Nuclear Transport Institute (WNTI) could carry out this action.

Only one-third of MS were able to provide details of the governmental body responsible for the promotion of the transport of radioactive materials. There are two related issues. First, if there is no designated body, then the Competent Authority can perform this role, which results in a situation that is unacceptable in terms of safety. Second, if there is no nominated body, then the specific responsibility for the issue of denial of shipments is unassigned.

Issue I-21. MS should identify a non-regulatory governmental entity to deal with industry facilitation and reports on denial of shipment, e.g. a ministerial department or agency dealing with transport may be suited for this purpose.

The SG and CTF noted during the second workshop that this would be an issue taken up at the IAEA General Conference.

Further information regarding denial of shipments was sought during the follow-up study in an attempt to clarify the situation in the Community. Concrete examples on the findings include the following:

Finland

- Some airlines categorically don't transport Class 7
- Some road freight companies categorically don't transport Class 7 or limit only to excepted packages
- Most sea freight companies categorically don't transport Class 7 or limit only to excepted packages

Ireland

- In 2017 we had a small number of examples of medical and industrial sources being returned by air that were denied due to aviation security protocols. The customers in cooperation with the Irish Aviation Authority (IAA), the Freight Forwarders at the Airport and the EPA have now taken out 'Known Consignor' status with the IAA to facilitate these shipments.

Luxembourg

- There has never been a formal denial of shipment following an application. However carrier or shippers have been informed that a shipment could be denied in cases where the carrier has no license or the type of transport is not covered by the carrier license (e.g.: above the limits).

Malta

- 1 transshipment denied by port authorities since port policy is not to handle Class 7. Case taken up by RPB and agreed that such instances are to be decided on a case by case basis.

Netherlands

- The only well known example is the denial of KLM Dutch Airlines to carry class 7. KLM is also the main handler of (dangerous) goods at Schiphol Airport, which means also other carriers cannot take class 7. As a result most radiopharmaceuticals produced near Schiphol Airport (in Petten) are carried by road to other airports (Frankfurt and Brussels) before flying out.

Spain

- Some cases of passenger shipping lines rejections to transport mobile radioactive gauges in local movements between Spanish islands.

Sweden

- Passenger ferries between Sweden - Finland and Sweden - Germany, unwillingness by shipping companies to carry RAM due to public opinion.

United Kingdom

- From the information we have collected, the biggest denial of shipment issue appears to be that of the sea freight companies – a situation that gets worse with the reducing number of shipping lines available to choose from as buy-outs and alliances continue to occur.
- Many organisations now have a policy to refuse class 7 completely.
- One UK dutyholder experienced the following in 2012:
    - 65 denials in total by sea, due to:
        - 60 denials due to company policy of carrier (UK x 44, Argentina x 16)
        - 2 denials due to port transit refusal (Vietnam x 1, Thailand x 1)
        - 1 denial due to being replaced by higher priority / value cargo (USA)
        - 1 denial due to refusal by the vessel captain (Argentina)
        - 1 denial due to issues arising from Member State variations (Germany/Israel)
    - During the first six months of 2013, the same dutyholder recorded 42 denials in total by sea, due to:
        - 37 denials due to company policy of carrier (UK x 33, Argentina x 4)
        - 4 denials due to port transit refusal (Vietnam x 1, South Africa x3)
        - 1 denial due to issues arising from Member State variations (Germany/Israel).
- Some examples from another UK based dutyholder:

    1. Prior to 2015, a particular transatlantic carrier offered a regular service for Class 7 cargo (including fissile enriched uranium) from Europe to North America. The industry was reliant on this service and the UK based dutyholder was able to regularly ship packages in batches of 4, 8 or 12. The United States is a large market for the UK based dutyholder and is vital to their business.

At short notice, this carriers service for fissile was withdrawn – leaving none of the large ocean carriers willing to accept the dutyholder's cargo. Since then, the UK dutyholder has been using a smaller tramp steamer company. This option is far less convenient and much more expensive. To make it as cost-effective as possible, the UK based dutyholder ships in maximum batches of 40 packages. This takes considerably more planning – both for the dutyholder in the UK to manage logistics in Europe to meet the vessel just-in-time, and also in North America, where deliveries need to be staged because the consignees cannot accept such volumes over a short period of time.

The transatlantic carrier continued to accept non-fissile Class 7 (natural uranium) until 2017, when it completely withdrew from Class 7. The UK duty holder stated that the reason given was it was a political decision by the carriers shareholder/owner. This leaves a limited number of transatlantic ocean carriers accepting Class 7 non-fissile. In 2017, one of the few remaining carriers withdrew the service from US to Europe (although it will still accept natural UF_6 from Canada to Europe).

2. The UN Council added an additional sub-risk to uranium hexafluoride (UF_6) of Toxic 6.1 last year and this came into force 01/01/18. As such this has changed the stowage category to category B. Since UF6 is Class 7, 6.1 and 8 it cannot be stowed near other corrosive materials.

   On one of the Hull-Rotterdam carrier services there are only a limited number of bays for category B and these are usually filled with other regular dangerous goods cargo. As a result the UK dutyholder has had shipments denied – particularly weekdays, even with advance planning. This has caused further issues, as in some cases they were aiming to load at a European port (as the only loading option in Europe for a vessel departing to China).

3. Two national shipping lines will accept fissile UF_6 – but only in the respective national interests of their countries.

4. There used to be a regular carrier for Class 7 cargoes from Europe to South Korea. However, some Chinese ports were added to the schedule, and these ports do not permit transit of Class 7 cargo, effectively blocking the east-bound route from Europe to South Korea.

   While the east-bound route was blocked, shipments to South Korea went from Europe to the east coast of the US, then by road to another port, loaded onto another vessel and through the Panama Canal to South Korea. Other shipments have been sent from Europe to the east coast of the US, transported by road across the US to the west coast and then loaded on a vessel to South Korea. The west-bound routes added 20 days to the transport and $100,000s per shipment.

   It appears that from June 2018, a shipping line will once again accept EUP from EU to South Korea, however it is too early to tell whether the issue will be fully resolved. The number of vessels per month will be a maximum of two, which might be insufficient. Meanwhile, empty cylinders, which are still considered Class 7, will continue to need to be taken via the Trans-Atlantic Route, as the service returning from Korea to Europe will transit Chinese ports after departing from Korea.

5. As of March 2017, a German port refuses spot calls of vessels with Class 7 cargo.

6. In 2015, the Suez Canal authorities prohibited Class 7 transits. This disrupted and delayed a shipment from the UK duty holder to China. The decision was reversed after considerable lobbying.

7. The consolidation of the shipping lines and new alliances have blocked some routes. For example, a carrier that used to accept Class 7 cargo to Japan has merged with other companies and they will cease to carry Class 7 because the other two parties of the merger refuse to accept the UK duty holder's cargo.

Industry

- State of Bremen, Germany:
  - The loading / unloading of nuclear fuel in Bremen sea ports has been banned since early 2012, following an amendment by the local Parliament of Bremen's Act on Port Operation (BAPO).
- No maritime service for Co- 60 from Liverpool to Dublin, meaning that trans-Atlantic source shipments via Liverpool to Dublin require a road transport within the UK.

- No trucking service from the port of Piraeus to Magoula Attica for Co-60.
- Reliance on single carrier to ship Co-60 from Montreal to Europe. Service does not always accept due to overbooking.

The Transport Facilitation Working Group (TFWG) was established to report to an inter-agency group composed of representatives of the IAEA, ICAO, and IMO Secretariats, as well as UNECE. Following a survey, the group indicated that denial of shipments is more likely to be an issue for smaller transporters. The overall view was that the root cause of the issues was the perception of the transport of radioactive materials. This finding is supported by earlier investigations carried out on behalf of the WNA.

The issue identified by the Netherlands regarding the handling of radioactive materials at Schiphol airport is particularly important: ground handlers prevent airlines from carrying radioactive materials. This results in the need to transport by road to a more distant airport for a very large proportion of the radiopharmaceuticals produced in Europe. This issue will become more significant as the use of short-lived radionuclides increases.

Another problem is shipping front-end material to the Republic of Korea. Indications are that facilities in the Republic of Korea are considering terminating supply contracts with European producers in favour of Russian producers. Last, but not least, there are layers of difficulty introduced through administrative aspects of regulations.

Two separate sources of information identified a common issue with the shipment of small quantities of fissile materials following the implementation of the 2012 Edition of the IAEA Transport Regulations (IAEA Safety Standards Series No. SSR-6). One of the most extensive explanations was a presentation to the WNA transport working group by Norman Kent of NKENT Consulting in the USA. While the consultant was based in the USA, the issue was identified as a global one.

In effect, the new regulations setting out controls for the transport of fissile material were split into three groups:

- Cases where the only concern is package limits;
- Cases where there are only consignment limits;
- Cases where accumulation control is required for conveyances.

The final category included packaging previously classified as fissile-excepted, as well as packages classified as fissile. During revision of the regulations, it was decided that all packages in the third category should be classified under fissile package numbers. Strictly speaking, this was not necessary but was introduced in an attempt to prevent the potential confusion of applying a CSI to fissile-excepted packages.

In line with this change, the IAEA INLEX group produced recommendations to significantly reduce the upper limit for the exemption of small quantities as stated in the Vienna Convention on Liability, which was duplicated in the associated Paris Convention. This effectively limited the exemption to the first two categories, whereas previously the fissile-excepted portion of the third category was also part of the small quantities exemption.

These two changes resulted in a reduction of available carriers and insurance for consignments in the third category that used to be classified as fissile-excepted.

Cases where this has resulted in issues include:

- Small samples of fissile material for research purposes;
- Residual quantities of fissile UF_6 in nominally empty 30B cylinders;
- UO_2 samples.

The ‘effective’ reduction in fissile limits is of the order of magnitude for consignments, and a factor of 5 for packages. This reduction is not a regulatory safety matter, but is an effect of the administrative approach to the accumulation control for packages which formerly were classified as fissile-excepted. In fact, the limits have increased in the regulations, but the effective restriction is that there are very few carriers that will transport material with this new description. The restriction relates to the wording used rather than any safety concern.

The possibility for specification of a system of control that maintains the current safety requirements while reducing the administrative issues that prevent shipments could be a valuable way forward. For example, changes to the administrative system of control could reduce barriers to the transport of fissile samples by simply reverting to the former classification system, while retaining the application of the CSI. Concerns over the use of the label "FISSILE" on fissile-excepted packages would be justified. However, it should be noted that the label "FISSILE" fails to meet the international standard for such labels and efforts have been made to replace it with a more appropriate label. This is not a firm proposal for change, but a demonstration that options for improvement could exist. Such options would also need to be taken to the IAEA INLEX group, and to the relevant OECD/NEA committee.

Issue I-22. Update the administrative means for controlling material that used to be termed fissile-excepted.

The SG and CTF noted during the second workshop that the proposal here does not involve making any change to the technical basis for safety, but simply reviewing the administrative processes for applying the controls (in particular the proper shipping names), since these have significant effects in terms of approval (multilateral/unilateral) and willingness to carry material. Issue I-12 also applies in this case.

8.7 GOOD PRACTICES

8.7.1 REVIEWS OF REGULATORY BURDEN

Seven MS confirmed they had carried out a review of the regulatory burden. Some MS indicated this is a requirement of their process of adopting legislation, and one MS indicated the application of the review to the proposed changes to the IAEA requirements.

8.7.2 SAFETY ENHANCEMENTS

Only two MS identified non-regulatory safety enhancements in the transport of radioactive materials; one was related to safety culture, the other to guidance material. This would suggest that prescriptive regulatory requirements do not lead to continuous enhancements to safety in the way that goal seeking, performance-based requirements might.

8.7.3 OTHER CONCEPTS

A number of good practices were identified by the SG and should be considered for implementation:

- Applying a preventive versus corrective approach to identify and share the best practices. Implementing an inspection programme, including two types of inspection:
    - *One-off inspections:* Inspections of a specific shipment at the loading or unloading site, or during transport. An inspection programme is established each year and each organisation is inspected at a frequency determined by different criteria, i.e. the quantities and types of packages being transported or handled, the nature and extent of the transport operations (e.g. percentage and frequency of transports involving radioactive material), the incidents and accidents in the past, the documented results and findings from previous inspections, the size, complexity and activities of the industry for which it has responsibility.
    - *Management system inspections (compliance audits):* Inspections to ensure that the registered organisation has implemented a management system for ensuring compliance with the applicable national regulations and international dangerous goods regulations and agreements relating to the safe transport of radioactive materials, with special attention on radiation protection programmes.
- Developing an application guide for the safety requirements for the transport of radioactive materials.

- Conducting surveys for:
  - Assessing weaknesses or challenges in the practical implementation of the transport safety requirements;
  - Planning targeted training or any other appropriate activities;
  - Enhancing the regulatory oversight for the transport of radioactive materials.
- The Competent Authority's radiation safety inspection activities, including the transport of radioactive materials, are from ISO Standard 17020, which provides for openness and transparency, as well as continuous assessment and improvement.

  There is a documented system providing a link between the legislation mandating the organisation and individual contributions to the delivery of goals, including corporate values and behavioural expectations.

  Systematic cooperation between the Competent Authority and the police significantly supports the Authority in the implementation of an integrated approach to the safety and security of radiation sources (including those being transported).

  The nuclear and radiological emergencies are well integrated at the national and regional levels in a framework for a major emergency management system and a national emergency coordination system following the 'all hazards approach'. The Competent Authority has a key role if a radiation emergency occurs.

  The information to the public on emergency planning prior to an emergency is very efficient in reaching all sectors of the population in Ireland. In addition, a coordination mechanism to inform the public in case an emergency has been established under the national emergency coordination group of the Government. The Competent Authority has an important role in these activities for informing the public.
- The development, maintenance and use of a comprehensive, Competent Authority, and web based database which goes beyond the collection of standard transport data by providing additional safety related data and the corresponding analysis tools necessary to perform dose assessments due to transport can help identify non-compliance and supports provincial emergency preparedness and planning.
- Detection and control of orphan sources by regulating the scrap metal industry.
- An informal group dealing with transport issues (mainly safety-related, ADR, etc.).
- Good practices produced by industry bodies.

8.8 DOCUMENTATION

A wide range of documents are required for transport safety and security. Some MS apply the requirements of directives, other MS appear to apply more detailed requirements. In terms of document requirements for consigning, **Table 4** provides a summary of the differences:

Table 4: Document requirements for consigning

	Documents	
MS	**Safety**	**Security**
Belgium	The carrier and other involved organizations (handling agents at airports, terminal operators at ports, etc.) should "be recognised by" the national CA.	For nuclear material, the carrier should have a general physical protection system agreed by the national CA, and for each transport or series of transports a specific physical protection system. For radioactive material, the national CA requests a security plan according to the modal regulations (e.g. Chapter 1.10 from ADR).

MS	Documents Safety	Security
Bulgaria	Emergency plan Radiation protection programme	Physical protection plan
Croatia	Approval for this activity Emergency Plan	Security Plan
Czech Republic	A licence from the national CA shall be required for carriage of radioactive or fissile materials, specifically for: a) carriage of fissile material; b) carriage of radioactive substances; c) carriage of radioactive or fissile materials under special arrangement; d) cross border shipments of radioactive waste and spent fuel.	Documents required for transport security: For shipments of radioactive material the document Security Plan according to part 1.10.3.2.of the ADR, RID, ADN, etc. For shipments of nuclear material Physical Protection Assurance Plan for the carriage of nuclear materials of categories I to III
Denmark	Documents according to ADR requirements	None. Only transport of fissile material require security documents.
Finland	Consignor needs a safety license; Air carriers need a license for all dangerous goods; For nuclear material such as fresh fuel, a license is needed.	Security Plan as in the modal regulations for nuclear material (such as fresh fuel)
France	Documents required by ADR / RID / ICAO TI / IMDG Code	For fissile materials, the carrier has to have an authorisation from the Ministry of Environment. For materials that fall under para 1.10 of ADR a Security Plan is needed.
Ireland	Management System, RPP, Appointment of RPA, RPO, DGSA, relevant training, written instructions, package approval certificate, conformity of the vehicle, Dangerous Goods Declaration with special form certificates etc., approval for sea transport, CA to CA consent (IAEA Category I), security arrangements.	Security provisions for the transport of High Activity Sources and non-HASS sources Transport Security Plan for high consequence dangerous goods.
Italy	The carrier needs a decree of authorisation issued by the Ministry of Economic Development When the activity per package is greater than 300 A_1 or 300 A_2 a single shipment approval is necessary.	In case of transport of “high consequence dangerous goods” a Security Plan has to be prepared by the consignor and the carrier. In case of transport of fissile material a passive Physical Protection Plan, prepared by the carrier and approved by the Ministry of Economic Development, is necessary

MS	Documents Safety	Security
Latvia	a) the name of the package, b) the UN dangerous load category mark "7" c) the UN number ("UN…..), d) the symbol or name of each nuclide, e) specification of the physical state and chemical composition of the radioactive material, indication of the dispersion level of the radioactive material, f) maximal total activity in the SI system, g) package category(I-WHITE, II-YELLOW, III-YELLOW), h) transportation index (only for II-YELLOW and III-YELLOW categories), i) criticality index (only for loads with fissile material), j) the identification signs assigned by CAs who issued the approval certificates, k) detailed description of the package composition in pack bagging, of the used material, of the gross mass, the basic external dimensions and the outward appearance, l) for loads with LSA-II or LSA-III materials as well as SCO-I and SCO-II objects - the ratio of total activity related to A2.	Cabinet Regulations "Requirements for Physical Protection of Sources of Ionising Radiation" (2002): Ch 7. Technical Requirements for Protection of Road Transport Vehicles 103. Road transport vehicles, which are utilised for the transportation of radioactive materials or nuclear materials under conditions of exclusive use, shall be secured against unauthorised use thereof by using blocking and automatic emergency alarm devices. p.106.In transporting radioactive substances located at a Category I protected facility, as well as certain protected sources, the vehicles shall be provided with a security escort.
Lithuania	In order to get license for transport of radioactive materials and nuclear materials in amounts detailed in Law on Nuclear Safety, applicant must supply the documents: copy of certificate for driver, on training to transport Class 7 dangerous goods; a Radiation Protection Program, in which the following must be included: a description of organisation and management of radiation protection, a copy of the document on appointment of a person responsible for the radiation protection at the enterprise, a copy of radiation protection qualification certificate and a copy of description of his duties; the list of the workers (divided in to A and B categories) involved in practices with sources; the copies of certificates confirming the professional qualification and	The Regulations on Physical Protection of Sources of Ionizing Radiation set the main requirements for security of sources. According to these regulations the Security plan during the transport of radioactive materials is required in case radioactive materials are being transported. The main security related document listed in the Regulations on the Issue of Licenses and Permits Necessary to Engage in Nuclear Energy Activities for the issuance of a licence to transport nuclear fuel cycle material, specified nuclear and fissile materials is the Plan on ensuring the physical protection of nuclear fuel cycle material, nuclear and fissile materials in transit.

MS	Documents Safety	Security
	qualification on radiation protection of every worker; the description of executing of individual monitoring and monitoring of work places; description of training and instructing of workers on radiation protection; the safe working manual (radiation protection instructions); the Quality Assurance Program and Plan of implementation of this Program; the list of personal protective equipment (name of protective equipment, led equivalent, the date of purchase and the date of examination of equipment); the Prevention of Accidents and Emergency Preparedness Plan; the description of security ensuring of the sources; description of transportation of sealed or unsealed sources or radioactive waste. … (2 more pages)	
Malta	Emergency card (local rules)	Emergency card (local rules)
Netherlands	A transport license for fissile material, package design approval certificate, special form certificate when applicable, etc. and all other transport documents as required by the modal regulations	1. Security Plan according to the modal regulations, if applicable; 2.Approved Security Plan for carriers of fissile materials within the scope of the IAEA CPPNMNF.
Poland	Complies with the regulations governing the carriage of dangerous goods (ADR and others)	Complies with the regulations governing the carriage of dangerous goods (ADR and others)
Romania	Technical documentation: copy of the transport license, conveyance documents, type approval certificate for transport packages, characteristics of the radionuclides, Radiation Protection Program for transport activity, loading, unloading and handling procedures for packages, IT, CSI, stowage and storage in transit procedures, decontamination procedure, documents	Physical Protection Plan, the security files of radioactive materials to be transported

MS	Documents Safety	Security
	which prove the training of the personnel involved in transport.	
Slovakia	Certificate of professional competence for transport of radioactive material, specifications of the planned shipment(s) and technical equipment, reasoning of the transport, transport order including the mode of transport, itinerary and radiation safety measures, description of the technical equipment for transportation, loading and unloading, risk evaluation based on the character of radioactive material, mode of transport and route, emergency plan, certificate of approval for the package(s), certificate of the technical ability of the vehicle, certificate of driver(s)´ training (class 7).	As for radioactive material in transport, no legislative obligation for any security documents, but at least licensees are asked during authorization process to submit a Transport plan according to ADR.
Slovenia	Licence for carrying out a radiation practice - for Cat. 1 and 2 sources.	Security Plan, as enshrined through 1.10 ADR.
Spain	Exactly those established in IAEA SSR-6	Authorisations are required for transports of nuclear materials category I, II and III. a Physical Protection Plan. Carriers transporting nuclear materials or radioactive sources category 1 and 2 have to be registered
Sweden	Permits, certificate were applicable, other ADR requirements	Permit for transport with requirements
United Kingdom	As per ADR / RID.	Carriers of Cat I -III nuclear material are required to have a Transport Security Statement that details their physical, personnel and information security arrangements approved by the national CA

In addition there are requirements on notification, as summarised in **Table 5** below.

Table 5: Requirements on notification

MS	Notifications Safety	Security
Belgium	Some shipments should be notified to the national CA prior to taking place: The shipment of Category 1 radioactive sources; The shipment of at least one package containing Class 7 dangerous goods for which the transport index exceeds 10 per package; The shipment of packages that require a shipment by exclusive use; The shipment of radioactive material from the UN-groups 3 and 4; The shipment of Type B(M) packages; and the shipments licensed by the national CA: The shipment of nuclear material from the physical protection group A; The shipment of radioactive waste and of spent fuel; The shipment of other than Type B(M) packages containing radioactive material with an activity greater than 3000A1 or 3000A2, or 1000 TBq; The shipment of packages containing Class 7 dangerous goods with a TI exceeding 200 per shipment; The shipment of large containers containing Class 7 dangerous goods with a total CSI exceeding 200 per vessel; The single shipment of Class 7 dangerous goods.	
Bulgaria	Declaration of non-compliance	Prior notification of the national CA for each shipment
Czech Republic	As required by IAEA	For shipments of radioactive material: notifications described in the Security Plan according to part 1.10.3.2.of the ADR, RID, ADN, etc. For shipments of nuclear material: notifications described in the Physical Protection Assurance Plan for the carriage of nuclear materials of categories I to III.
Denmark	None. For transportation of fissile material, notifications are required though.	None. For transportation of fissile material, notifications and contact to the national CA are required

MS	Notifications Safety	Security
Finland	As in the modal regulations.	As in the modal regulations.
France	For fissile materials and for packages quoted in 5.1.5.4 of ADR, a notification to the national CA should be sent 7 working days prior to shipments	For fissile materials, an application for an authorisation should be sent at least 15 days prior to the shipment to the Ministry of Environment.
Greece	Authorisation applies in the country	
Ireland	Approval for sea transport, CA to CA consent (for IAEA Category I).	Approval for sea transport, CA to CA consent (for IAEA Category I). Notification of the route to the Police
Italy	Notification of the shipment of radioactive material, non-fissile or fissile excepted, is necessary when the activity per package transported is greater than 30 A_1 or 30 A_2. In case of transport of fissile material, other than fissile excepted, a safety notification is always required	A notification is required in case of transport of "high consequence dangerous goods" or fissile material other than fissile excepted
Latvia	The consignor sends notification to that (those) foreign country(ies) CA to which or through where the load will be transported, at least 7 days before the transportation	If due to some reasons it is impossible to transport a load with fissile material, the carrier shall immediately inform the Security Police
Lithuania	In order to import, export, transit and transport of radioactive material, radioactive waste in B(U), B(M) or C packages licensee must notify the national regulator in writing on its intentions to transport such materials 7 working days before the shipment and provide this information: 1. date of shipment; 2. consignee; 3. radionuclides and their activity; 4. number of the sources. The main safety notifications are: * The copies of the certificate of preparedness of the vehicle driver to transport dangerous cargoes in accordance with the ADR, which must be valid for certain type of transportation and for dangerous cargoes; * Information about the company's safety specialist dealing with the transportation of dangerous cargoes	The main security notification is a free format declaration stating that the applicant has an agreement with the organisation which performs physical protection of the consignment and with the organisation which performs the function of the response forces.
Malta	Each import or site transfer has to be notified to the national CA	Transport is only allowed between origin and end use points. Driver cannot leave his vehicle un-attended, otherwise no security notification is received
Netherlands	Transport pre-notifications	Specific Security Plan in case of the carriage of fissile materials within the scope of IAEA CPPNMNF
Poland	complies with the regulations governing the carriage of dangerous goods (ADR and others)	Complies with the regulations governing the carriage of dangerous goods (ADR and others)

MS	Notifications Safety	Security
Romania	Notification of the shipments for type B(U) and B(M) and fissile packages, annual report of the authorized carriers	Notification of all national CA involved in safe deployment of the transport activities
Slovakia	Announcement of shipment of any radioactive material is required at least 24 hours prior to the shipment.	Announcement of shipment of high activity sources (3000A1, 3000A2 or more then 1000 TBq) is required at least 7 days prior to the shipment.
Slovenia	48-hour notification for certain shipments of radioactive material/sources (i.e. for all shipments which would require licensing under ADR. 5.1.5.5).	Exchange of information with regard to threat(s) is shared (for rad. material, Cat. 1 and 2 sources) through a letter - annual assessment of current transport-related threats, issued by the Police
Spain	Those established in IAEA SSR-6 and some specifically defined by the authorisations given to consignors of fissile material, radioactive wastes and high activity sources	Notifications are required for nuclear materials category I, II and III, radioactive sources category 1 and 2 and shipments of more than 500 kg of natural uranium
Sweden	As required in the transport permit	As required in the transport permit
United Kingdom	As per ADR / RID.	Carriers are required to have an approved Transport Security Plan for all movements of Cat I-III nuclear material. In addition they must notify the competent security authority of the precise nature/quantity of the NM they are transporting 7 days before the shipment.

There are three pieces of EU/Community legislation of primary importance when considering documentation requirements. Each of these three aims to provide a harmonised documentation requirement for transport.

Directive 2008/68/EC, as modified by Commission Directive 2016/2309, applies to all transports of radioactive materials and includes a standard format. While a standard form is recognised worldwide and it is not required to be used in the precise format provided, it is common practice for the standard form to be used. This applies to shipments within an MS, as well as between MS and to and from third States. This legislation is facilitation legislation – in other words, stricter requirements may not be applied.

Regulation 1493/93 applies to the transfer of sources between MS. This is an effective import/export document for sealed sources, and as such applies to less than 50% of the material transported. Shipments that take place within an MS are not covered by this document.

Council Directive 2006/117/EURATOM of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel along with Commission Decision of 5 March 2008 establishing the standard document for the supervision and control of shipments of radioactive waste and spent fuel referred to in Council Directive 2006/117/Euratom, provides an import/export document that is applicable to spent fuel and radioactive waste. Again, this only applies to a small number of shipments, probably less than 5%, and out of these only to cross-border shipments. This documentation also includes transport information that duplicates information in the standard transport document (e.g. A-1 box 6, box 9), and additional information that is not required for the purpose of transport safety, but which may be restricted in relation to transport security (e.g. A-1 combination of boxes 2, 3, 8, 9 and 12). In addition, the standard form fails to clearly link to the EU legislation for transport, and quotes out of date IAEA requirements (e.g. A-1 box 9). It is difficult to relate some of the information requests in the standard form to the purpose of the directive (e.g. the volume of the ISO container used, since this often has no relevance to the contents volume).

It is proposed that the information required for transport by 2008/68/EC (and other associated EU legislation) be removed from the standard form in 2006/117/EURATOM and the form revised to focus on the transfer of material between regulatory jurisdictions. Issue I-16 applies in this case.

8.9 COSTS

There was a wide variation in the costs provided in MS responses, which suggests that further clarification is needed. It was suggested that a detailed list be drawn up for the following cases:

- A licence to carry;
- A licence to consign;
- A B(U) package approval where the application is full and complete.

More information was collected as part of the follow-up questions. Some assumptions were required, which meant that a range of values was provided by some MS. Estimates involved review times for approvals and estimating the amount of work required.

The first set of results estimated the cost of a licence to carry materials, focusing on charges to carriers (**Figure 5**). Only those MS that reported charging are included, and MS that do not require a licence or issue licences free of charge are not plotted. The variation in costs is around three orders of magnitude over those MS that levy charges.

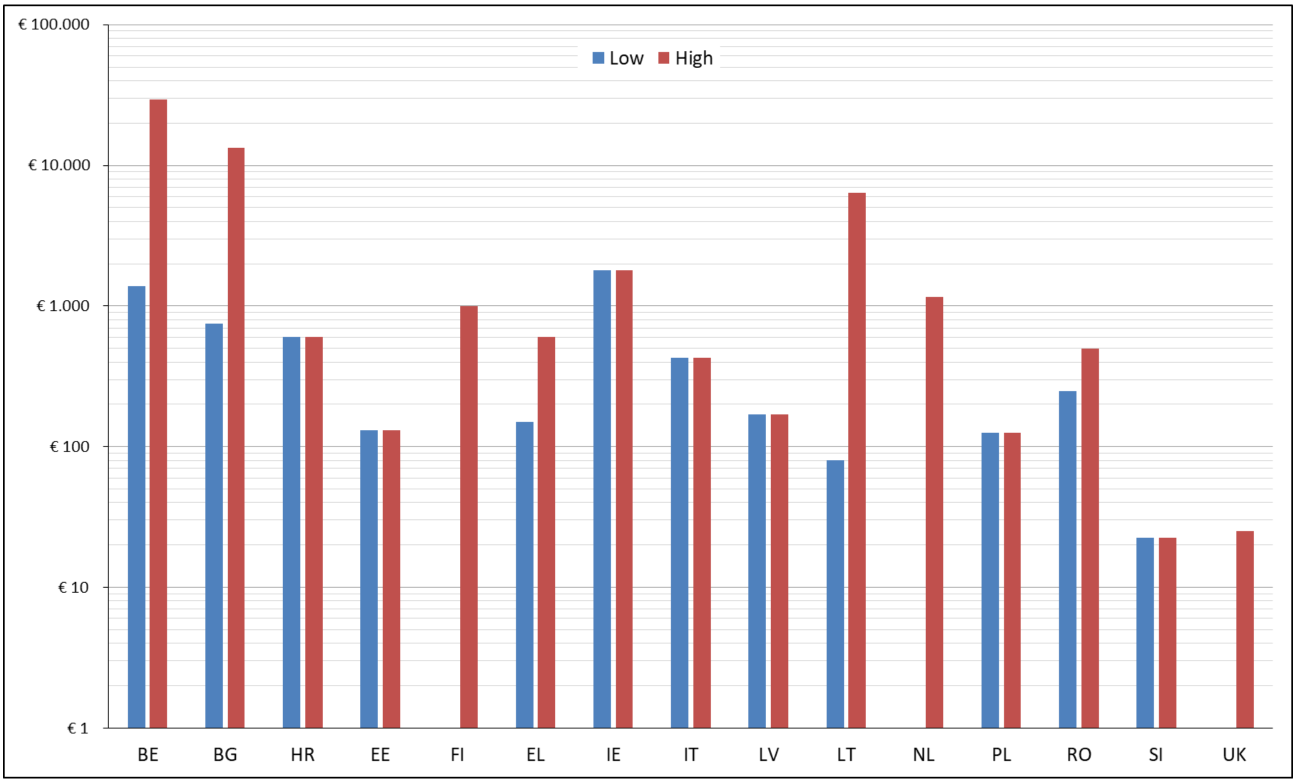


Figure 5: Costs of Licence to Carry Materials.

The second set of results looked at the cost of a licence to consign, focusing on charges for consignors (**Figure 6**). Remembering that the consignor has the primary responsibility for safety, it is interesting to note that the charges to consignors are generally lower than those for carriers. In addition, consignors tend to be based in one MS, while carriers can operate in multiple MS. If charges are related to the work of the Competent Authority, the focus of efforts might be misplaced.

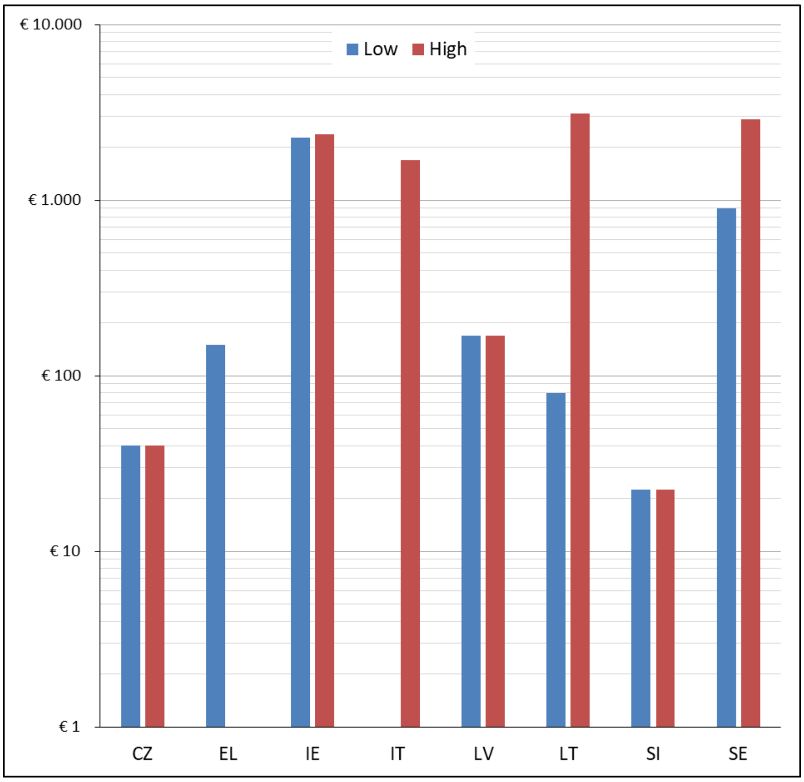


Figure 6: Costs of Licence to Consign.

The third area looked at was the cost of a new B(U) approval (**Figure 7**). The choice of B(U) approval was made because it is valid for all MS. In other words, the certificate is valid for the entire EU, regardless of the issuing country. Based on the costs and the regulatory experience, it appears that the Czech Republic might offer the most cost-effective service to the industry.

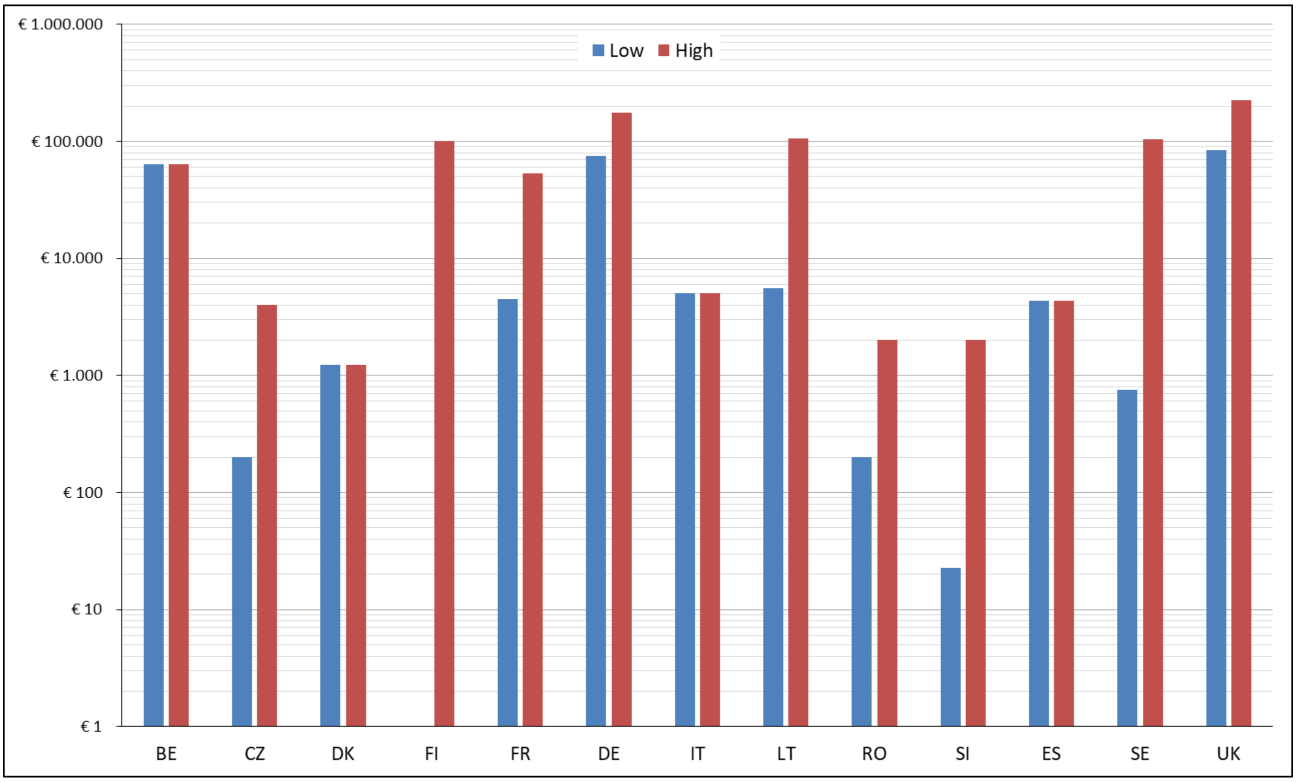


Figure 7: Costs of New B(U) Approval.

The cost of licences can vary greatly, with comparable regulatory work being charged at a difference of two to three orders of magnitude. While costs might vary between MS, it is almost impossible to see how this range of costs can be justified. Based on the information collected on the number of carriers and the number of carrier inspections performed, the total income for each MS can be estimated and compared with the number of inspections. There are models for licencing for transport which are available in the EU.

8.10 SUMMARY OF SPECIFIC ISSUES

From the analysis of the specific issues presented here, the strand that seems to link most areas is the need for clear and transparent information. Certainly, the need for information that is accessible to the public on the level of public exposure to radiation is important. As an example, the EU could establish a simple reference page that links to the latest assessment of public exposure by each MS. This action would go a long way to improving transparency. The cost of such improvements would also not be excessive. Overall, this is an area which would benefit from improvements that could be made with limited effort.

9 IMPLEMENTING THE BSS DIRECTIVE FOR TRANSPORT

A number of articles in the BSS Directive were identified by the Consultant as being relevant for transport, and MS were asked to provide information on their implementation with respect to consignors and carriers. This section of the report examines the data on the Articles in the BSS Directive concerning transport of radioactive materials.

9.1 BACKGROUND ARTICLES

Some general areas of relevance from the BSS Directive that assist interpretation are set out first in sections 9.1.1 to 9.1.5.

9.1.1 PREAMBLE

(36) Member States should benefit from the application of a graded approach to regulatory control, which should be commensurate with the magnitude and likelihood of exposures resulting from the practices, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations.

(37) There is a benefit in having the same activity concentration values both for the exemption of practices from regulatory control and for the clearance of materials from authorised practices. After a comprehensive review, it has been concluded that the values recommended in IAEA publication Application of the Concepts of Exclusion, Exemption and Clearance (IAEA 2004 Safety Standards Series RS-G-1.7) can be used both as default exemption values, replacing the activity concentration values laid down in Annex I to Directive 96/29/Euratom, and as general clearance levels, replacing the values recommended by the Commission in Radiation Protection No 122 (Radiation Protection 122: Practical Use of the Concepts of the Clearance and Exemption).

(38) Member States should be able to grant specific exemption from authorisation for certain practices involving activities above the exemption values.

(39) Specific clearance levels, as well as corresponding Community guidance (Radiation Protection 89: Recommended radiological protection criteria for the recycling of metals from dismantling of nuclear installations, Radiation Protection 113: Recommended Radiological Protection Criteria for the Clearance of Buildings and Building Rubble from the Dismantling of Nuclear Installations, Radiation Protection 122: Practical Use of the Concepts of the Clearance and Exemption), remain important tools for the management of large volumes of materials arising from the dismantling of authorised facilities.

(45) The IAEA together with the World Health Organisation, the Food and Agricultural Organisation, the International Labour Organisation, the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development, and the Pan-American Health Organisation have revised the International Basic Safety Standards in the light of the ICRP's new Publication 103, and the Commission has informed the IAEA of its decision of 6 August 2012 to co-sponsor that document on behalf of the European Atomic Energy Community.

9.1.2 ARTICLE 2 SCOPE

Requirements:

1. This Directive applies to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation which cannot be disregarded from a radiation protection point of view or with regard to the environment in view of long-term human health protection.

2. This Directive applies in particular to:

(a) the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import to, and export from the Community of radioactive material;

(b) the manufacture and the operation of electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5 kilovolt (kV);

(c) human activities which involve the presence of natural radiation sources that lead to a significant increase in the exposure of workers or members of the public, in particular:

(i) the operation of aircraft and spacecraft, in relation to the exposure of crews;

(ii) the processing of materials with naturally-occurring radionuclides;

(d) the exposure of workers or members of the public to indoor radon, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past human activity;

(e) the preparedness for, the planning of response to and the management of emergency exposure situations that are deemed to warrant measures to protect the health of members of the public or workers.

9.1.3 ARTICLE 3 EXCLUSION FROM THE SCOPE

Requirements:

This Directive shall not apply to:

(a) exposure to the natural level of radiation, such as radionuclides contained in the human body and cosmic radiation prevailing at ground level;

(b) exposure of members of the public or workers other than air or spacecrew to cosmic radiation in flight or in space;

(c) above ground exposure to radionuclides present in the undisturbed earth's crust.

9.1.4 ARTICLE 4 DEFINITIONS

Requirements:

“activity” (A) is the activity of an amount of a radionuclide in a particular energy state at a given time. It is the quotient of dN by dt, where dN is the expectation value of the number of nuclear transitions from that energy state in the time interval dt:

$A = dN / dt$

The unit of activity is the becquerel (Bq);

“authorisation” means the registration or licensing of a practice;

“clearance levels” means values established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive;

“emergency” means a non-routine situation or event involving a radiation source that necessitates prompt action to mitigate serious adverse consequences for human health and safety, quality of life, property or the environment, or a hazard that could give rise to such serious adverse consequences;

“exemption level” means a value established by a competent authority or in legislation and expressed in terms of activity concentration or total activity at or below which a radiation source is not subject to notification or authorisation;

“high-activity sealed source” means a sealed source for which the activity of the contained radionuclide is equal to or exceeds the relevant activity value laid down in Annex III;

“licence” means permission granted in a document by the competent authority to carry out a practice in accordance with specific conditions laid down in that document;

“notification” means submission of information to the competent authority to notify the intention to carry out a practice within the scope of this Directive;

“planned exposure situation” means an exposure situation that arises from the planned operation of a radiation source or from a human activity which alters exposure pathways, so as to cause the exposure or potential exposure of people or the environment. Planned exposure situations may include both normal exposures and potential exposures.

“practice” means a human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation;

“radiation source” means an entity that may cause exposure, such as by emitting ionising radiation or by releasing radioactive material;

“radioactive material” means material incorporating radioactive substances;

“radioactive source” means a radiation source incorporating radioactive material for the purpose of utilising its radioactivity;

“radioactive substance” means any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view;

“registration” means permission granted in a document by the competent authority, or granted by national legislation, through a simplified procedure, to carry out a practice in accordance with conditions laid down in national legislation or specified by a competent authority for this type or class of practice;

“sealed source” means a radioactive source in which the radioactive material is permanently sealed in a capsule or incorporated in a solid form with the objective of preventing, under normal conditions of use, any dispersion of radioactive substances;

“source container” means an assembly of components intended to guarantee the containment of a sealed source, where it is not an integral part of the source but is meant for shielding the source during its transport and handling;

“undertaking” means a natural or legal person who has legal responsibility under national law for carrying out a practice, or for a radiation source (including cases where the owner or holder of a radiation source does not conduct related human activities);

9.1.5 INTERPRETATION OF ARTICLES 2–4

A key issue is the definition of a practice, and the scope of the Directive. The transport requirements set out for road, rail, sea and air provide a list of excluded transport, including:

- Transport of humans following incorporation of radioactive materials;
- Transport of animals following incorporation of radioactive materials;
- Radioactive materials incorporated into the means of transport.

As a result, the scope of the BSS Directive extends beyond the scope of the directives and regulations related to the transport of radioactive materials.

One issue is to define *what* is to be regulated. Article 2.2(a) provides a list of what needs to be regulated, which includes transport. This is “the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import to, and export from the Community of radioactive material “. Although the word “and” is used in this list, it is clear that only some of these apply in order for regulatory control to be necessary.

Transport is not defined in the BSS Directive, nor is it defined in any of the related legislation, except in the IAEA Transport Regulations (IAEA Safety Standards Series No. SSR-6), which state:

“Transport comprises all operations and conditions associated with, and involved in, the movement of radioactive material; these include the design, manufacture, maintenance and repair of packaging, and the preparation, consigning, loading, carriage including in-transit storage, unloading and receipt at the final destination of loads of radioactive material and packages.”

This same statement is included in the ADR with the term “transport” replaced by “carriage”. In turn, carriage is defined as follows:

“Carriage means the change of place of dangerous goods, including stops made necessary by transport conditions and including any period spent by the dangerous goods in vehicles, tanks and containers made necessary by traffic conditions before, during and after the change of place.”

There is a clear overlap between the BSS Directive and the transport requirements (also a directive and regulation). A good example is Article 88, which assigns the responsibility of ensuring the maintenance of sources and containers to the licence holder for high activity sources.

Clarity is important in the definition of ‘to whom’ regulatory control should be applied. There are two main groups of people: the carriers and consignors.

The question as to whether each activity requires regulatory control through notification or authorisation is one area where different approaches might be used. For example, it is difficult to process radioactive materials without holding them — in this case it would not be expected that a separate control regime is applicable for processing and holding. Similarly, it is impossible for transport to take place if radioactive materials are not held or imported. The issue is that transport can take place in multiple jurisdictions, while the source of the transport can only be in one jurisdiction.

In some ways there is a similarity with emergency response arrangements for facilities near borders. The facility only exists in one jurisdiction, while the requirement for emergency planning and response might be appropriate in multiple jurisdictions.

9.2 ARTICLE 24 GRADED APPROACH TO REGULATORY CONTROL

9.2.1 ARTICLE 24 REQUIREMENTS

1. Member States shall require practices to be subject to regulatory control for the purpose of radiation protection, by way of notification, authorisation and appropriate inspections, commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving radiological safety.

2. Without prejudice to Articles 27 and 28, where appropriate, and in accordance with the general exemption criteria set out in Annex VII, regulatory control may be limited to notification and an appropriate frequency of inspections. For this purpose, Member States may establish general exemptions or allow the competent authority to decide to exempt notified practices from the requirement of authorisation on the basis of the general criteria specified in Annex VII; in the case of moderate amounts of material, as specified by Member States, the activity concentration values laid down in Annex VII, Table B, column 2 may be used for this purpose.

3. Notified practices which are not exempted from authorisation shall be subject to regulatory control through registration or licensing.

General exemption and clearance criteria

(a) The general criteria for the exemption of practices from notification or authorisation or for the clearance of materials from authorised practices are as follows:

(i) the radiological risks to individuals caused by the practice are sufficiently low, as to be of no regulatory concern; and

(ii) the type of practice has been determined to be justified; and

(iii) the practice is inherently safe.

(b) Practices involving small amounts of radioactive substances or low activity concentrations, comparable to the exemption values laid down in Table A or Table B are deemed to fulfil criterion (iii).

(c) Practices involving amounts of radioactive substances or activity concentrations below the exemption values laid down in Table A, Part 1, or Table B, are deemed to comply with criterion (i) without further consideration. This is also the case for the values in Table A, Part 2, with the exception of the recycling of residues in building materials or the case of specific exposure pathways, for instance, drinking water.

(d) In the case of moderate amounts of material, as specified by Member States for specific types of practice, the activity concentration values laid down in Table B, column 2, may be used instead of the values laid down in Table A, Part 1, for the purpose of exemption from authorisation.

(e) For the purpose of exemption from notification or for the purpose of clearance, where amounts of radioactive substances or activity concentrations do not comply with the values laid down in Table A or Table B, an assessment shall be made in the light of the general criteria (i) to (iii) above. For compliance with the general criterion (i), it shall be demonstrated that workers should not be classified as exposed workers, and the following criteria for the exposure of members of the public are met in all feasible circumstances:

— For artificial radionuclides:

The effective dose expected to be incurred by a member of the public due to the exempted practice is of the order of 10 μSv or less in a year.

— For naturally-occurring radionuclides:

The dose increment, allowing for the prevailing background radiation from natural radiation sources, liable to be incurred by an individual due to the exempted practice is of the order of 1 mSv or less in a year. The assessment of doses to members of the public shall take into account not only pathways of exposure through airborne or liquid effluent, but also pathways resulting from the disposal or recycling of solid residues. Member States may specify dose criteria lower than 1 mSv per year for specific types of practices or specific pathways of exposure.

For the purpose of exemption from authorisation, less restrictive dose criteria may be applied.

TABLE B

Total activity values for exemption (column 3) and exemption values for the activity concentration in moderate amounts of any type of material (column 2)

Radionuclide	Activity concentration (kBq kg $^{-1}$)	Activity (Bq)
H-3	1×10^{6}	1×10^{9}
Be-7	1×10^{3}	1×10^{7}
C-14	1×10^{4}	1×10^{7}
Co-60	1×10^{1}	1×10^{5}
Cs-137	1×10^{1}	1×10^{4}

Source: BSS Directive Annex VII, Table B

9.2.2 ARTICLE 24 INTERPRETATION

Article 24 requires MS to apply the concept of graded approach to regulatory control. The regulatory control is specified in terms of three actions:

- Notification;
- Authorisation;
- Inspection.

The decision on the application of these controls is based on two criteria:

- Likely exposures;
- Effectiveness of any regulatory control.

The Directive provides both a methodology and a set of default minimum values to be used for consideration of the likely exposures. The activity concentrations in Table B are offered as default values for the exemption of notified practices from authorisation for moderate amounts of materials. There does not appear to be a legal definition of moderate amounts.

A particular issue is that the default values relate to exposures averaged over a year. It is unusual for a transport company to hold material for a complete year and as a result the default values are likely to be overly restrictive for transport. A reference which looks at this issue is:

FRANCOIS, P., et al., "The application of exemption values to the transport of radioactive materials", IRPA 9 (Proc. 9th IRPA Int. Congr. Vienna, 1996), Vol. 4, IRPA, Vienna (1996) 674.

On this basis it would appear reasonable to establish the Table B values as the exemption level for transport, which would harmonise levels between Directives.

Furthermore, Directive 2008/68/EC, as modified by Commission Directive 2016/2309, EU Regulations 965/2012 and 376/2014 and maritime modal regulations, take the definition of the graded approach from the IAEA Transport Regulations, which in turn take the definition from the IAEA Basic Safety Standards. The BSS Directive differs significantly from the IAEA Basic Safety Standards in that the IAEA definition of the graded approach includes exemption from regulatory requirements, while the BSS Directive does not. As a result, this creates a conflict when applying the BSS Directive graded approach to transport. The IAEA graded approach is explicit in terms of the transport requirements in place in the EU.

9.2.3 APPLICATION OF ARTICLE 24 TO CARRIERS AND CONSIGNORS

The issue with application to a person is to what extent it should be applied to consignors and carriers.

One issue regarding application is that the organisation may be based outside of the MS and maybe outside of the Community. In addition, the carrier may transit multiple MS, it is unlikely to have a permanent inventory of radioactive materials, and it cannot be held responsible for all of the activities prescribed in the Directive.

9.2.4 MEMBER STATE RESPONSE REGARDING ARTICLE 24

The response of MS with regard to the application of Article 24 of the BSS Directive is presented in **Table 6**.

Table 6: Transposition of BSS Directive Article 24

	Consignor Responsibility	Carrier Responsibility
Belgium	Included in the authorization as facility. Chapter II of GRR-2001 with the 3 classes of facilities (I, II and III) from users of 'small' sources (for example brewery) (class II), special from sources (for example gammagraphy) (class II) to nuclear facilities (class I)	Included in the 4 UN-groups for the recognition as carrier of class 7 dangerous goods: - UN-group 1: excepted package - UN-group 2: radioactive material - UN-group 3: fissile material - UN-group 4: UF_6 See article 20 of RD-transport
Bulgaria	nfi	nfi
Croatia	In progress	In progress
Czech Republic	Yes	Yes
Denmark	nfi	nfi
Estonia	Yes, according to the Radiation Act the Radiation Practice Licence is necessary to have for keeping and transporting of radiological materials. Radioactive substances and apparatuses containing radioactive substances in which the activity or activity concentration of radionuclides exceeds the exemption level shall be transported by road, railway and air and waterway pursuant to the procedure provided for in legislation concerning hazardous loads. Depending of the category of radioactive sources or the extent of risk connected with radiation practices, difference is made between: 1) low risk radiation practices during which an exposed worker incurs or may incur an effective dose of up to one millisievert per year; 2) moderate risk radiation practices during which an exposed worker incurs or may incur an effective dose of up to six millisievert per year; 3) high risk radiation practices during which an exposed worker incurs or may incur an	Yes, according to the Radiation Act the Radiation Practice Licence is necessary to have for keeping and transporting of radiological materials. Radioactive substances and apparatuses containing radioactive substances in which the activity or activity concentration of radionuclides exceeds the exemption level shall be transported by road, railway and air and waterway pursuant to the procedure provided for in legislation concerning hazardous loads. Depending of the category of radioactive sources or the extent of risk connected with radiation practices, difference is made between: 1) low risk radiation practices during which an exposed worker incurs or may incur an effective dose of up to one millisievert per year; 2) moderate risk radiation practices during which an exposed worker incurs or may incur an effective dose of up to six millisievert per year; 3) high risk radiation practices during which an exposed worker incurs or may incur an

	Consignor Responsibility	Carrier Responsibility
	effective dose exceeding six millisievert per year.	effective dose exceeding six millisievert per year.
Finland	No transport specific requirements	Compliance with the legislation on the transport of dangerous goods. A license of STUK is required for the transport of high-activity sealed sources.
France	nfi	X future amendment of public health code
Germany	nfi	nfi
Greece	Prime responsibility assigned to consignor; graded approach applies	the same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	The graded approach to regulatory control is being adopted. Those consigning HASS will be licensed. Those consigning non-HASS may fall into licensing or registration depending on a number of factors. Compliance with the ADR and Radiation Protection Legislation is required.	The graded approach to regulatory control is being adopted. Those transporting HASS will be licensed. Those transporting non-HASS will be registered. Compliance with the ADR and Radiation Protection Legislation is required.
Italy	A licence is requested to ship radioactive material	A licence is requested to carry radioactive material
Latvia	In order to ensure the performance of protection measures the operator (i.e. any organization involved in transport, including the consignor, the carrier, the port operator and the consignee) shall develop a radiation safety quality assurance programme. The graded approach is reflected in the scope and content of safety assessment as well as different requirements are applicable to different types of activities and facilities	In order to ensure the performance of protection measures the operator (i.e. any organization involved in transport, including the consignor, the carrier, the port operator and the consignee) shall develop a radiation safety quality assurance programme. The graded approach is reflected in the scope and content of safety assessment as well as different requirements are applicable to different types of activities and facilities
Lithuania	Consignor must apply for the license or registration depending on the category of the source	Carrier must apply for the license or registration depending on the category of the source
Luxembourg	Not applicable. There are no consigners in Luxembourg. If a used sealed sources is returned the license holder for the use of the sources is responsible for the consignment	Licensing of carriers, including for excepted packages.
Malta	Not specific to consignor, same as any other user,	Not specific to carrier, same as any other user,
Netherlands	Graded approach is reflected both in the transport regulations and on general (e.g. the system of notification and licensing). The consignor is responsible to comply.	Graded approach is reflected both in the transport regulations and on general (e.g. the system of notification and licensing). The carrier is responsible to comply.
Poland	Poland is currently at the implementation stage of the BSS directive.	Poland is currently at the implementation stage of the BSS directive.

	Consignor Responsibility	Carrier Responsibility
Romania	Gradual approach preparedness of emergency plan and written instructions for carrier	Gradual approach in elaboration of radiation protection programme
Slovenia	The requirements of all cited articles of BSSD were transposed into national legislation. The consignor should notify possession, use, trading, shipment in the community, export and any other management of the radioactive material with activities above exemption levels.	The carrier should notify radiation practice - transportation of radioactive or nuclear material. Graded approach is applied in need for licensing of both radiation practices. See comment under Art. 27.
Spain	All consignors are radioactive facilities or nuclear facilities, so the need an authorisation to carry out their activities	Carriers are subjected to registration process except those transporting only excepted packages
Sweden	License needed for transport of levels above table. Special consideration for high activity sources. Inspections and Audits carried out by Authority.	Modal transport regulations apply. Inspections carried out by Authority.
United Kingdom	Article 24 is implemented through IRR17 Regulations 5-7. IRR17 applies the graded approach to all employers at work with ionising radiations including consignors. Notifications and applications for registration or consent from consignors must be made to HSE as the appropriate authority.	Article 24 is implemented through IRR17 Regulations 5-7. IRR17 applies the graded approach to all employers at work with ionising radiations including carriers. Notifications and applications for registration or consent from carriers must be made to HSE as the appropriate authority.

The application of the graded approach varies in MS, with some MS applying the graded approach to the size of the source being carried, others to the people involved, and yet others to the regulatory requirements. Activity levels for the application of regulatory requirements vary by as much as six orders of magnitude across the EU. While there is no issue in the case of fixed facilities, for transport it is essential that there is a degree of commonality across the EU to ensure that there are no conflicting requirements.

9.3 ARTICLE 25 NOTIFICATION

9.3.1 ARTICLE 25 REQUIREMENTS

1. Member States shall ensure that notification is required for all justified practices, including those identified according to Article 23. The notification shall be made prior to the practice commencing or, for existing practices, as soon as possible once this requirement is applicable. For practices subject to notification, Member States shall specify the information to be provided in conjunction with the notification. Where an application for an authorisation is submitted, no separate notification is needed.

Practices may be exempted from notification, as specified in Article 26.

2. Member States shall ensure that notification is required for workplaces specified in Article 54(3), and for existing exposure situations that are managed as a planned exposure situation, as specified in Article 100(3).

3. Notwithstanding the exemption criteria laid down in Article 26, in situations identified by Member States where there is concern that a practice identified in accordance with Article 23 may lead to the presence of naturally-occurring radionuclides in water liable to affect the quality of drinking water supplies or affect any other exposure pathways, so as to be of concern from a radiation protection point of view, the competent authority may require that the practice be subject to notification.

4. Human activities involving radioactively contaminated materials resulting from authorised releases or materials cleared in accordance with Article 30 shall not be managed as a planned exposure situation and, hence, are not required to be notified.

9.3.2 ARTICLE 25 INTERPRETATION

Article 25 requires notification of all justified practices unless exempted by Article 26 (or 25(4)). The levels set in Article 26 are variable depending on the MS concerned. Notification is not required if the practice is required to be authorised.

The reference to Article 30 in Article 25(4) goes back to the default clearance levels and the State defined levels for exemption. This leads to a specific issue related to the application of Article 25(4), where different levels are set in different MS. Strictly speaking, material which has been cleared according to Article 30 does not require notification. However, a common issue in the Community is existing levels of Cs-137 contamination resulting from the Chernobyl accident. As a result, clearance levels for this isotope might be set by some MS at higher levels than the 0.1 Bq/g default. The Consultant has identified this occurrence in some MS. If this material is transported to another MS that uses the default values, a confusing situation arises that the material is not subject to notification, whereas material with the same activity concentration originating in the MS will need notification. It is impossible to determine the tracking of cleared material since there will be no Directive requirement for transport or waste shipment documentation. Conversely, an MS with a very low clearance level could take advantage of higher clearance levels in a neighbouring State simply by transferring the material to a waste processing facility — in effect, dumping.

Notification relates to the justified practice and not to the entities carrying out the practice. It applies to transport at levels below the exemption levels set in the Transport Regulations, although it may be appropriate to apply the transport exemption levels as the default for transport, given their basis. Notification is required by default, unless the MS chooses to exempt a practice from notification.

9.3.3 APPLICATION OF ARTICLE 25 TO CARRIERS AND CONSIGNORS

An issue related to transport is the risk of multiple notifications if notification is applied to the entities rather than the practice. This is particularly relevant when the requirement is applied in every MS. Thus, a single MS might require multiple notifications of the practice if it applies this requirement to both consignors and carriers. Likewise, if a MS does not recognise the notification of a transport practice in another MS, this will result in multiple notification requirements.

Should variable levels be set, a transport activity might require notification on a patchwork basis across the Community.

9.3.4 MEMBER STATE RESPONSE ON ARTICLE 25

The response of MS with regard to the application of Article 25 of the BSS Directive is presented in **Table 7.**

Table 7: Transposition of BSS Directive Article 25

	Consignor Responsibility	Carrier Responsibility
Belgium	No notification in Belgium. A facility using radioactive material should be authorized.	No notification in Belgium. A carrier of class 7 dangerous goods should be recognized
Bulgaria		
Croatia	In progress	In progress
Czech Republic	Yes	No
Denmark		
Estonia	Estonia don't use informing, which is replaced by Radiation Practice Licence indefinite time. Low risk practices Licences are in fore indefinite time. Moderate and high risk practices Licences are in force 5 years.	Estonia don't use informing, which is replaced by Radiation Practice Licence indefinite time. Transportation is moderate risk practice (Licence is in force 5 years).
Finland	No transport specific requirements	No transport specific requirements. Compliance with the legislation on the transport of dangerous goods.
France	nfi	X future amendment of public health code
Germany	nfi	nfi
Greece	prime responsibility assigned to consignor; graded approach applies	the same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	Notification. Notification is required for all justified practices. An application for an authorisation (licence or registration)may be submitted through our existing portal. The Agency shall produce guidelines specifying the information to be provided in the notification process.	Notification. Notification is required for all justified practices. An application for an authorisation (licence or registration)may be submitted through our existing portal. The Agency shall produce guidelines specifying the information to be provided in the notification process.
Italy	No separate notification is requested because the practice is authorized	No separate notification is requested because the practice is authorized
Latvia	There is no provision in the legal framework for activities to be authorized only via the notification process. Licence or registration is necessary for all activities which exceed the Regulations values.	There is no provision in the legal framework for activities to be authorized only via the notification process. Licence or registration is necessary for all activities which exceed the Regulations values.
Lithuania	Notification is required for all justified practices, except for the cases, when application for an authorisation is submitted	Notification is required for all justified practices, except for the cases, when application for an authorisation is submitted
Luxembourg		idem 24
Malta	Notification needed	Notification needed
Netherlands	All transports must be notified or licensed by the consignor or carrier (or consignee).	All transports must be notified or licensed by the consignor or carrier (or consignee).

	Consignor Responsibility	Carrier Responsibility
Poland		
Romania	Notification of transport activities(type B(U), B(M), C and fissile packages) before the start of them (three working day).	Notification before and after the transport activities (type B(U), B(M), C and fissile packages). Annual report for all transported radioactive materials
Slovenia	See above	See above
Spain	see above	see above
Sweden	License apply for transport	Notification apply according to modal regulations and terms in license.
United Kingdom	Article 25 is implemented through IRR17 Regulation 5. All consignors are required to comply with the notification IRR17 Regulations 5 where the relevant radionuclide specific activity concentration or quantity is exceeded (IRR17 Schedule 7 Columns 2 and 3 respectively).	Article 25 is implemented through IRR17 Regulation 5. All carriers are required to comply with the notification IRR17 Regulations 5 where the relevant radionuclide specific activity concentration or total activity is exceeded (IRR17 Schedule 7 Columns 2 and 3 respectively).

There is a wide variety of applications of this article in MS. Some MS do not use the graded approach, other MS have applied the notification requirements to entities involved in the practice. The situation across the Community is confusing. It does not appear that any MS considers notification by other MS in their legislation.

One issue to be considered is that the upper level for notification is the exemption level in the Transport Regulations. They cover all dangerous goods where there is a need for safety regulation. Issue I-3 also applies in this case.

9.4 ARTICLE 26 EXEMPTION FROM NOTIFICATION

9.4.1 ARTICLE 26 REQUIREMENTS

1. Member States may decide that justified practices involving the following do not need to be notified:

(a) radioactive materials where the quantities of the activity involved do not exceed in total the exemption values set out in Table B, column 3, of Annex VII, or higher values that, for specific applications, are approved by the competent authority and satisfy the general exemption and clearance criteria set out in Annex VII; or

TABLE B

Total activity values for exemption (column 3) and exemption values for the activity concentration in moderate amounts of any type of material (column 2)

Radionuclide	Activity concentration (kBq kg $^{-1}$)	Activity (Bq)
H-3	1×10^{6}	1×10^{9}
Be-7	1×10^{3}	1×10^{7}
C-14	1×10^{4}	1×10^{7}
Co-60	1×10^{1}	1×10^{5}
Cs-137	1×10^{1}	1×10^{4}

Source: BSS Directive Annex VII, Table B

(b) without prejudice to Article 25(4), radioactive materials where the activity concentrations do not exceed the exemption values set out in Table A of Annex VII, or higher values that, for specific applications, are approved by the competent authority and satisfy the general exemption and clearance criteria set out in Annex VII; or

TABLE A

Activity concentration values for exemption or clearance of materials which can be applied by default to any amount and to any type of solid material

Radionuclide	Activity concentration (kBq kg $^{-1}$)
H-3	100
Be-7	10
C-14	1
Co-60	0,1
Cs-137	0,1

Source: BSS Directive Annex VII, Table A Part 1

(c) apparatus containing a sealed source, provided that:

(i) the apparatus is of a type approved by the competent authority;

(ii) the apparatus does not cause, in normal operating conditions, a dose rate exceeding 1 µSv · h $^{-1}$ at a distance of 0.1 m from any accessible surface; and

(iii) conditions for recycling or disposal have been specified by the competent authority; or

(d) any electrical apparatus provided that:

(i) it is a cathode ray tube intended for the display of visual images, or other electrical apparatus operating at a potential difference not exceeding 30 kilo volt (kV), or it is of a type approved by the competent authority; and

(ii) it does not cause, in normal operating conditions, a dose rate exceeding 1 $\mu Sv \cdot h^{-1}$ at a distance of 0.1 m from any accessible surface.

E. Member States may exempt specific types of practices from the notification requirement subject to compliance with the general exemption criteria established in point 3 of Annex VII, on the basis of an assessment showing that exemption is the best option.

9.4.2 ARTICLE 26 INTERPRETATION

The values in Table A of the BSS Directive of radionuclide concentrations are lower than the exemption values in the transport requirements implemented through Directive 2008/68/EC. At the same time, 2008/68/EC prohibits MS from making more restrictive safety requirements (and any variations are subject to approved and published derogations). This introduces a potential conflict, in particular when related to the requirement for notification in Article 26 of the BSS Directive. However, this Directive also contains a provision that allows MS to avoid this conflict.

The BSS Directive sets conditions that, if met, will allow MS to apply higher values than those in Table A. Several options apply; however, the main criteria are:

- The radiological risks to individuals caused by the practice are sufficiently low as to be of no regulatory concern (workers should not be classified as exposed workers);
- The type of practice has been determined to be justified;
- The practice is inherently safe (the effective dose expected to be incurred by a member of the public due to the exempted practice is of the order of 10 µSv or less in a year).

For transport, because of the inherent limitation in quantities, the limited time of shipment and the low frequency of exposures, a specific assessment was carried out. The reference to this work is:

"FRANCOIS, P., et al., "The application of exemption values to the transport of radioactive materials", IRPA 9 (Proc. 9th IRPA Int. Congr. Vienna, 1996), Vol. 4, IRPA, Vienna (1996) 674."

The principles for the exemption values in the Transport Regulations are:

- The radiation risks to individuals caused by the exempted practice or source should be sufficiently low as to be of no regulatory concern (a collective dose of 1 man·Sv in a year of practice for normal conditions).
- The collective radiological impact of the exempted practice or source should be sufficiently low as to not warrant regulatory control under the prevailing circumstances (an individual effective dose of 10 µSv in a year for normal conditions).
- The exempted practices and sources should be inherently safe, with no appreciable likelihood of scenarios arising that could lead to a failure to meet the above.

As a result, the apparent conflict between the two Directives only occurs in cases where MS choose to use default values for transport notification rather than choosing to match the notification requirements of the BSS Directive for transport with the transport exemption values of Directive 2008/68/EC.

Article 26 provides the methodology for exemption from notification, which may be on the basis of MS specification (based on a specified methodology), or the default values of Table A concentrations or Table B quantities.

The State specified exemption is normally based on the total amount of material within the practice, but can be limited to small quantities with higher values (with the specific example of transport provided), so long as the generic criteria are satisfied.

Exemption from notification is optional; however, if it is not applied then all activities with very small quantities of radioactive materials will require notification.

A further option for exemption relates to sealed sources in type approved apparatus. The complexity of this for transport is significant, given that items may have type approval in consignee and consignor MS, but not in transit MS.

9.4.3 APPLICATION OF ARTICLE 26 TO CARRIERS AND CONSIGNORS

The notification exemption is set out based on justified practices, not in terms of entities carrying out the practices. However, carriers and consignors dealing with exempted justified practices should not be subject to the requirement to notify. It should be noted that notification applies to transport of any quantity of radioactive material unless a specific exemption is issued.

The option for not applying an exemption from notification will effectively create a notification requirement for transport of material at concentrations well below the transport exemption levels.

9.4.4 MEMBER STATE RESPONSE TO ARTICLE 26

The response of MS with regard to the application of Article 26 of the BSS Directive is presented in **Table 8.**

Table 8: Transposition of BSS Directive Article 26

	Consignor Responsibility	Carrier Responsibility
Belgium	No exemption of notification in Belgium. A facility using radioactive material should be authorized.	No exemption of notification in Belgium. A carrier of class 7 dangerous goods should be recognized
Bulgaria		
Croatia	In progress	In progress
Czech Republic	Yes	No
Denmark		
Estonia	Yes, by Radiation Act: Exemption level is the value of activity or activity concentration of radioactive substances at or below which no radiation practice licence is required. Exemption is allowed, if activity concentration is higher than exemption level, but effective dose for person is below 30 microSv per year and exemption is according to radiation safety assessment is best solution for economical, social or environmental reason.	Yes, by Radiation Act: Exemption level is the value of activity or activity concentration of radioactive substances at or below which no radiation practice licence is required. Exemption is allowed, if activity concentration is higher than exemption level, but effective dose for person is below 30 microSv per year and exemption is according to radiation safety assessment is best solution for economical, social or environmental reason.
Finland	Transport of radioactive substances is exempted from notification.	Except for high activity sealed sources, transport of radioactive substances is exempted from notification.
France	nfi	X future amendment of public health code

	Consignor Responsibility	Carrier Responsibility
Germany	nfi	nfi
Greece	Prime responsibility assigned to consignor; graded approach applies	The same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	Exemption from Notification. The Agency may exempt justified practices as per Article 26 of the BSS.	Exemption from Notification. The Agency may exempt justified practices as per Article 26 of the BSS.
Italy	The practice (transport) is exempted from authorization where the activity of radioactive materials does not exceed the exemption values of Table B, column 3, of Annex VII of BSSD	The practice (transport) is exempted from authorization where the activity of radioactive materials does not exceed the exemption values of Table B, column 3, of Annex VII of BSSD
Latvia	Licencing or registration is not necessary if the IRS is radioactive material with radioactivity (of corresponding nuclide) which does not exceed the prescribed by Regulations value.	Licencing or registration is not necessary if IRS is radioactive material with radioactivity (of corresponding nuclide) does not exceed the prescribed by Regulations value.
Lithuania	Notification is not required, if radioactive materials used in the quantities of the activity do not exceeding in total the exemption values	Notification is not required, if radioactive materials used in the quantities of the activity do not exceeding in total the exemption values
Luxembourg		Exemption values from annexe VII, table B.
Malta	No exemptions from licensing.	No exemptions from licensing.
Netherlands	Only transports of NORM with activity concentrations of 10 times exemption values are exempted from authorisation. However the use must be registered by the consignor/consignee.	Only transports of NORM with activity concentrations of 10 times exemption values are exempted from authorisation.
Poland		
Romania	The radioactive materials excepted from the transport authorization or excepted activity concentration, apparatus containing low activity radioactive sources excepted from authorization by the competent authorities, electrical apparatus excepted from authorization by competent authorities	The radioactive materials excepted from the transport authorization or excepted activity concentration, apparatus containing low activity radioactive sources excepted from authorization by competent authorities, electrical devices excepted from authorization by competent authorities
Slovenia	Exemption is related to activities and type approval and is in line with BSSD requirements	Exemption is related to activities and type approval and is in line with BSSD requirements
Spain	See above	See above
Sweden	N/A	N/A
United Kingdom	Article 26 exemption from notification Implemented by IRR17 Schedule 1	Article 26 exemption from notification Implemented by IRR17 Schedule 1

The application of exemption varies from MS to MS, with the application of a wide variety of systems and levels. This effectively creates an administrative barrier to trade for the smallest quantities of radioactive material, which does not exist for larger quantities. It is the opposite of the graded approach in practice.

Examination of a default level for transport that can be applied across the Community should be considered as an option. Alternatively, the Community should apply Footnote 18 from the IAEA BSS, even though BSS Directive has taken decision on whether or not to apply it.

9.5 ARTICLE 27 REGISTRATION OR LICENSING

9.5.1 ARTICLE 27 REQUIREMENTS

1. Member States shall require either registration or licensing of the following practices:

(a) the operation of radiation generators or accelerators or radioactive sources for medical exposures or for non-medical imaging purposes;

(b) the operation of radiation generators or accelerators, except electron microscopes, or radioactive sources for purposes not covered by point (a).

2. Member States may require registration or licensing for other types of practices.

3. The regulatory decision to submit types of practices to either registration or licensing may be based on regulatory experience, taking into account the magnitude of expected or potential doses, as well as the complexity of the practice.

9.5.2 INTERPRETATION OF ARTICLE 27

Article 27 includes a requirement to register or licence certain activities, including the 'operation' of radiation sources. Since transport does not involve any of these activities, it is only included in this requirement should a MS choose to apply it.

9.5.3 APPLICATION OF ARTICLE 27 TO CARRIERS AND CONSIGNORS

This requirement applies to practices within a type of practice, not to entities involved in the practice.

9.5.4 MEMBER STATE RESPONSES ON ARTICLE 27

The response of MS with regard to the application of Article 27 of the BSS Directive is presented in **Table 9.**

Table 9: Transposition of BSS Directive Article 27

	Consignor Responsibility	Carrier Responsibility
Belgium	See response on article 24 of BSS	See response on article 24 of BSS
Bulgaria		
Croatia	In progress	In progress
Czech Republic	Yes	No

	Consignor Responsibility	Carrier Responsibility
Denmark		
Estonia	Estonia don't use informing, which is replaced by Radiation Practice Licence indefinite time. Low risk practices Licences are in for indefinite time. Moderate and high risk practices Licences are in force 5 years	Estonia don't use informing, which is replaced by Radiation Practice Licence indefinite time. Transportation is moderate risk practice (Licence is in force 5 years).
Finland	No transport specific requirements	No transport specific requirements
France	nfi	X future amendment of public health code
Germany	nfi	nfi
Greece	Prime responsibility assigned to consignor; graded approach applies	The same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	Registration or Licensing. (3) The Agency shall, in accordance with paragraphs (1) and (2), determine which justified practices are subject to registration or licensing. The Agency shall base its decision to submit a type of practice to registration or licensing on regulatory experience taking into account: (a) the magnitude of expected or potential doses resulting from the practice; (b) the impact that regulatory control may have in reducing such doses or improving radiological safety; (c) the complexity of the practice; (d) safety, security and any safeguards required having regard to the circumstances in which the relevant practice is proposed to be carried out. See answer to Article 24 above.	Registration or Licensing. (3) The Agency shall, in accordance with paragraphs (1) and (2), determine which justified practices are subject to registration or licensing. The Agency shall base its decision to submit a type of practice to registration or licensing on regulatory experience taking into account: (a) the magnitude of expected or potential doses resulting from the practice; (b) the impact that regulatory control may have in reducing such doses or improving radiological safety; (c) the complexity of the practice; (d) safety, security and any safeguards required having regard to the circumstances in which the relevant practice is proposed to be carried out. See answer to Article 24 above.
Italy	A licence is requested to ship radioactive material	A licence is requested to carry radioactive material
Latvia	According to the Law on Radiation Safety and Nuclear Safety, Chapter III Section 11, that states "any activities with sources of ionising radiation are subject to licensing or registration" - Radiation Safety Centre requires operator to receive a licence or registration.	According to the Law on Radiation Safety and Nuclear Safety Chapter III Section 11 that states "any activities with the IRS are subject to licensing or registration" - Radiation Safety Centre requires operator to receive a licence or registration.
Lithuania	Consignor must apply for the license or registration depending on the category of the source	Carrier must apply for the license or registration depending on the category of the source
Luxembourg		idem 24
Malta	No registration considered	No registration considered

	Consignor Responsibility	Carrier Responsibility
Netherlands	There is no registration for transport in the Netherlands.	There is no registration for transport in the Netherlands.
Poland		
Romania	The registration is applied for: radioactive sources and radiological installation excepted from authorization (calibration sources or testing sources having an activity less then 370 MBq each, radiological installation containing alpha and beta active, radiological installation containing gamma sources having an activity less then 3.7 GBq, radiological installation containing radiation generators with potential difference less then 80 Kv.	No registration. Authorization for the transport activities of the radioactive materials with total activities over the values presented in Table B, column 3 of the transport regulations
Slovenia	License for export of radioactive and nuclear material and for shipment of nuclear material into the community and transit of radioactive material with important activity (dangerous sources category 2 - activities 10D and above) is needed. Approval of shipments of sealed sources between EU Member States is controlled through Council Regulation (EURATOM) No. 1493/93.	License for transportation of nuclear material with amounts above those defined in the Table 6 of the Decree UV1 is needed. License for transportation of radioactive material is needed if radiation practice includes transportation of radioactive material with activities 10D and above.
Spain	See above	See above
Sweden	Licensing applies.	nfi
United Kingdom	Article 27 is implemented by IRR17 Regulations 6 and 7. Regulation 6 requires consignors to gain registration from the appropriate authority (HSE) where the relevant radionuclide specific activity concentration is exceeded (IRR17 Schedule 7 Column 4 for less than 1000kg of material or IRR17 Schedule 7 Column 2 for more than 1000kg of material). Regulation 7 defines which practices require licensing (termed consent in IRR17) in GB. There are no additional practices involving transport which GB has chosen to license rather than register.	Article 27 is implemented by IRR17 Regulations 6 and 7. Regulation 6 requires carriers to gain registration from the appropriate authority (HSE) where the relevant radionuclide specific activity concentration is exceeded (IRR17 Schedule 7 Column 4 for less than 1000kg of material or IRR17 Schedule 7 Column 2 for more than 1000kg of material). Regulation 7 defines which practices require licensing (Consent) in GB. There are no additional practices involving transport which GB has chosen to license rather than register.

The approaches used vary and are inconsistent across the Community. Some MS apply registration to transport consignors, some to carriers, some to both, and some apply a methodology consistent with the Directive. There are MS which apply no licensing/registration requirement to transport.

9.6 ARTICLE 28 LICENSING

9.6.1 ARTICLE 28 REQUIREMENTS

Member States shall require licensing for the following practices:

(a) the deliberate administration of radioactive substances to persons and, in so far as the radiation protection of human beings is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;

(b) the operation and decommissioning of any nuclear facility and the exploitation and closure of uranium mines;

(c) the deliberate addition of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products, and the import of such products;

(d) any practice involving a high-activity sealed source;

(e) the operation, decommissioning and closure of any facility for the long-term storage or disposal of radioactive waste, including facilities managing radioactive waste for this purpose;

(f) practices discharging significant amounts of radioactive material with airborne or liquid effluent into the environment.

9.6.2 INTERPRETATION OF ARTICLE 28

In terms of transport, Article 28 requires the licencing of practices involving a high-activity sealed source. It is considered that transport is included in this requirement. As a result, the transport of high activity sealed sources should only take place if the practice is licenced. It should be noted that this requirement only applies if the radioactive material is a high activity sealed source — the same quantity of material outside of a sealed capsule does not require licencing. Compliance with Article 87 is a prerequisite to the issuing of a licence.

9.6.3 APPLICATION OF ARTICLE 28 TO CARRIERS AND CONSIGNORS

The decision as to whether Article 28 applies to consignors or carriers is related closely to Article 2 and the definition of a practice.

> This Directive applies in particular to:
>
> (a) the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import to, and export from the Community of radioactive material
>
> "practice" means a human activity that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation;

Certain States have chosen to treat the activity list in Article 2 as a list of practices. However the link is no longer clear in the new BSS Directive, though it is possible to consider the production and distribution of high activity sources as a human activity which incorporates transport.

A crucial aspect is the link to Article 87, which includes requirements that must be in place prior to issuing a licence that the carrier cannot fulfil. It is impossible for a carrier to demonstrate compliance with the requirements necessary for the granting of a licence.

9.6.4 MEMBER STATE RESPONSES ON ARTICLE 28

The responses of MS with regard to the application of Article 28 of the BSS Directive are presented in **Table 10.**

Table 10: Transposition of BSS Directive Article 28

	Consignor Responsibility	Carrier Responsibility
Belgium	See response on article 24 of BSS	See response on article 24 of BSS
Bulgaria		
Croatia	In progress	In progress
Czech Republic	Yes	No
Denmark		
Estonia	Look answer to Article 24.	Transportation is moderate risk practice (Licence is in force 5 years).
Finland	No transport specific requirements	A license of STUK is required for the transport of high-activity sealed sources.
France	nfi	X future amendment of public health code
Germany	nfi	nfi
Greece	Prime responsibility assigned to consignor; graded approach applies	The same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	Licensing. The graded approach to regulatory control is being adopted. Those consigning HASS will be licensed as will he exportation for disposal of radioactive waste from the State to another Member State or third country. Those consigning non-HASS may fall into licensing or registration depending on a number of factors. Compliance with the ADR and Radiation Protection Legislation is required.	Licensing. The graded approach to regulatory control is being adopted. Those transporting HASS will be licensed as will the exportation for disposal of radioactive waste from the State to another Member State or third country. Those transporting non-HASS will be registered. Compliance with the ADR and Radiation Protection Legislation is required.
Italy	A licence is requested to ship radioactive material	A licence is requested to carry radioactive material
Latvia	Two different types of authorizations are applicable to the transport activities of radioactive sources – if radioactivity exceeds the registration limit not more than 1000 times, then the applicant has to receive registration. If the limit is exceeded more than 1000 times, then licence has to be received. Radioactivity limits are set out in Cabinet Regulations No 752. Graded approach is reflected in the different duration terms of the authorizations – a licence is valid for 10 years, while registration does not have an expiry date.	Two different types of authorizations are applicable to the transport activities of radioactive sources – if radioactivity exceeds the registration limit not more than 1000 times, then the applicant has to receive a registration. If limit is exceeded more than 1000 times, then licence has to be received. Radioactivity limits are set out in Cabinet Regulations. Graded approach is reflected in the different duration terms of the authorizations – licence is valid for 10 years, while registration does not have an expiry date.

	Consignor Responsibility	Carrier Responsibility
Lithuania	License is needed, if: 1) practice involves I-V category sources used in medicine and veterinary (in vivo); 2) practice involves I-IV category sources used for non-medical or veterinary purposes; 3) practice involves I-III category sources used in gauges. Registration is needed, if practice involve other sources, than enlisted above	License is needed, if: 1) practice involves transport of I-V category sources used in medicine and veterinary (in vivo); 2) practice involves transport of I-IV category sources used for non-medical or veterinary purposes; 3) practice involves transport of I-III category sources used in gauges. Registration is needed, if practice involve other sources, than enlisted above
Luxembourg		idem 24
Malta	Need licensing	Need licensing
Netherlands	See above (art. 25).	See above (art. 25).
Poland		
Romania	The activities within nuclear medicine, operation and decommissioning of any nuclear installation, exploitation and closing of uranium mine, any practice perform with high sealed radioactive sources	Transport and transit of radioactive materials, approval of transport package design, shipment of radioactive material in type B(M), C and packages containing fissile material or UF_6, transport under special arrangements
Slovenia	See above	See above
Spain	See above	See above
Sweden	Special consideration applies for transport of high activity sources.	Modal transport regulations apply.
United Kingdom	Article 28 is implemented by IRR17 Regulation 7. All consignors involved in the practice of transporting High Activity Sealed Sources (HASS) are required to gain a license (termed consent in IRR17) from the appropriate authority (HSE) prior to transporting HASS.	Article 28 is implemented by IRR17 Regulation 7. All carriers involved in the practice of transporting High Activity Sealed Sources (HASS) are required to gain a license ("consent") from the appropriate authority (HSE) prior to transporting HASS.

The situation across the community is less diverse for licencing than for notification. However the requirements are placed on both consignors and carriers. If the definition of a practice would take into account multiple types of activities it would simplify the application of these processes and would clarify the primary responsibility for safety. This is developed further in the next section.

9.7 ARTICLE 29 AUTHORISATION PROCEDURE

9.7.1 ARTICLE 29 REQUIREMENTS

1. For authorisation purposes, Member States shall require the provision of information relevant to radiation protection that is commensurate with the nature of the practice and the radiological risks involved.

2. In the case of licensing and when determining what information must be provided under paragraph 1, Member States shall take into account the indicative list in Annex IX.

Indicative list of information for licence applications as referred to in Article 29

(a) Responsibilities and organisational arrangements for protection and safety.

(b) Staff competences, including information and training.

(c) Design features of the facility and of radiation sources.

(d) Anticipated occupational and public exposures in normal operation.

(e) Safety assessment of the activities and the facility in order to:

> (i) identify ways in which potential exposures or accidental and unintended medical exposures could occur;
>
> (ii) estimate, to the extent practicable, the probabilities and magnitude of potential exposures;
>
> (iii) assess the quality and extent of protection and safety provisions, including engineering features, as well as administrative procedures;
>
> (iv) define the operational limits and conditions of operation.

(f) Emergency procedures.

(g) Maintenance, testing, inspection and servicing so as to ensure that the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime.

(h) Management of radioactive waste and arrangements for the disposal of such waste, in accordance with applicable regulatory requirements.

(i) Management of disused sources.

(j) Quality assurance.

3. A licence shall include, as appropriate, specific conditions and reference to requirements in national legislation so as to ensure that the elements of the licence are legally enforceable, and impose appropriate restrictions on the operational limits and conditions of operation. National legislation or the specific conditions shall also require, when appropriate, the formal and documented implementation of the principle of optimisation.

4. Where applicable, national legislation or a licence shall include conditions on the discharge of radioactive effluent, in accordance with the requirements laid down in Chapter VIII for the authorisation of the release of radioactive effluent into the environment.

9.7.2 ARTICLE 29 INTERPRETATION

Article 29 applies to cases of authorisation (i.e. licencing under Article 28 or registration under Article 27). This applies to the transport of high activity sources and any other transport for which an MS chooses to require registration. The list of items to be considered for licencing is specified in the Directive.

For registration, the information to be gathered is subject to a graded approach.

9.7.3 APPLICATION OF ARTICLE 29 TO CARRIERS AND CONSIGNORS

It is clear that several aspects of the licencing information cannot be supplied by the carrier and may not be available to the consignor (for example, the management of disused sources). There is no clarity in the Directive over multiple entities having partial responsibility for certain aspects. However, this issue must be clear for transport.

9.7.4 RESPONSES OF MEMBER STATES ON ARTICLE 29

The responses of MS with regard to the application of Article 29 of the BSS Directive is presented in **Table 11.**

Table 11: Transposition of BSS Directive Article 29

	Consignor Responsibility	Carrier Responsibility
Belgium	See response on article 24 of BSS	See response on article 24 of BSS
Bulgaria		
Croatia	In progress	In progress
Czech Republic	Yes	No
Denmark		
Estonia	All descriptions are is in the Radiation Act.	All descriptions are is in the Radiation Act.
Finland	N.A.	The legislation prescribes the information to be provided for a license.
France	nfi	X future amendment of public health code
Germany	nfi	nfi
Greece	Prime responsibility assigned to consignor; graded approach applies	The same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	Authorisation Procedure. As per existing procedures for application, amendments and renewal, through our Portal.	Authorisation Procedure. In determining the conditions to be attached to a registration, the Agency shall have regard to - (a) the nature of the practice and the circumstances in which it is carried out, including any equipment used in carrying it out, (b) the nature of the radiation source to which the practice relates, (c) the levels of exposure from the radiation source to which the practice relates. As per existing procedures for application,

	Consignor Responsibility	Carrier Responsibility
		amendments and renewal, through our Portal.
Italy	The application for licence shall contain at least the information listed in Appendix IX of BSSD	The application for licence shall contain at least the information listed in Appendix IX of BSSD
Latvia	The requirements that have to be fulfilled to receive the authorization depend on the radioactivity value of radioactive sources that are going to be transported – emergency preparedness, security assurance, civil liability insurance. Responsible for establishing and implementing the radiation quality assurance programme.	The requirements that have to be fulfilled to receive the authorization depend on the radioactivity values of radioactive sources that are going to be transported – emergency preparedness, security assurance, civil liability insurance. Responsible for establishing and implementing the radiation quality assurance programme.
Lithuania	Consignor must apply for the license or registration depending on the category of the source (see para 7.1.5) and provide necessary documents relevant to radiation protection that is commensurate with the nature of the practice and the radiological risks involved	Carrier must apply for the license or registration depending on the category of the source (see para 7.1.5) and provide necessary documents relevant to radiation protection that is commensurate with the nature of the practice and the radiological risks involved
Luxembourg	0	Carrier has to apply. Documents to be submitted are defined.
Malta	Same as for other users, each import is separately authorised	Same as for other users. Each import has to be separately notified to the RPB by carrier
Netherlands	The consignor or carrier that applies for a license (or notifies) must comply with the requirements of such application (legal periods, items that need to be addressed by the applicant for a valid application). These requirements are laid out in the Dutch Administrative Law Act and the Dutch Nuclear Energy Act (legal 'procedures' to be followed by applicant and Government) and also by the Dutch Decree Transport of RAM (containing the specifics of the items that need to be in the application).	See consignor.
Poland		
Romania	Providing the documents and information relevant from the radiological point of view	Providing the documents and information relevant from the radiological point of view
Slovenia	The content of application is defined by the regulation JV12	The content of application is defined by the Regulation JV2/SV2
Spain	Consignor shall apply for the authorisation to the MINETAD, who issues the license base on the technical report of the CSN	Carriers shall apply for the registration to the MINETAD, who send the information to the CSN
Sweden	Graded approach is applied for authorisation.	nfi

	Consignor Responsibility	Carrier Responsibility
United Kingdom	Under IRR17 the appropriate authority (HSE) grants registrations or licenses (consents) based upon information submitted by the consignor. Licenses and registrations are issued by the appropriate authority including specific conditions for compliance.	Under IRR17 the appropriate authority (HSE) grants registrations or licenses (consents) based upon information submitted by the carrier. Licenses and registrations are issued by the appropriate authority including specific conditions for compliance.

The situation in MS includes three generic cases: no licence requirements, licence required and a graded approach.

9.8 ARTICLE 68 TASKS FOR THE UNDERTAKING

9.8.1 ARTICLE 68 REQUIREMENTS

Member States shall require the undertaking to carry out the following tasks:

(a) achieve and maintain an optimal level of protection of members of the public;

(b) accept into service adequate equipment and procedures for measuring and assessing exposure of members of the public and radioactive contamination of the environment;

(c) check the effectiveness and maintenance of equipment as referred to in point (b) and ensure the regular calibration of measuring instruments;

(d) seek advice from a radiation protection expert in the performance of the tasks referred to in points (a), (b) and (c).

9.8.2 INTERPRETATION OFARTICLE 68

Article 68 sets out certain specific requirements for undertakings, namely:

- Optimise protection of the public;
- Have equipment and procedures for measuring public exposure and environmental contamination (ensuring they are calibrated);
- Seek advice from a radiation protection expert on these issues.

9.8.3 APPLICATION OF ARTICLE 68 TO CARRIERS AND CONSIGNORS

This requirement relates to those in the transport regulations dealing with contamination and segregation. For either a consignor or carrier it is impossible to regulate optimised protection on a national basis; the full transport operation must be considered. As a result, the transport regulations set specific requirements that are internationally reviewed to ensure optimised protection of the public. A key part of this is the radiation protection programme (RPP).

9.8.4 MEMBER STATE RESPONSES ON ARTICLE 68

The responses of MS with regard to the application of Article 68 of the BSS Directive are presented in **Table 12.**

Table 12: Transposition of BSS Directive Article 68

	Consignor Responsibility	Carrier Responsibility
Belgium	With the authorization-system for the facilities (see response on article 24 of BSS), its own measuring instruments, the inspections program of the facilities and the monitoring (TELERAD system) FANC comply with the article 68 of BSS	With the recognition-system for the carrier of class 7 dangerous goods and other involved parties (for example handling at sea ports and airports) (see response on article 24 of BSS), its own measuring instruments, the inspections program of the carriers of class 7 dangerous goods and other involved parties and the monitoring (TELERAD system) FANC comply with the article 68 of BSS
Bulgaria		
Croatia	In progress	In progress
Czech Republic	Yes	Yes
Denmark		
Estonia	Optimization of exposure and obligations of holder of a radiation practice licence are described in the Radiation Act. Also recognition of radiation experts are described in the Radiation Act.	Optimization of exposure and obligations of holder of a radiation practice licence (included radiation monitoring) are described in the Radiation Act. Also recognition of radiation experts are described in the Radiation Act.
Finland	No transport specific requirements	Optimisation of protection is a general requirement for all practices. A licensee for transport of high activity sealed sources shall seek advise from a radiation protection expert.
France	x future amendment of the decree n°2007-1557 of 2 November 2007	x future amendment of the decree n°2007-1557 of 2 November 2007
Germany	nfi	nfi
Greece	Prime responsibility assigned to consignor; graded approach applies	The same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	Tasks for the Undertaking. The Agency shall ensure that, where appropriate, dose constraints are established by undertakings and employers for the purpose of prospective optimisation of protection: (a) for occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking: (i) in the case of outside workers the dose constraint shall be established in cooperation	Tasks for the Undertaking. The Agency shall ensure that, where appropriate, dose constraints are established by undertakings and employers for the purpose of prospective optimisation of protection: (a) for occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking: (i) in the case of outside workers the dose constraint shall be established in cooperation

	Consignor Responsibility	Carrier Responsibility
	between the employer and the undertaking; (ii) in all cases the dose constraint shall be established in accordance with guidelines issued by the Agency. (b) for public exposure, the dose constraint shall be set by the undertaking for the individual dose that members of the public receive from the planned operation of a specified radiation source in accordance with guidelines issued by the Agency. For the purposes of meeting its responsibilities under Regulation 28(1), the undertaking shall seek advice from a radiation protection adviser or advisers within their areas of competence, and approved under Regulation 78, and shall provide the radiation protection adviser or advisers with access, adequate information and facilities for the discharge of his or her functions in relation to the following: (a) the examination and testing of protective devices and measuring instruments; (b) the prior critical examination of plans for installations from the point of view of radiation protection; (c) the acceptance into service of new or modified radiation sources from the point of view of radiation protection; (d) the regular checking of the effectiveness of protective devices and techniques; (e) the regular calibration of measuring instruments and the regular checking that they are serviceable and correctly used.	between the employer and the undertaking; (ii) in all cases the dose constraint shall be established in accordance with guidelines issued by the Agency. (b) for public exposure, the dose constraint shall be set by the undertaking for the individual dose that members of the public receive from the planned operation of a specified radiation source in accordance with guidelines issued by the Agency. For the purposes of meeting its responsibilities under Regulation 28(1), the undertaking shall seek advice from a radiation protection adviser or advisers within their areas of competence, and approved under Regulation 78, and shall provide the radiation protection adviser or advisers with access, adequate information and facilities for the discharge of his or her functions in relation to the following: (a) the examination and testing of protective devices and measuring instruments; (b) the prior critical examination of plans for installations from the point of view of radiation protection; (c) the acceptance into service of new or modified radiation sources from the point of view of radiation protection; (d) the regular checking of the effectiveness of protective devices and techniques; (e) the regular calibration of measuring instruments and the regular checking that they are serviceable and correctly used.
Italy	The tasks listed in article 68 should be carried out according with the Radiation Protection Programme and with the advice of the radiation protection expert	The tasks listed in article 68 should be carried out according with the Radiation Protection Programme and with the advice of the radiation protection expert
Latvia	To ensure packaging of the cargo according to packaging requirements prescribed by Cabinet Regulations. For procedure of preparation the licence application and safe delivery of the cargo the consignor is strictly recommended to use the services of radiation protection experts in the transportations scope.	To ensure safe transportation of cargo according to requirements, including appropriately trained and instructed drivers of vehicles, as well as appropriately trained and instructed other participating workers. Ensure development and fulfilment of action plan for emergency situations.
Lithuania	Consignor is obliged to: 1) achieve and maintain an optimal level of protection of members of the public; 2) accept into service adequate equipment and procedures for measuring and assessing exposure of members of the public and	Carrier is obliged to: 1) achieve and maintain an optimal level of protection of members of the public; 2) accept into service adequate equipment and procedures for measuring and assessing exposure of members of the public and

	Consignor Responsibility	Carrier Responsibility
	radioactive contamination of the environment; 3) check the effectiveness and maintenance of equipment as referred to in point (2) and ensure the regular calibration of measuring instruments; 4) seek advice from a radiation protection expert in the performance of the tasks referred to in points (1), (2) and (3)	radioactive contamination of the environment; 3) check the effectiveness and maintenance of equipment as referred to in point (2) and ensure the regular calibration of measuring instruments; 4) seek advice from a radiation protection expert in the performance of the tasks referred to in points (1), (2) and (3)
Luxembourg		no specific requirements for carriers. Those obligations apply to the establishment manager of all type of licensees, including carriers license holders.
Malta	Same as for other users	Same as for other users
Netherlands	These requirements are detailed in the Dutch Nuclear Energy Act, Dutch Decree Transport of RAM (which also refers to the Modal Transport Regulations), but also partly in the Radiation Protection Decree (that covers all generic aspect for the use of RAM which also applies to the practise of transport). Both the consignor and the carrier have to comply to these regulations.	See consignor.
Poland		
Romania	The consigner shall designates one ore more safety experts and develop a Safety report in order to protect the people and the environment	To develop a radiation protection programme is a authorization requirement . The carrier shall designates one ore more safety experts for road. inland water and rail is the same a requirement for authorization
Slovenia	The consignor is responsible for the proper preparation of the packages and if relevant he should seek advice of the RPE in issues related to the radiation protection.	The carrier should prepare Assessment of Radiation Protection and RPE should give independent opinion about the document. In practice, the document is usually prepared directly by the RPE. Assessment of Radiation Protection also includes measures of protection of members of public and propose equipment and procedures for measuring and assessing exposure of members of the public and radioactive contamination of the environment if necessary.
Spain	To comply with all requirements established by the RPSCRI	To comply with all requirements established by the RPSCRI
Sweden	Implemented in authority regulations	nfi
United Kingdom	The following apply to all employers at work with ionising radiation including consignors: 68(a) IRR17 Regulations 9, 12, 20 68(b) IRR17 Regulation 20(3)	The following apply to all employers at work with ionising radiation including carriers: 68(a) IRR17 Regulations 9, 12, 20 68(b) IRR17 Regulation 20(3)

	Consignor Responsibility	Carrier Responsibility
	68(c) IRR17 Regulation 20(4) 68(d) IRR17 Regulation 14, Schedule 4, para.3	68(c) IRR17 Regulation 20(4) 68(d) IRR17 Regulation 14, Schedule 4, para.3

A number of MS have no requirements for transport, while other MS simply apply the Directive almost *ad literam*. Few MS make the link between the transport requirements and the BSS Directive requirements, which are aimed at achieving the same end result.

Numerous studies have been carried out, including under the auspices of the EC, which demonstrate that exposures to members of the public and environmental contamination are extremely low for transport complying with the relevant requirements.

9.9 ARTICLE 69 EMERGENCY RESPONSE

9.9.1 ARTICLE 69 REQUIREMENTS

1. Member States shall require the undertaking to notify the competent authority immediately of any emergency in relation to the practices for which it is responsible and to take all appropriate action to reduce the consequences.

2. Member States shall ensure that, in the event of an emergency on their territory, the undertaking concerned makes an initial provisional assessment of the circumstances and consequences of the emergency and assists with protective measures.

3. Member States shall ensure that provision is made for protective measures with regard to:

(a) the radiation source, to reduce or stop the radiation, including the release of radionuclides;

(b) the environment, to reduce the exposure to individuals resulting from radioactive substances through relevant pathways;

(c) individuals, to reduce their exposure.

4. In the event of an emergency on or outside its territory, the Member State shall require:

(a) the organisation of appropriate protective measures, taking account of the real characteristics of the emergency and in accordance with the optimised protection strategy as part of the emergency response plan, whereby the elements to be included in an emergency response plan are indicated in Section B of Annex XI;

(b) the assessment and recording of the consequences of the emergency and of the effectiveness of the protective measures.

5. The Member State shall, if the situation so requires, ensure that provision is made to organise the medical treatment of those affected.

B. Elements to be included in an emergency response plan

For emergency preparedness:

1. Reference levels for public exposure, taking into account the criteria laid down in Annex I;

2. Reference levels for emergency occupational exposure taking into account Article 53.

3. Optimised protection strategies for members of the public who may be exposed, for different postulated events and related scenarios;

4. Predefined generic criteria for particular protective measures;

5. Default triggers or operational criteria such as observables and indicators of on-scene conditions;

6. Arrangements for prompt coordination between organisations having a role in emergency preparedness and response and with all other Member States and with third countries which may be involved or are likely to be affected;

7. Arrangements for the emergency response plan to be reviewed and revised to take account of changes or lessons learned from exercises and events.

Arrangements shall be established in advance to revise these elements, as appropriate during an emergency exposure situation, to accommodate the prevailing conditions as these evolve throughout the response.

For emergency response:

The response to an emergency exposure situation shall be undertaken through the timely implementation of preparedness arrangements, including but not limited to:

1. Promptly implementing protective measures, if possible, before any exposure occurs;

2. Assessing the effectiveness of strategies and implemented actions and adjusting them as appropriate to the prevailing situation;

3. Comparing the doses against the applicable reference level, focusing on those groups whose doses exceed the reference level;

4. Implementing further protection strategies, as necessary, based on prevailing conditions and available information.

9.9.2 INTERPRETATION OFARTICLE 69

Article 69 requires the notification of an emergency to the authorities by the undertaking. It also sets out the elements of an emergency response plan. The article provides further details on the preparation and response to emergencies.

While transport guidance indicates that emergency response should be on an all-hazards basis, this does not seem to be incorporated in the BSS Directive. As a result, transport emergency plans may have more requirements than set out in the BSS Directive.

9.9.3 APPLICATION OF ARTICLE 69 TO CARRIERS AND CONSIGNORS

The transport regulations provide a generic requirement related to emergency planning which, in effect, follows the requirements of the BSS Directive. In this respect, Section B of Annex XI provides a guide to the content expected in an emergency plan for transport. The basis in transport sets out responsibilities for both the consignor and carrier to have emergency response plans, with the consignor providing the detailed information to be used by the carrier. For certain modes there are internationally agreed initial plans for carriers. This allocation of responsibilities is consistent with the BSS Directive.

9.9.4 RESPONSES OF MEMBER STATES ON ARTICLE 69

The responses of MS with regard to the application of Article 69 of the BSS Directive are presented in **Table 13.**

Table 13: Transposition of BSS Directive Article 69

	Consignor Responsibility	Carrier Responsibility
Belgium	1) The facilities should notify the FANC any of significant event (including incident and accident). See article 67.2 of the GRR-2001 2) The facilities should have emergency procedures (see article 5.1 of the GRR-2001) 3) Royal Decree of 17 October 2003 lays down the nuclear and radiological emergency response plan	1) The carriers of class 7 dangerous goods and other involved parties should notify the FANC of any significant event (including incident and accident). See chapter 11 (articles 136 and 137) of the RD-transport 2) The carriers of class 7 dangerous goods and other involved parties should have emergency procedures (see article 25 § 3 of the RD-transport) 3) Royal Decree of 17 October 2003 lays down the nuclear and radiological emergency response plan covers, among other situations, radiological accidents involving the transport of radioactive material requesting a coordination at national level
Bulgaria		
Croatia	In progress	In progress
Czech Republic	Yes	Yes
Denmark		
Estonia	Radiation Act: A holder of a radiation practice licence has the obligation to immediately inform the Environmental Board and the Emergency Centre of loss, theft or unauthorised use of radiation sources and of any incidents or accidents which took place during radiation practices and resulted in unintentional exposure of workers or members of the public; alleviate the consequences of accidental exposure situations; ensure the safety of the radiation source by correct installation and placement of the radiation source in the premises, mark the radiation source and the premises and use protective equipment;	Radiation Act: A holder of a radiation practice licence has the obligation to immediately inform the Environmental Board and the Emergency Centre of loss, theft or unauthorised use of radiation sources and of any incidents or accidents which took place during radiation practices and resulted in unintentional exposure of workers or members of the public; alleviate the consequences of accidental exposure situations; ensure the safety of the radiation source by correct installation and placement of the radiation source in the premises, mark the radiation source and the premises and use protective equipment;
Finland	No transport specific requirements	A licensee for transport of high activity sealed sources shall be prepared for emergencies and report such like all licensees.
France	x ASN guide n ° 31: Transport event reporting methods	x ASN guide n ° 31: Transport event reporting methods
Germany	nfi	nfi

	Consignor Responsibility	Carrier Responsibility
Greece	Prime responsibility assigned to consignor; graded approach applies	The same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	Emergency Response. An undertaking carrying on a practice shall, in accordance with guidelines issued by the Agency, immediately upon a radiological emergency arising from the practice, notify the Agency of the emergency. At the same time the undertaking shall inform the local emergency services of the circumstances with respect to the emergency. (2) In relation to such an emergency, the undertaking shall make an initial provisional assessment of the circumstances surrounding, and the possible consequences of, the emergency and submit a statement in writing of that assessment to the Agency as soon as possible but not later than 24 hours after the commencement of the emergency. (3) The undertaking shall undertake or assist with any protective measures appropriate to the circumstances of the radiological emergency. (4) The protective measures referred to in paragraph (3) shall include, if the situation so requires, protective measures related to – (a) the radiation source, to reduce or stop the radiation, including the release of radionuclides; (b) the environment, to reduce the exposure to individuals resulting from radioactive substances through relevant pathways; and (c) individuals, to reduce exposure and, where necessary, organise the medical treatment of those affected. (5) The undertaking and the relevant local authority or authorities, in whose functional area or areas protective measures are being taken, shall co-operate with one another with regard to those measures. (6) The undertaking, the relevant local authority or any other organisation responsible for the organisation of emergency response or protective measures shall provide radiological monitoring and medical surveillance for those involved in the taking of the measures, as appropriate. (7) The undertaking shall ensure that when a radiological emergency occurs the population actually affected by the emergency is informed without delay of the factors of the	Emergency Response. An undertaking carrying on a practice shall, in accordance with guidelines issued by the Agency, immediately upon a radiological emergency arising from the practice, notify the Agency of the emergency. At the same time the undertaking shall inform the local emergency services of the circumstances with respect to the emergency. (2) In relation to such an emergency, the undertaking shall make an initial provisional assessment of the circumstances surrounding, and the possible consequences of, the emergency and submit a statement in writing of that assessment to the Agency as soon as possible but not later than 24 hours after the commencement of the emergency. (3) The undertaking shall undertake or assist with any protective measures appropriate to the circumstances of the radiological emergency. (4) The protective measures referred to in paragraph (3) shall include, if the situation so requires, protective measures related to – (a) the radiation source, to reduce or stop the radiation, including the release of radionuclides; (b) the environment, to reduce the exposure to individuals resulting from radioactive substances through relevant pathways; and (c) individuals, to reduce exposure and, where necessary, organise the medical treatment of those affected. (5) The undertaking and the relevant local authority or authorities, in whose functional area or areas protective measures are being taken, shall co-operate with one another with regard to those measures. (6) The undertaking, the relevant local authority or any other organisation responsible for the organisation of emergency response or protective measures shall provide radiological monitoring and medical surveillance for those involved in the taking of the measures, as appropriate. (7) The undertaking shall ensure that when a radiological emergency occurs the population actually affected by the emergency is informed without delay of the factors of the

	Consignor Responsibility	Carrier Responsibility
	emergency, of the steps to be taken and, as appropriate, the health protection measures applicable to it. (8) The information supplied pursuant to paragraph (7) shall include, where relevant to the type of emergency, the following: (a) information on the type of emergency that has occurred and, where possible, its characteristics (e.g. origin, extent and probable development); (b) advice on protection, which, depending on the type of emergency, may; (i) cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements; (ii) be accompanied, where necessary, by special warnings for certain groups of the members of the public; (c) announcements recommending cooperation with instructions or requests. (9) Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm. This Regulation applies to the national response to nuclear and radiological emergencies arising from events taking place either inside or outside the State. (2) After consultation with such other Minister of the Government (if any) who might, in the opinion of the Minister, be concerned in the matter, the Minister shall prepare a plan which shall be known as the “National Emergency Plan for Nuclear/Radiological Accidents” (NEPNA) and is in these Regulations referred to as “the NEPNA”. (3) The NEPNA shall make provision for preparedness and response to nuclear and radiological emergencies taking place both inside and outside the State and shall include, as a minimum, the following – (a) provision for the issue and receipt of notifications and other information about radiation emergencies that may occur; (b) arrangements for the organisation of appropriate protective measures, taking	emergency, of the steps to be taken and, as appropriate, the health protection measures applicable to it. (8) The information supplied pursuant to paragraph (7) shall include, where relevant to the type of emergency, the following: (a) information on the type of emergency that has occurred and, where possible, its characteristics (e.g. origin, extent and probable development); (b) advice on protection, which, depending on the type of emergency, may; (i) cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements; (ii) be accompanied, where necessary, by special warnings for certain groups of the members of the public; (c) announcements recommending cooperation with instructions or requests. (9) Decisions introducing or altering an exposure pathway for existing and emergency exposure situations shall be justified in the sense that they should do more good than harm. This Regulation applies to the national response to nuclear and radiological emergencies arising from events taking place either inside or outside the State. (2) After consultation with such other Minister of the Government (if any) who might, in the opinion of the Minister, be concerned in the matter, the Minister shall prepare a plan which shall be known as the “National Emergency Plan for Nuclear/Radiological Accidents” (NEPNA) and is in these Regulations referred to as “the NEPNA”. (3) The NEPNA shall make provision for preparedness and response to nuclear and radiological emergencies taking place both inside and outside the State and shall include, as a minimum, the following – (a) provision for the issue and receipt of notifications and other information about radiation emergencies that may occur; (b) arrangements for the organisation of appropriate protective measures, taking

	Consignor Responsibility	Carrier Responsibility
	account of the characteristics of the radiation emergency; (c) provision for ensuring that when a nuclear or radiological emergency occurs the population actually affected by the emergency is informed without delay of the factors of the emergency, of the steps to be taken and, as appropriate, the health protection measures applicable to it; (d) provision for the assessment and recording of the consequences of the nuclear or radiological emergency and of the effectiveness of the protective measures; (e) the criteria for evaluating the need for protective measures and procedures for the optimisation of such measures; (f) arrangements for review and revision of the elements referred to in subparagraph (d) as appropriate during an emergency, to accommodate the prevailing conditions as these evolve throughout the response; (g) specifying the duties of Ministers of the Government, local authorities and other public bodies with regard to the measures to be taken under the NEPNA and the procedures to be followed by them for the purposes of co-ordinating those measures; (h) the procedures for ensuring that the public is kept fully informed of the nature and extent of any risks to which they might be exposed and of any actions taken to minimise or reduce such risks; (i) criteria and arrangements for termination of an emergency; (j) arrangements for prompt coordination between organisations having a role in emergency preparedness and response, consistent with the arrangements described in the Framework for Major Emergency Management and the Strategic Emergency Management framework; and (k) arrangements for notification, sharing of information and coordination with other countries which may be involved or are likely to be affected by the emergency. (4) The information supplied pursuant to subparagraph (3)(c) shall include, where relevant to the type of emergency, the following- (a) information on the type of emergency that has occurred and, where possible, its characteristics (e.g. origin, extent and	account of the characteristics of the radiation emergency; (c) provision for ensuring that when a nuclear or radiological emergency occurs the population actually affected by the emergency is informed without delay of the factors of the emergency, of the steps to be taken and, as appropriate, the health protection measures applicable to it; (d) provision for the assessment and recording of the consequences of the nuclear or radiological emergency and of the effectiveness of the protective measures; (e) the criteria for evaluating the need for protective measures and procedures for the optimisation of such measures; (f) arrangements for review and revision of the elements referred to in subparagraph (d) as appropriate during an emergency, to accommodate the prevailing conditions as these evolve throughout the response; (g) specifying the duties of Ministers of the Government, local authorities and other public bodies with regard to the measures to be taken under the NEPNA and the procedures to be followed by them for the purposes of co-ordinating those measures; (h) the procedures for ensuring that the public is kept fully informed of the nature and extent of any risks to which they might be exposed and of any actions taken to minimise or reduce such risks; (i) criteria and arrangements for termination of an emergency; (j) arrangements for prompt coordination between organisations having a role in emergency preparedness and response, consistent with the arrangements described in the Framework for Major Emergency Management and the Strategic Emergency Management framework; and (k) arrangements for notification, sharing of information and coordination with other countries which may be involved or are likely to be affected by the emergency. (4) The information supplied pursuant to subparagraph (3)(c) shall include, where relevant to the type of emergency, the following- (a) information on the type of emergency that has occurred and, where possible, its characteristics (e.g. origin, extent and

	Consignor Responsibility	Carrier Responsibility
	probable development); (b) advice on protection, which, depending on the type of emergency, may: (i) cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements; (ii) be accompanied, where necessary, by special warnings for certain groups of the members of the public; (c) announcements recommending cooperation with instructions or requests; (d) This information and advice shall be supplemented, if time permits, by information on the basic facts about radioactivity and its effects on human beings and on the environment. (5) The Minister, after consultation with the Agency, shall arrange for the carrying out of drills and exercises to test the NEPNA at suitable intervals and for periodic review and amendment of the NEPNA to take account of changes or lessons identified from exercises and events.	probable development); (b) advice on protection, which, depending on the type of emergency, may: (i) cover the following: restrictions on the consumption of certain foodstuffs and water likely to be contaminated, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of protective substances, evacuation arrangements; (ii) be accompanied, where necessary, by special warnings for certain groups of the members of the public; (c) announcements recommending cooperation with instructions or requests; (d) This information and advice shall be supplemented, if time permits, by information on the basic facts about radioactivity and its effects on human beings and on the environment. (5) The Minister, after consultation with the Agency, shall arrange for the carrying out of drills and exercises to test the NEPNA at suitable intervals and for periodic review and amendment of the NEPNA to take account of changes or lessons identified from exercises and events.
Italy	An emergency response plan should be prepared and submitted with the application for licence	An emergency response plan should be prepared and submitted with the application for licence
Latvia	-	Shall develop a plan for preparedness to radiological emergencies and actions to be accomplished in the event of radiological emergency (hereinafter – the action plan) in an object which might cause the radiological emergency initiated damage. Protection measures regarding residents who may be under the threat of radiological emergency shall be provided in the action plan. The carrier co-ordinates his action plan with the: - RSC; - the local government if the total radioactivity value of radioactive substances in the area controlled by the operator is equal or exceeds the limits specified in the Annex 1 of these Regulations; - the State Fire-Fighting and Rescue Service if the consequences of radiological emergency might affect the residents and the environment outside the area controlled by the operator.

	Consignor Responsibility	Carrier Responsibility
		The driver of the vehicle performs the emergency protection measures that are specified in the safety data sheet of the IRS and informs the RSC, the Rescue Service and the relevant local government regarding the event
Lithuania	Consignor is obliged to: 1) notify the competent authority immediately of any emergency in relation to the practices for which it is responsible and to take all appropriate action to reduce the consequences; 2) make an initial provisional assessment of the circumstances and consequences of the emergency and assist with protective measures; 3) ensure that provision is made for protective measures with regard to: a) the radiation source, to reduce or stop the radiation, including the release of radionuclides; b) the environment, to reduce the exposure to individuals resulting from radioactive substances through relevant pathways; c) individuals, to reduce their exposure. 4) taking into account the consequences of the emergency and of the effectiveness of the protective measures prepare emergency response plan; 5) ensure that provision is made to organise the medical treatment of those affected.	Carrier is obliged to: 1) notify the competent authority immediately of any emergency in relation to the practices for which it is responsible and to take all appropriate action to reduce the consequences; 2) make an initial provisional assessment of the circumstances and consequences of the emergency and assist with protective measures; 3) ensure that provision is made for protective measures with regard to: a) the radiation source, to reduce or stop the radiation, including the release of radionuclides; b) the environment, to reduce the exposure to individuals resulting from radioactive substances through relevant pathways; c) individuals, to reduce their exposure. 4) taking into account the consequences of the emergency and of the effectiveness of the protective measures prepare emergency response plan; 5) ensure that provision is made to organise the medical treatment of those affected.
Luxembourg		included into the licensing conditions of the carriers.
Malta	Same as for other users	Same as for other users
Netherlands	The consignor (and carrier) is required to notify emergencies and take action based on the specific license conditions and general regulations (the ones mentioned above).	See consignor.
Poland		
Romania	Is applied the Emergency Response plan by the response team of the consigner in order to mitigate the consequences of the accident in order to protect people and environment	Is applied the Emergency Response plan
Slovenia	Consignor is responsible to notify the CA in emergency situation occurring during preparation of the package or during other	Carrier is responsible to notify the CA in emergency situations during transport.

	Consignor Responsibility	Carrier Responsibility
	activities before transport is starting to take place.	
Spain	Consignor have to have an Emergency Plan, which shall include transport events. This document is part of the documentation to be included in the application for authorisation	Carriers have to have an Emergency Plan included in their Radiation Protection Programs, which have to be available to the competent authority
Sweden	Implemented in authority regulations	nfi
United Kingdom	To be implemented in new transport legislation: See BEIS Consultation document https://www.gov.uk/government/consultations/revised-requirements-for-radiological-protection-emergency-preparedness-and-response	To be implemented in new transport legislation: See BEIS Consultation document https://www.gov.uk/government/consultations/revised-requirements-for-radiological-protection-emergency-preparedness-and-response

For those MS which have implemented these requirements there seems to be good agreement on the need for notification of an emergency. The importance of the RPP was not identified by many States, even though this is a key requirement covering this area.

9.10 ARTICLE 87 REQUIREMENTS FOR CONTROL OF HIGH-ACTIVITY SEALED SOURCES

9.10.1ARTICLE 87 REQUIREMENTS

Member States shall ensure that, before issuing authorisation for practices involving a high-activity sealed source:

(a) adequate arrangements have been made for the safe management and control of sources, including when they become disused sources. Such arrangements may provide for the transfer of disused sources to the supplier or their placement in a disposal or storage facility or an obligation for the manufacturer or the supplier to receive them;

(b) adequate provision, by way of a financial security or any other equivalent means appropriate for the source in question, has been made for the safe management of sources when they become disused sources, including the case where the undertaking becomes insolvent or ceases its activities.

9.10.2 INTERPRETATION OF ARTICLE 87

Article 87 sets out prerequisites that must be in place prior to an MS issuing an authorisation for a practice involving a high-activity sealed source. These are:

- Management of the sources must be in place, including the end of life;
- Financial security must be in place for the source when it becomes disused.

9.10.3 APPLICATION OF ARTICLE 87 TO CARRIERS AND CONSIGNORS

This article was chosen because of the difficulty for a carrier to demonstrate these items, thus raising questions as to whether the carrier is the appropriate object of authorisation, or whether the regulatory requirements should apply only where multiple entities are involved. It seems reasonable that a consignor can provide the information required if it is the distributor of sources. However, a scheduled carrier is unlikely to have access to this information, particularly if the consignor is based in a different MS. The prerequisites may well be in place for MS of origin and MS of delivery, but transit MS may not have financial security in their jurisdiction.

9.10.4 RESPONSES OF MEMBER STATES ON ARTICLE 87

The responses of MS with regard to the application of Article 87 of the BSS Directive is presented in **Table 14.**

Table 14: Transposition of BSS Directive Article 87

	Consignor Responsibility	Carrier Responsibility
Belgium	See chapter XIII of the GRR-2001	See chapter XIII of the GRR-2001 + See response on article 24 of BSS (recognition of the carrier)
Bulgaria	0	0
Croatia	In progress	In progress
Czech Republic	Yes	No
Denmark		
Estonia	According to the Radiation Act an Application for radiation practice licence shall include a recovery plan of radiation source after the termination of use of the radiation source and data on radioactive waste, equipment containing thereof and financial collaterals required for recovery of radioactive waste. The financial collaterals shall include costs of dismantling, transportations, storing etc.	According to the Radiation Act carrier don't shall have a recovery plan and financial collaterals.
Finland	No transport specific requirements	No transport specific requirements.
France	x (public health code)	nfi
Germany	nfi	nfi
Greece	prime responsibility assigned to consignor; graded approach applies	the same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	Requirements for control of high-activity sealed sources 69. The Agency shall ensure, prior to granting a licence The Agency shall ensure, prior to granting a licence for a practice involving a high-activity sealed source, that - (a) adequate arrangements have been made	Requirements for control of high-activity sealed sources 69. The Agency shall ensure, prior to granting a licence The Agency shall ensure, prior to granting a licence for a practice involving a high-activity sealed source, that - (a) adequate arrangements have been made

	Consignor Responsibility	Carrier Responsibility
	for the safe and secure management and control of sources, including when they become disused sources. These arrangements may provide for the transfer of disused sources to the supplier or their placement in a disposal or storage facility or an obligation for the manufacturer or supplier to receive them; (b) adequate provision, by way of a financial security or any other equivalent means appropriate for the source in question, has been made for the safe and secure management of sources when they become disused sources, including cases where the undertaking becomes insolvent or ceases its activities.	for the safe and secure management and control of sources, including when they become disused sources. These arrangements may provide for the transfer of disused sources to the supplier or their placement in a disposal or storage facility or an obligation for the manufacturer or supplier to receive them; (b) adequate provision, by way of a financial security or any other equivalent means appropriate for the source in question, has been made for the safe and secure management of sources when they become disused sources, including cases where the undertaking becomes insolvent or ceases its activities.
Italy	The requirements for control of HASS are evaluated under the licensing process. A security plan for transport of HASS shall be adopted according to section 1.10.3 of ADR	A security plan for transport of HASS shall be adopted according to section 1.10.3 of ADR
Latvia	The consignor shall ensure that after transportation will be kept observance of requirements of the high activity sealed source (HASS) control, including: 1) provision of the transporting HASS with photos of the source model and container, 2)provision of this HASS with appropriate recording material in compliance with Regulations, 3) before the HASS delivery assures the consignee has received a licence for practices with such source.	As the Regulations require to accomplish leakage tests in case of radiation accident or incident, the carrier shall inform the consignee about all essential conditions of the performed transportation procedure.
Lithuania	Sealed sources can be imported to the Republic of Lithuania only in case adequate arrangements have been made for the safe management and control of sources including when they become disused and consignor provides the written commitment of the source provider or manufacturer to take the source back after its useful lifecycle has ended. Consignee is obliged to sign contract with Radioactive Waste Management Agency (RATA) for the disposal of the used sealed sources for the case of the failure to return sources to the consignor due to any reasons that may occur and obtain insurance for the amount of the RATA services.	-
Luxembourg	0	No additional obligation for carriers

	Consignor Responsibility	Carrier Responsibility
Malta	Same as other HASS users	Not specified for carriers, but in practice, carriers are not authorised to store or keep any sources
Netherlands	In case of transfer of HASS between member States the consignor has to request approval from the member state of the consignee (Euratom 1493/93). Also the transport of HASS (which requires a license) is only justified after the licensee (usually consignor of carrier) has checked the consignee is authorised to receive the HASS. The financial security for HASS is required through the Dutch Radiation Protection Decree.	See consignor.
Poland	0	
Romania	The Romanian competent authority during the authorization process requires to applicant to prove the existing of adequate measures for safety management and control of the high activity sources like: transfer of the sources to supplier or final storage or obligation of the supplier to receive the spent sealed radioactive sources. All these measures are the conditions written in license.	N/K
Slovenia	Consignor is responsible for financial securities if necessary and to provide security plan in case of transit of radioactive material with important activity.	The carrier of HASS sources should obtain license to perform radiation practice - transportation of radioactive material. During the licensing the CA considers some additional issues related to HASS sources (security plan,…).
Spain	Just considered in the authorisation process	No apply to carriers
Sweden	Implemented in authority regulations	nfi
United Kingdom	HASS regulations (enforced by environmental regulator)	HASS regulations (enforced by environmental regulator)

Although there is some variation in requirements, a few MS apply them to carriers, with the majority focusing on the consignor.

9.11 ARTICLE 88 SPECIFIC REQUIREMENTS FOR LICENSING OF HIGH-ACTIVITY SEALED SOURCES

9.11.1ARTICLE 88 REQUIREMENTS

In addition to the general licensing requirements set out in Chapter V, Member States shall ensure that the licence for a practice involving a high-activity sealed source includes, but does not have to be limited to:

(a) responsibilities;

(b) minimum staff competencies, including information and training;

(c) minimum performance criteria for the source, source container and additional equipment;

(d) requirements for emergency procedures and communication links;

(e) work procedures to be followed;

(f) maintenance of equipment, sources and containers;

(g) adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a manufacturer, a supplier, another authorised undertaking or a waste disposal or storage facility.

9.11.2 INTERPRETATION OF ARTICLE 88

Article 88 sets out the minimum requirements that an MS must include in the licence for a practice involving a high-activity sealed source. Sub-paragraphs (c) and (f) are particularly relevant since they require in the licence the establishment of performance criteria and maintenance of the source and container.

9.11.3APPLICATION OF ARTICLE 88 TO CARRIERS AND CONSIGNORS

Carriers cannot have a responsibility for the performance criteria or maintenance requirements for the source or the package. If a consignor is a source distributor, it can be expected to carry this responsibility.

9.11.4RESPONSES OF MEMBER STATES ON ARTICLE 88

The responses of MS with regard to the application of Article 88 of the BSS Directive are presented in **Table 15.**

Table 15: Transposition of BSS Directive Article 88

	Consignor Responsibility	Carrier Responsibility
Belgium	See chapter XIII of the GRR-2001	See chapter XIII of the GRR-2001 + See response on article 24 of BSS (recognition of the carrier)
Bulgaria		
Croatia	In progress	In progress
Czech Republic	Yes	Yes
Denmark		

	Consignor Responsibility	Carrier Responsibility
Estonia	According to the Radiation Act: In addition to the provisions of § 53 of the General Part of the Environmental Code Act, a radiation practice licence shall indicate: 1) number and date of issue of the radiation practice licence; 2) name of radiation practice; 3) data on and description of radiation sources; 4) methods of management of radioactive waste, maximum quantities and management and storage facilities thereof; 5) maximum quantities of radioactive emissions, and modes of release thereof into the environment; 6) requirements for radiation safety and radiation monitoring arising from radiation practice and the specific character thereof; 7) risk level of the radiation practice; 8) existence of financial collateral. (2) A radiation practice licence issued for radiation practice related to high-activity sources contains the following information in addition to the provisions of subsection (1) of this section: 1) radiation protection competence of the workers, including informing and training of them; 2) requirements for the radiation source, container of the radiation source and additional equipment and their maintenance; 3) proper radiation safety management of disused sources until delivery thereof to a manufacturer, another person holding the radiation practice licence or radioactive waste storage facilities.	According to the Radiation Act: In addition to the provisions of § 53 of the General Part of the Environmental Code Act, a radiation practice licence shall indicate: 1) number and date of issue of the radiation practice licence; 2) name of radiation practice; 6) requirements for radiation safety and radiation monitoring arising from radiation practice and the specific character thereof; 7) risk level of the radiation practice Also requirements related to shipment registry shall be included.
Finland	N.A.	These requirements for licensing are prescribed in the legislation and are applicable for the transport of high activity sealed sources.
France	nfi	X licensing of carriers (in the future articles R. 1333-146 and following of public health code)
Germany	nfi	nfi
Greece	Prime responsibility assigned to consignor; graded approach applies	The same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	The Agency shall ensure that, as a minimum, conditions covering the following areas are specified in a licence for a practice involving a	The Agency shall ensure that, as a minimum, conditions covering the following areas are specified in a licence for a practice involving a

	Consignor Responsibility	Carrier Responsibility
	high-activity sealed source: (a) responsibilities; (b) minimum staff competencies, including information and training; (c) minimum performance criteria for the source, source container and additional equipment; (d) requirements for emergency procedures and communication links; (e) work procedures to be followed; (f) maintenance of equipment, sources and containers; (g) adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a manufacturer, a supplier, another authorised undertaking or a waste disposal or storage facility. Record keeping by the undertaking 71. (1) An undertaking responsible for high-activity sealed sources shall keep records of all high-activity sealed sources under its responsibility, their location and transfer. The records shall include the information set out in Schedule 11. (2) An undertaking responsible for high-activity sealed sources shall provide the Agency with the information contained in the records referred to in paragraph (1), in a format specified by the Agency – (a) without undue delay, at the time of the establishment of such record, which shall be as soon reasonably practicable after the source is acquired; (b) at intervals, determined by the Agency, of not more than 12 months thereafter; (c) if the situation on the information sheet has changed; (d) without undue delay upon the closure of records for a specific source when the undertaking no longer holds this source, whereby the name of the undertaking or waste disposal or storage facility to which the source is transferred shall be included; (e) without undue delay upon the closure of such records when the undertaking no longer holds any sources; (f) whenever so requested by the Agency. (3) The undertaking's records shall be available for inspection by the Agency. Record keeping by the competent authority 72. The Agency shall keep records of any	high-activity sealed source: (a) responsibilities; (b) minimum staff competencies, including information and training; (c) minimum performance criteria for the source, source container and additional equipment; (d) requirements for emergency procedures and communication links; (e) work procedures to be followed; (f) maintenance of equipment, sources and containers; (g) adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a manufacturer, a supplier, another authorised undertaking or a waste disposal or storage facility. Record keeping by the undertaking 71. (1) An undertaking responsible for high-activity sealed sources shall keep records of all high-activity sealed sources under its responsibility, their location and transfer. The records shall include the information set out in Schedule 11. (2) An undertaking responsible for high-activity sealed sources shall provide the Agency with the information contained in the records referred to in paragraph (1), in a format specified by the Agency – (a) without undue delay, at the time of the establishment of such record, which shall be as soon reasonably practicable after the source is acquired; (b) at intervals, determined by the Agency, of not more than 12 months thereafter; (c) if the situation on the information sheet has changed; (d) without undue delay upon the closure of records for a specific source when the undertaking no longer holds this source, whereby the name of the undertaking or waste disposal or storage facility to which the source is transferred shall be included; (e) without undue delay upon the closure of such records when the undertaking no longer holds any sources; (f) whenever so requested by the Agency. (3) The undertaking's records shall be available for inspection by the Agency. Record keeping by the competent authority 72. The Agency shall keep records of any

	Consignor Responsibility	Carrier Responsibility
	undertaking authorised to perform practices with high-activity sealed sources and of the high-activity sealed sources held. These records shall include the radionuclide involved, the activity at the time of manufacture or, if this activity is not known, the activity at the time of the first placing on the market or at the time the undertaking acquired the source, and the type of source. The Agency shall keep the records up to date, taking transfers of the sources and other factors into account. Control of high-activity sealed sources 73. (1) An undertaking carrying out activities involving high-activity sealed sources shall comply with the requirements set out in Schedule 12. (2) The manufacturer, supplier, and undertaking shall ensure that high-activity sealed sources and containers comply with the requirements for identification and marking as set out in Schedule 13. There are also obligations for the undertaking under the ADR for the carriage of high-consequence dangerous goods by road and the necessity to have a transport security plan.	undertaking authorised to perform practices with high-activity sealed sources and of the high-activity sealed sources held. These records shall include the radionuclide involved, the activity at the time of manufacture or, if this activity is not known, the activity at the time of the first placing on the market or at the time the undertaking acquired the source, and the type of source. The Agency shall keep the records up to date, taking transfers of the sources and other factors into account. Control of high-activity sealed sources 73. (1) An undertaking carrying out activities involving high-activity sealed sources shall comply with the requirements set out in Schedule 12. (2) The manufacturer, supplier, and undertaking shall ensure that high-activity sealed sources and containers comply with the requirements for identification and marking as set out in Schedule 13. There are also obligations for the undertaking under the ADR for the carriage of high-consequence dangerous goods by road and the necessity to have a transport security plan.
Italy	The specific requirements for licensing of practice involving HASS are evaluated during the licensing process.	The specific requirements are evaluated during the licensing process for transport of HASS.
Latvia	In the authorisation process submits a statement ensuring that after the finishing of the HASS use the HASS will be returned to the supplier or will be placed in the repository.	n/a
Lithuania	During authorisation process Consignor among other documents must provide: 1) The list of the workers (divided in to A and B categories, specifying and justifying the future occupational exposure), the copies of certificates confirming the professional qualification and qualification on radiation protection of every worker, listed above, copies of documentation about the training to operate a particular source of ionizing radiation; 2) Description of training and instructing of radiation workers on radiation protection; 3) The description of executing of individual monitoring and monitoring of work places, the copy of protocols of equivalent dose rate	During authorisation process Carrier among other documents must provide: 1) The list of the workers (divided in to A and B categories, specifying and justifying the future occupational exposure), the copies of certificates confirming the professional qualification and qualification on radiation protection of every worker, listed above, copies of documentation about the training to operate a particular source of ionizing radiation; 2) Description of training and instructing of radiation workers on radiation protection; 3) The description of executing of individual monitoring and monitoring of work places, the copy of protocols of equivalent dose rate

	Consignor Responsibility	Carrier Responsibility
	measurements of work places if they are not performed by The Radiation Protection Centre, or information about the equivalent dose rate measurements of work places (date and registration number) if they are performed by The Radiation Protection Centre; 4) The safe working manual (radiation protection instructions) 5) The quality assurance program and plan of its implementation; 6) Emergency preparedness plan; 7) The plan of management of radioactive waste; 8) The list of authorised persons who will be able to install and perform technical supervision of equipment with the sources of ionizing radiation; 9) Certificates and other technical documentation representing the detailed information about the sources (leakage tests of the sealed sources, copies of other technical documentation that may influence the assessment of the radiation protection).	measurements of work places if they are not performed by The Radiation Protection Centre, or information about the equivalent dose rate measurements of work places (date and registration number) if they are performed by The Radiation Protection Centre; 4) The safe working manual (radiation protection instructions) 5) The quality assurance program and plan of its implementation; 6) Emergency preparedness plan; 7) Description of transportation of sealed or unsealed sources or radioactive waste in case if transportation is necessary for the licensed activities; 8) The copy of valid ADR driving licenses in case if radioactive materials or radioactive waste will be transported; 9) Information about the vehicles for transport of radioactive materials or radioactive waste (models of the cars, their registry numbers, additional equipment for radiation protection and measures of security); 10) Information about the basis of appointment of expert of transportation of dangerous goods, the copy of the certificate valid for a certain transportation type and certain group of dangerous goods;
Luxembourg		No additional obligation for carriers
Malta	Same as other HASS users	Not considered for carriers, however need to comply with transport
Netherlands	The Dutch Radiation Protection Decree covers these items. Of course specific requirements concerning e.g. the transport container and radiation protection programs are covered in the Modal Transport Regulations which are binding through the Dutch Decree Transport of RAM.	See consignor, mainly RPP.
Poland		
Romania	See Art 87	N/K
Slovenia	-	The Assessment of Radiation Protection which is the main licensing document together with the procedures for safe transport and for acting in case of emergency include all the provisions of the Art. 88. of the BSSD.

	Consignor Responsibility	Carrier Responsibility
Spain	Only responsibilities for the Competent Authority of the Member States	No apply to carriers
Sweden	Implemented in authority regulations	nfi
United Kingdom	IRR17 Regulation 7(1)(g) Consent IRR17 Regulation 15(2) Training	IRR17 Regulation 7(1)(g) Consent IRR17 Regulation 15(2) Training

Several MS have addressed the issue of applying these requirements to carriers. Lithuania has set out precise requirements for consignors and carriers, while Netherlands has identified that these requirements are best satisfied through links to the modal requirements.

9.12 ARTICLE 98 EMERGENCY PREPAREDNESS

9.12.1ARTICLE 98 REQUIREMENTS

1. Member States shall ensure that emergency response plans are established in advance for the various types of emergencies identified by an assessment of potential emergency exposure situations.

2. The emergency response plans shall include the elements defined in Section B of Annex XI.

3. The emergency response plans shall also include provision for the transition from an emergency exposure situation to an existing exposure situation.

4. Member States shall ensure that emergency response plans are tested, reviewed and, as appropriate, revised at regular intervals, taking into account lessons learned from past emergency exposure situations and taking into account the results of the participation in emergency exercises at national and international level.

5. The emergency response plans shall, where appropriate, incorporate relevant elements of the emergency management system referred to in Article 97.

9.12.2INTERPRETATION OF ARTICLE 98

Article 98 sets out the key requirements related to emergency preparedness and, as noted previously, they are called up in the Transport Regulations. The essentials include:

- Planning;
- Testing (exercising);
- Review;
- Revision.

9.12.3APPLICATION OF ARTICLE 98 TO CARRIERS AND CONSIGNORS

These requirements apply to both consignors and carriers. However, the importance of an integrated, all-hazard plan for transport means they can only be applied as part of a more comprehensive set of requirements. For example, there are often passengers involved in transport even where radioactive materials are concerned. Because of this, the emergency planning and response system relies on both consignors and carriers. The consignor can provide specific emergency response requirements for their consignment, while the carrier can consolidate a number of consignments and can provide modal specific response plans. An essential part of this is the segregation of requirements related to incompatible loads set out in the Transport Regulations.

9.12.4MEMBER STATE RESPONSES ON ARTICLE 98

The responses of MS with regard to the application of Article 98 of the BSS Directive are presented in **Table 16.**

Table 16: Transposition of BSS Directive Article 98

	Consignor Responsibility	Carrier Responsibility
Belgium	Royal Decree of 17 October 2003 lays down the nuclear and radiological emergency response plan covers, among other situations, radiological accidents involving the transport of radioactive material requesting a coordination at national level	Royal Decree of 17 October 2003 lays down the nuclear and radiological emergency response plan covers, among other situations, radiological accidents involving the transport of radioactive material requesting a coordination at national level
Bulgaria		
Croatia	In progress	In progress
Czech Republic	Yes	Yes
Denmark		
Estonia	Radiation Act: According to the Emergency Act, a radiological emergency response plan shall be prepared to ensure readiness to respond to radiological emergencies.	Radiation Act: According to the Emergency Act, a radiological emergency response plan shall be prepared to ensure readiness to respond to radiological emergencies.
Finland	-	See answer to article 69.
France	X licensing of carriers (in the future articles R. 1333-13 and following of public health code) ASN guide n ° 17 relating to the content of the management plans for incidents and accidents involving the transport of radioactive substances	x ASN guide n ° 17 relating to the content of the management plans for incidents and accidents involving the transport of radioactive substances
Germany	nfi	nfi
Greece	Prime responsibility assigned to consignor; graded approach applies	The same for the carrier, as undertaking, when consignor or, consignor and consignee, are located abroad
Ireland	Emergency Preparedness. Emergency Preparedness for Licensed Undertakings 54. (1) In the case of a practice which is subject to licence, the undertaking shall - (a) evaluate the possibility of a radiological emergency resulting from the practice and evaluate the potential exposures to workers and members of the public; (b) based on the evaluation, prepare an emergency response plan to deal with such	Emergency Preparedness. Emergency Preparedness for Licensed Undertakings 54. (1) In the case of a practice which is subject to licence, the undertaking shall - (a) evaluate the possibility of a radiological emergency resulting from the practice and evaluate the potential exposures to workers and members of the public; (b) based on the evaluation, prepare an emergency response plan to deal with such

	Consignor Responsibility	Carrier Responsibility
	an emergency: that emergency response plan shall be prepared after consultation with a radiation protection adviser, the Agency and, where appropriate, the local authority within whose functional area the undertaking carries on the practice, hereafter in these Regulations referred to as “the relevant local authority”. (2) The undertaking shall - (a) submit a copy of the emergency response plan referred to in subparagraph (1)(b) to the Agency and, where appropriate, the relevant local authority as soon as may be after it is prepared; (b) carry out drills and exercises to test the emergency response plan at regular intervals; (c) ensure that, where appropriate, suitably trained personnel are available for technical, medical and health intervention; and (d) ensure that any person under the control of the undertaking who may be involved in or may be affected by the emergency response plan is given suitable instruction in the arrangements of the plan. Note: extracts from the draft SI giving effect to the new BSSD are provided above but it is not currently law as it going through the parliamentary process.	an emergency: that emergency response plan shall be prepared after consultation with a radiation protection adviser, the Agency and, where appropriate, the local authority within whose functional area the undertaking carries on the practice, hereafter in these Regulations referred to as “the relevant local authority”. (2) The undertaking shall - (a) submit a copy of the emergency response plan referred to in subparagraph (1)(b) to the Agency and, where appropriate, the relevant local authority as soon as may be after it is prepared; (b) carry out drills and exercises to test the emergency response plan at regular intervals; (c) ensure that, where appropriate, suitably trained personnel are available for technical, medical and health intervention; and (d) ensure that any person under the control of the undertaking who may be involved in or may be affected by the emergency response plan is given suitable instruction in the arrangements of the plan.
Italy	An emergency response plan should be prepared and submitted with the application for licence	An emergency response plan should be prepared and submitted with the application for licence
Latvia	n/a	In order to receive a licence or a registration certificate shall develop a plan for preparedness to radiological emergencies and the action plan in the event of radiological emergency in an object which might cause the radiological emergency initiated damage. Protection measures regarding residents who may be under threat of radiological emergency shall be provided in the action plan.
Lithuania	Consignor is obliged to: 1) prepare emergency response plan in advance for the various types of emergencies identified by an assessment of potential emergency exposure situations; 2) ensure that emergency response plans are tested, reviewed and, as appropriate, revised at least once per year, taking into account lessons learned from past emergency exposure situations and taking into account	Carrier is obliged to: 1) prepare emergency response plan in advance for the various types of emergencies identified by an assessment of potential emergency exposure situations; 2) ensure that emergency response plans are tested, reviewed and, as appropriate, revised at least once per year, taking into account lessons learned from past emergency exposure situations and taking into account

	Consignor Responsibility	Carrier Responsibility
	the results of the participation in emergency exercises at the level of the licensee, municipality, state or international level, also taking into account recent changes of the legislation.	the results of the participation in emergency exercises at the level of the licensee, municipality, state or international level, also taking into account recent changes of the legislation.
Luxembourg		Responsibility of the Government
Malta	Same as other user	Same as other user
Netherlands	The responsibilities of the consignor and carrier are laid down in art 6.7 and 6.8 of the Dutch Radiation Protection Decree, which also applies to transport based on art 1b. of the Dutch Decree Transport RAM.	See consignor.
Poland		
Romania	N/K	N/K
Slovenia	The consignor should have established the instruction for acting in case of emergencies for the activities like preparation of packages and other activities before the transport is starting to take place.	The carrier establishes the specific instruction for acting in case of emergencies as part of radiation practice. On the national level, there is a National Emergency Response Plan for Nuclear and Radiological Accidents which covers also the emergencies related to transport.
Spain	Consignor have to have an Emergency Plan, which shall include transport events. Tis document is part of the documentation to be included in the application for authorisation	Carriers have to have an Emergency Plan included in their Radiation Protection Programs, which have to be available to the competent authority
Sweden	Implemented in authority regulations	nfi
United Kingdom	To be implemented in new transport legislation: See BEIS Consultation document https://www.gov.uk/government/consultations/revised-requirements-for-radiological-protection-emergency-preparedness-and-response	To be implemented in new transport legislation: See BEIS Consultation document https://www.gov.uk/government/consultations/revised-requirements-for-radiological-protection-emergency-preparedness-and-response

A variety of approaches are set out, but generally the concept is that the carrier and consignor should make plans, with different areas of emphasis for each.

9.13 SUMMARY OF BSS DIRECTIVE IMPLEMENTATION FOR TRANSPORT

Transport regulations were developed to provide an internationally harmonised method of implementing the IAEA Basic Safety Standards. It was recognised that individual State variations caused significant blockages to transport, with no added value in terms of safety.

The regulatory system involves the development of standards through the IAEA and UNECE and then implementation through modal bodies. The modal requirements are implemented in the EU through a mixture of regulations and directives. As a result, the EU has effectively implemented the IAEA Basic Safety Standards in transport in a harmonised way for around 20 years.

The need for specific regulations for transport can be addressed through, for example, consideration of simple regulations such as those related to worker exposure. Workers can easily travel through and outside numerous MS (for example in international waters). The ability of each State to regulate is based on the activities within its borders. Therefore, the ability to limit the exposure of transport workers depends on an internationally adopted methodology that can be regulated in clearly identified states. In transport this is manged through regulations such as segregation, accumulation and radiation protection programmes.

The overall effect of the latest BSS Directive appears to be the introduction of significant dissonance to the regulation of transport in the Community. This is particularly apparent where the hazards are lowest. Different MS have implemented the BSS Directive in transport in different ways. Italy, Lithuania and Spain appear to have been particularly careful in interpreting the directive. Issue I-4 can also be applied in this case.

The varied application of the exemption levels in the Community is not so important if strict border controls are in place. However, in the context of transport and open borders, significant issues in ensuring compliance and managing the control of low activity radioactive materials may arise.

This is one of the areas with the largest variation in application in the Community, and this variation impedes open trade between MS, especially with the removal of border controls. Some concerns exist over the IAEA derived values for clearance, which appear to be currently under review.

Given the time-scales for amending and updating these values, initial work on the next update is likely to start in the near future. Consideration over the need to provide guidance to any foundation work could be important in ensuring that changes are not made without appropriate justification, including for the application of fixed levels for the community.

The importance of all areas of expertise sharing views with each other was accepted by the SG and CTF during the second workshop. This was identified as an area where work was currently ongoing

Issue I-23: The involvement of transport experts in reviews of the BSS and shipment directives is necessary. Activities are currently under way which cover this matter.

The extent to which the Article 31 group had sufficient technical competence in the area of transport regulation was questioned, but no information was available as to whether there was a suggestion for a desired level of competence for membership. Similarly, this could also apply to the expert group on the shipment directive. Issue I-12 also applies in this case.

10 CASE STUDIES

A number of case studies were identified to assist in describing the processes around the transport of radioactive materials and to identify the difficulties in carrying out such transport. The cases followed a standard format, essentially identifying the who, what, when and where of each stage, along with the costs of regulatory compliance. The case studies are included in Annex A6 of this report.

10.1 URGENT MEDICAL SHIPMENTS

The first study examined the shipments of urgent medical products. Key considerations included the following:

- Manufacture and transport are related to specific patient needs and require delivery just in time;
- While the packages might appear to be simple boxes, in some cases the specification can be very detailed (e.g. specification of the type of sealing tape to be used);
- Transport is often booked on the day of transport.

The overall impression from this case study was that lives depended on transport being able to be carried out with little or no advance planning. This type of shipment is the most common in the Community, and the effect of shipping problems on human lives should be kept in mind when considering the transport of radioactive materials. The industry indicated that at the present time there was enough capacity for the delivery of products, although delays could require shipment of more than double the number of isotopes due to decay en route.

The infrastructure limit suggests that neither safety nor security of transport can be fully optimized. Longer journeys increase vulnerability in terms of security, while additional activity and transport time increases exposure of workers and the public (although these are normally well within limits). Specific examples of existing barriers were identified by the industry. Issue I-12 also applies in this case.

The methodology for the air segregation limits is provided as an example in the IAEA’s guidance, along with the values assumed in the calculations. The data provided for this report (and values identified in recent studies) suggest that the values assumed were conservative by around an order of magnitude, particularly for the type of air shipments commonplace in Europe.

Issue I-24. The air segregation limits were identified as being potentially overly restrictive.

10.2 NORM

The second case study examined the import of exempted naturally occurring radioactive material (NORM) from outside of the EU in order to supply essential industry within the EU. One of the complexities with this type of material is that the packagings used for transport are generally those that already exist for the transport of other materials. The ability of a Competent Authority to oversee the manufacture of such packages, when the carriage of radioactive materials is not considered at the time of manufacture, is clearly impossible. The emphasis on the activities of the consignor are clear for this type of shipment. Moreover, the amount of document checking for the shipment is significant. This could be an area where duplication of effort exists.

The industry provided lists of specific problems, including the examples of four companies which indicated that they no longer were shipping to/from Europe due to problems with shipping radioactive materials. One key issue is port acceptance. If ships call at a scheduled sequence of ports, it only requires one to prohibit the materials to result in the carriage to all ports on the route being affected. The issue of ensuring port acceptance of goods complying with the IMDG code should be considered.

Some companies identify problems with Competent Authorities, many of which do not accept that there is a problem. It would seem that a simple resolution system using subject experts might be of benefit where there is a perception by industry of insufficient regulatory action. Issues I-12 and I-46 also apply in this case.

Issue I-25: A review of barriers to maritime transport, including 'special' conditions applied by ports, and how these might affect the ability of the EU to compete globally should be produced (for example, by the WNA).

The second workshop indicated that the WNA might be the appropriate body to carry out this activity.

10.3 DUAL PURPOSE CASKS

A small case study on dual purpose casks was conducted to demonstrate specific issues. The current regulatory infrastructure includes ageing management standards in the transport requirements. However, their application is not required until the transport has taken place.

There is no universal standard that is applied in a harmonized manner for the approval of packaging for storage. Without this, there are safety risks involved in the international trade using dual purpose casks. Issue I-19 applies in this case.

10.4 RADIOISOTOPE SAMPLES

A case study on the transport of radioisotope samples was planned but could not be completed because information on such shipments was difficult to acquire from MS. After multiple requests, two examples identifying specific issues were provided by the CTF.

A recent regulatory change resulted in small amounts of fissile material being classified as fissile, rather than fissile excepted, as before. The change was administrative in nature but has resulted in significant additional costs (particularly approval costs) for shipping these materials. The suggestion that this change be reviewed has been accepted and is being planned for the next review cycle of the IAEA transport regulations.

Another issue was how to classify samples being shipped for identification. While the use of the term 'SAMPLE' can be used for other dangerous goods, it cannot be used for radioactive materials. The ability to identify packages suitable for the sample designation proved difficult. The suggested creation of a European Package Information System would be an effective solution to this issue.

Overall, several minor issues that could affect the shipment of samples were identified, though they have already been covered by the solutions proposed in the main body of this report.

11 CONCLUSIONS AND RECOMMENDATIONS

The process of reaching conclusions and recommendations involved a number of stages, the details of which are included in Annex A7. After discussions among the SG and CTF during the second workshop, 25 issues were considered to be a priority and included in this final report. Each of these issues (or action areas) were considered carefully to develop a reduced number of proposals for improvement that could to a manageable number of action plans. These were grouped initially in terms of their difficulty. During the second workshop, the SG and CTF reviewed them and provided guidance on action plans, where appropriate, resulting in the following recommendations.

1. **Review the different reporting provisions, including Council Directive 2006/117/Euratom and its single standard document, Regulation 1493/93, which involve information reporting on transport:**

    - Outline the goals for the simplification of reporting requirements.

The Commission is best placed to lead on this recommendation.

2. **Establish better communication between regulators reflecting on existing best practices. Encourage sharing of information by Competent Authorities during the assessment of package designs, effectively enhancing harmonisation and the time scale of regulatory assessment:**

    - Communicate between Competent Authorities on the assessment of packages.

MS are best placed to lead on this recommendation.

3. **Establish a European Package Information System based on experience with the IAEA's PACKTRAM. The extent of the information stored and the packages recorded would be established as part of the planning phase. The extent to which it could enable simplification of information sharing on packages not requiring CA approval is worth considering:**

    - Based on experience with PACKTRAM, identify useful information (and information that creates a collection burden);
    - Consider whether an existing system can be adapted to the purpose;
    - Determine the system specifications, at a minimum including package approval information (e.g. package type, approval date, expiry date);
    - Consider hosting and long term operation (e.g. JRC);
    - Create an information system and populate from existing data;
    - Define a sustainable system for maintaining the database.

The Commission and MS are best placed to lead on this recommendation, but will require industry support.

4. **Enhance the level of training of regulators, industry, and first responders in the short term; in the long(er) term establish a comprehensive capacity building system (UK good practice):**

Short term:

- Develop cross-training of transport experts and radiation protection experts.

Long term:

- Consider UK good practice;
- Gather information in a coordinated manner on short and long term requirements;
- Establish a co-ordinated programme (including industry/regulator partnerships) for developing competence for transport.

MS are best placed to lead on this recommendation.

5. **Ensure effective coordination between groups dealing with different aspects of the safety of radioactive materials by enhancing communication between experts using modern technology:**

- Share MS expert contacts between the three groups (radiation protection, waste and transport) to encourage coordination at the national level (making use of groups such as EACA);
- Establish Commission contact points for each group and ensure that information on expert opinions and proposals s shared.

The Commission is best placed to lead on this recommendation.

6. **Assign responsibility to the EU and national bodies to facilitate the transport of radioactive materials separate from the regulatory bodies. An initial task for this group is a review of all ports in the EU to establish their ability to handle radioactive materials, including restrictions in terms of times and paperwork. In addition, the proposal is to carry out a legal review of the barriers currently in place:**

- Request MS to appoint a non-regulatory government body to facilitate the transport of radioactive materials, and ensure that this is made public;
- Implement activities related to DoS as required, including:
  - Review of the costs of any new regulatory proposals affecting the transport of radioactive materials;
  - Review of all ports in the EU to establish their ability to handle radioactive materials, including restrictions in terms of times and paperwork;
  - Legal review of the barriers reported as being currently in place due to diverging implementation of directives.

The Commission and industry are best placed to lead on this recommendation.

7. **Ensure the transparency of required reports, and encourage the publication of other information. Consider making use of a simple consolidated report as an efficient means of promulgating information.**

Ensure that the report remains simple, but consider including the following:

- Collecting consolidated incident data;
- Conducting a peer review of the data;
- Assessing public exposure information (see BSS Directive Article 66).

The Commission and MS are best placed to lead on this recommendation.

8. **Continue and coordinate reviews of the need for necessary safety improvements. The most significant safety changes to the IAEA's transport regulations have been European-led.**

Consider building on existing groups (e.g. EACA, MedNet) for reviews of regulatory issues. In addition, establish a prioritised list of issues which may require significant changes to regulations, including:

- Air segregation requirements.;
- Administrative requirements for former fissile-excepted material.
- Definition of waste. The EC will decide whether there is a need for an activity;
- Consideration of ageing management of dual-purpose casks prior to loading;
- Examination of issues related to self-approved packages, including current best practices.

The Commission and MS are best placed to lead on this recommendation.

9. **Consider adopting the simplest means of encouraging harmonised compliance, mainly through the production of guidance documents. Important aspects, such as those listed below, should be identified and prioritised.**

- Establish a prioritised list of guidance documents, considering:
    - Consignor and carrier responsibilities (taking into account the ADR);
    - Application of the graded approach in compliance assurance;
    - Assessment of exposures to the public (see BSS Directive Article 66).
- Produce the documents on a prioritised basis.
- Establish a transport operational learning forum for industry for producing guidance from lessons learned.

MS are best placed to lead on this recommendation.

Some additional items that were identified by the SG and CTF as worth noting during the second workshop are presented in Annex A7.[21]

[21] In the process of refining the work to be carried out to produce a manageable list, a number of items were removed at the second workshop. However, a request was made that these items should be retained for future reference. These items are also presented in Annex A7.

ANNEXES

A1 STANDING WORKING GROUP

A2 MS IRRS

A3 QUESTIONNAIRES

A4 QUESTIONNAIRE RESPONSE — INDUSTRY INFRASTRUCTURE

A5 QUESTIONNAIRE RESPONSE — REGULATORY INFRASTRUCTURE

A6 CASE STUDIES

A7 WORKING METHOD

A8 DATA RECORDING

A1 STANDING WORKING GROUP

A Standing Working Group (SWG) was established by a resolution of the European Parliament 22/1/1982 (OJ C 40/42). This resolution contained many of the same issues as the those in A5-0040/2001:

- A desire for a reduction in shipments and application of the proximity principle, and development of routes avoiding populated areas;
- The need for review of data and assessment of the risks;
- A need for more transparency and presentation of information to public, workers and first responders.

There were other issues that are still valid today:

- Avoidance of denial of shipments. Barriers to transport were recognised as a problem by the European Parliament, not simply as a financial problem, but as a safety issue. It called for standardised regulations, coherent authorisations and standardised forms. Community certified training was a concept that was proposed.
- Clarification of responsibilities of carrier and consignor on a community basis. The Parliament expressed a wish that a Community system be established to define the responsibilities of carriers and consignors.
- Establishment of a Community emergency response network. This was suggested as being based on hospital experts.

This resolution also called for the establishment of a special permanent working party consisting of Commission and national experts for:

- Exchange of information;
- Studying recommendations made by the European Parliament;
- Preparing proposals for community action;
- Studying any other questions related to the transport of radioactive materials;
- Reporting annually to the European Parliament.

The last available Minutes of the SWG are from 2011.

A1.1 EUROPEAN FUNDED RESEARCH

The SWG provided advice to the Commission over several years on research funding. The list of research areas included:

- Review of community status:
    - Legislation governing the transport of radioactive materials in EU MS was reviewed;
    - Emergency plans related to the transport of radioactive materials in EU MS were reviewed;
    - Studies compared and evaluated regulatory aspects of the transport of radioactive materials in EU MS and Applicant Countries; the effort required to achieve full compliance with EU Directives by the Applicant Countries was determined; the possible impact (i.e. the potential benefits and drawbacks) of the integration of the Applicant Countries into the EU was evaluated.
- Assessment of risk:

- Risk evaluations were conducted for various types of transport of radioactive materials ;
- Safety evaluations were conducted corresponding to various types of containers.

- Harmonised documentation:
  - A proposal was made for harmonised formats for shipment notification, approval and incident/accident notification.
- Incident reporting:
  - A new proposal was made for the INES scale (i.e. the severity of accidents);
  - A new system and format for the notification of incidents/accidents were proposed, as well as a corresponding database model for data compilation.
- Leading the development of international regulations:
  - Studies were carried out to expand knowledge of low specific activity materials and surface contaminated objects (LSA/SCO);
  - It was proved that the transport of consumer goods containing small quantities of radioactive materials does not have a radiological impact and, as a consequence, international regulations for the transport of radioactive materials were amended;
  - Studies were carried out in order to contribute to the qualification of 'low dispersible materials' (LDM).
- Radiation protection (in particular, contamination):
  - Analyses were made of the decontamination methods used in Member States with nuclear programmes for the decontamination of containers transporting irradiated fuel;
  - Recommendations, following the ALARA principle, were made on decontamination methods and monitoring of the containers transporting irradiated fuel to reduce doses received by workers and the population;
  - Dose rate limits for the transport of radioactive materials were reviewed, including a survey of radiation protection programmes for transport;
  - The radiation protection programmes for the transport of radioactive materials in Member States were studied and examples of radiation protection programmes were proposed;
  - Harmonisation of procedures for ensuring non-contamination of containers for irradiated fuel transport was proposed.

A1.2 PREVIOUS STUDIES

A previous report by the SWG on the 'Safe Transport of Radioactive Materials in the European Union' was an annex to a communication from the Commission to the Council and European Parliament (COM(2006) 102 final). This was the fifth in a series of such reports.

The report and the communication estimated the number of shipments in the European Union based on a report in 2003 on transport statistics. The 2003 statistical study, which covered MS as well as other States (some of which are still not MS), focused on information important for the estimation of exposures to workers, and confirmed that worker exposure ranged up to 10–20mSv per year. The analysis identified a low accident rate and noted that there were well developed emergency arrangements in place to deal with them.

A number of issues were identified as being 'current' in the report:

- Use of transport containers for storage. This essentially relates to the issue of ageing management of transport packages during interim and long-term storage. The concern is that after an extended storage period it may be impossible or very costly to demonstrate compliance with the regulations in place at the time.
- Denial of shipments (high on the list of current issues).
- Contamination on the outside of packages. This was noted as an issue that was being managed. In the years prior to the report there had been evidence of contamination on the outside of packages (predominantly nuclear fuel packages) and the suggestion that some regulatory bodies had failed to take effective enforcement action. This led to the temporary cessation of certain shipments of radioactive materials in a large part of Europe.
- Thermal protection for UF_6 (Nat U) packages. This was an issue under discussion due to changes in IAEA regulations. The interpretation with respect to large natural uranium (48Y) cylinders was disputed between regulators and at least one technical service organisation (TSO).

A number of initiatives were identified where harmonisation could be of benefit, some of which remain relevant. These included assessment and licencing. A detailed study on this issue was carried out in 2004, looking at differences in methodology in MS. The study concluded that the steps required to achieve a harmonised system included:

- Maintaining the current harmonised legal standard in the Community;
- Communicating clear responsibilities to Competent Authorities ensuring they maintain capacity;
- Communicating clear responsibilities to TSOs;
- Communicating responsibilities for performing regulatory tests;
- Identifying the costs of certification.

Harmonisation of emergency arrangements was identified as an area for improvement. While acknowledging that the arrangements in individual States were well developed, it was noted that they differed significantly. This can cause difficulties for transport through multiple States. It was suggested that exercises should be developed.

In order to develop information sharing for accidents and to aid communication with the public and the media, it was suggested that the INES system be applied throughout the Community.

A third area that the report looked at was communication. This covered a number of different areas:

- The report detailed the low risk to the public from the transport of radioactive materials and contrasted this with the public view of the risks (claimed but not substantiated in the report). The need to explain the scientific evidence to the public was seen as a means to improve public acceptance of the transport of radioactive materials.
- The report proposed that sharing of information in confidence by State authorities with the Community could lead to an effective means of providing timely information to the European Parliament on issues of concern, noting that trials had proved successful.

A1.3 VIEWS OF THE EUROPEAN PARLIAMENT

The European Parliament did not respond to the communication on the fifth report, but did respond to the communication on the fourth report (A5-0040/2001). Some opinions in this European Parliament resolution may be seen as being applicable today:

- A desire for a reduction in shipments and application of the proximity principle, and development of routes avoiding populated areas. This would involve the gathering of shipment information and maps of routes; assessment of the risks involved and the benefits of the shipments; assessment of public exposures; and assessing the benefits of transporting material for reprocessing.
- More efforts on compliance, including the Commission enforcing application of directives. The request was for increased compliance monitoring, in particular by independent bodies, making results readily available. Radiation protection programmes were to be used and compliance checked by Competent Authorities. And, in cases where MS failed to ensure compliance, the Commission would instigate infringement action.
- A need for more transparency and information to public, workers and first responders. This information would include advance notification of shipments of hazardous material through or near local authority areas. Providing the information in advance would include providing details to emergency services. The proposal was for additional information to be required to transport workers following Community based requirements, and for the Commission to make the information available on the internet.
- The importance of a research budget to support the Community's efforts to drive world progress. The European Parliament recognised that a Community research budget played an essential role, not just in informing the public, but also in the helping the Community take a leading role in reviewing and revising international requirements.

While a number of initiatives have taken place as a result of the fourth report, the lack of feedback from the European Parliament on the fifth report makes it difficult to determine to what extent their concerns have been addressed. As shown in the following sections, this study identifies some that still appear to be relevant.

A1.4 ISSUES RELEVANT TO THIS STUDY

Issues that have been identified in the report of the SWG and by the European Parliament of relevance to this study include:

- Ageing management of transport containers used for storage. A section reviewing this in light of the IAEA proposals is in the questionnaire (5.2).
- Denial of shipments. A section reviewing this is in the questionnaire (5.3).
- Contamination of packages. A section reviewing this is in the questionnaire (2.4.4).
- Assessment of public exposures. A section reviewing this is in the questionnaire (3.1.2).
- Harmonised assessment and approval (licencing). A section reviewing this is in the questionnaire (2.11).
- Harmonised emergency arrangements. A section reviewing this is in the questionnaire (2.2).
- Introduction of the INES system. A question reviewing this is in the questionnaire (3.2.1).
- Improved communication. A section reviewing this is in the questionnaire (3.3).
- Improved compliance (RPP). Sections reviewing this are in the questionnaire (2.9.4; 2.3; 2.4).
- Clarification of responsibilities between carriers and consignors. A section reviewing this is in the questionnaire (2.4.1).
- Community based training. A section reviewing this is in the questionnaire (2.12).

A2 MS IRRS REPORTS – TRAM RELEVANT TEXT

The MS IRRS reports were examined for a number of MS and the relevant text is reproduced here, where possible (some reports were not available).

A2.1 BELGIUM

IAEA-NS-IRRS-2013/12

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO BELGIUM

Brussels, Belgium, 1 to 13 of December 2013

5. AUTHORIZATION

5.6. AUTHORIZATION OF TRANSPORT ACTIVITIES

Belgium has established the following legislation pertaining amongst others to the safe transport of radioactive material:

- Law of 15 April 1994The implementation of this law in Royal decree of 20 July 2001 (GRR-2001)

Articles 3 and 18 of the Law of 15 April 1994 stipulate the responsibility of the FANC for the transport of radioactive material.

Article 57 of GRR-2001 requires that transport activities shall comply with the provisions laid down in international modal agreements and regulations governing the carriage of dangerous materials and that these may only be performed subject to a preliminary license. Since these modal agreements are transpositions of the IAEA transport regulations for each mode of transport (air, sea, road railway and inland waterways), it can be concluded that all provisions in TS-R-1 Regulations for the Safe Transport of Radioactive Material are addressed in the authorization process (e.g. shipment, special arrangement, package design, radioactive material in special form).

During the interview with transport experts from the Belgian counterpart on this issue it was mentioned that a revision of Chapter VII of GRR-2001 is under planning. The revision would entail a simplification of the authorization process for low-risk radioactive materials. Since it has not yet been decided how this can be done in the most effective manner, all options are kept open, but an exemption from the licensing requirement is no longer excluded. The planned revision of Chapter VII of GRR-2001 aims at establishing and/or improving the graded approach in all regulatory areas and for all modes of transport. Simultaneously there is a trend to make a transition from a repressive approach in the regulation towards a preventive approach. This implies that in transport activities more emphasis is placed on registration of carriers on one hand, and to focus more on inspections and compliance audits. The FANC intends to perform a consultation with its stakeholders on the proposed revision at several phases during the revision process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The above formulation in article 57 of GRR-2001 does not permit to deviate from the general requirement of a license for a transport activity. Variations exist in the type of license (general, specific or special), depending on the frequency of shipments and on the activity of the material. In all cases, irrespective of the source strength, a license procedure must be undertaken.

It is questionable whether this is in compliance with the graded approach demanded in article 1 of GSR Part 1 and with FANC's own policy regarding a graded approach, which is adopted in many other areas.	
(1)	BASIS: GSR Part 1 para 4.33 states that "Prior to the granting of an authorization the applicant shall be required to submit a safety assessment …the extent of regulatory control applied shall be commensurate with the radiation risks…"
S12	Suggestion: The regulatory body should consider the introduction of a system in which a notification procedure for transports of low risk radioactive material would replace the present licensing requirement.

5.7. SUMMARY

Although Belgium has decided not to build any more nuclear power plants, an authorization process is well established for approving modifications to the existing plants and for construction as well as operation of other facilities, such as new research reactors and waste disposal facilities. The IRRS Team considers that an area where improvements should be implemented is related to the approval of changes in the surroundings of an existing nuclear site: an evaluation of the impact of the changes on the nuclear facilities should be performed by the regulatory body before approval for those changes is granted by the relevant authorities.

6. REVIEW AND ASSESSMENT

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

Since the safety during transport of radioactive material is primarily ensured by the design of the package, review and assessment of applications for transport licenses is mainly achieved by reviewing and assessing the technical aspects of a package and the source specifications such as special form material or low dispersible material. These design aspects include issues such as mechanical properties, thermodynamics, criticality, radiation protection etc. Many foreign designs are submitted to the FANC for certification or validation and require to be assessed by the regulatory body.

A document promoted on the FANC website (PDSR Guide, http://www.fanc.fgov.be/GED/00000000/2600/2632.pdf) is meant to assist both the applicant and the FANC reviewer. It contains unique information on the licensing process and the requirements for a successful application. It enables the applicant to check which documents in support of his application are expected by the regulatory authority. At the same time the reviewer/assessor at the FANC could trust that the information supplied is complete. This would usually prevent or diminish the administrative burden to request additional information. The document includes many references to applicable paragraphs in IAEA Safety Guide No.TS-G-1.1 in the case that more detailed guidance on technical elements is necessary.

6.7. SUMMARY

Review and assessment for class I facilities is mostly performed by Bel V, while the FANC intervenes when review and assessment are related to changes of the license. Very recent improvements in the coordination and definition of roles between FANC and Bel V will be further formalised and documented in the respective management systems.

The type of documents subject to review and assessment is very diverse in scope and content and the regulatory body applies a graded approach which it is recommended for further optimization with the definition of suitable criteria.

Belgium has a long tradition with periodic safety reviews for all class I facilities and covering all lifetime phases including dismantling as an application of a graded approach. As some of these facilities are approaching forty years of operation, the issues related to long term operation (mechanical as well as design ageing) have been taken up within the periodic safety reviews.

The review and assessment process for evaluating the suitability of radiation source facilities has been examined and found to be adequate.

The safety assessment of certain models of transport packages, required for certification and validation of these packages, is reviewed and assessed by the FANC. In order to assist both the regulatory body and the applicant of a license for a specific package design, the FANC has placed a guidance document with detailed information on its website with drawings specifications, calculations and other supporting documents for all types of packages.

7. INSPECTION

7.8. INSPECTION OF TRANSPORT ACTIVITIES

The inspection programme for transport follows a graded approach and includes all types of inspections (announced, unannounced, reactive, and proactive). All parties involved in a transport chain (consignor, carrier and consignee) are subjected to inspections which are focused on mainly 3 areas of interest: administrative (license, transport documents), equipment and conveyance, radiation protection.

Inspections are carried out by FANC staff only; however joint inspections occur incidentally with inspectors from other countries (e.g. joint inspections have been carried out with an inspector from ASN (France)).

For carriers of radioactive material, the FANC has developed an inspection programme (document SP 007-02) that follows a graded approach. It implies that each licensed carrier is inspected at a frequency determined by the risk, nature and frequency of the transports undertaken. It typically takes into account the following items:

- transport of nuclear materials
- holding one or several transport licenses
- holding one or several special transport licenses
- quantity and type of packages being transported
- nature and scope of transport operations
- previous incidents and accidents
- results and observations from previous inspections
- nationality and size of the company, complexity and diversity of the action proposed by the carrier
- means of transport (number and type) used by the carrier

The minimum frequency of inspections is once in 5 years since this ties in with the maximum period for which a transport license is granted.

<table>
<tr><th colspan="2">RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</th></tr>
<tr><td colspan="2">Observation: FANC has established an inspection programme for carriers (document SP 007-02) for ensuring compliance with the regulations in the area of transport of radioactive materials. It is exemplary for the graded approach, which has been adopted for many regulatory functions exercised by the regulatory body in Belgium.

It has also attracted the attention of regulatory authorities in other countries (e.g. in France, an overview was given in ASN’s monthly journal CONTROLE nr.193).</td></tr>
<tr><td>(1)</td><td>BASIS: GSR Part 1 para. 2.5 (10) states that “The legal and regulatory framework for safety shall set out the following:

Provision for the inspection of facilities and activities, and for the enforcement of regulations, in accordance with a graded approach”</td></tr>
<tr><td>GP4</td><td>Good Practice: The inspection programme for carriers of radioactive materials is graded based on risk and is recognized by other countries as a good practice.</td></tr>
</table>

7.9. SUMMARY

The FANC and Bel V deliver the inspection programme for class I and IIA facilities; while the FANC and the AIOs deliver it for the class II and III facilities and activities. The planning and delivery of inspections are a shared responsibility for class I and IIA between the FANC and Bel V. Appropriate communication allows for a good exchange of information between the two organizations. The 3-year Integrated Inspection and Control Strategy using past inspection results and operational feedback is evidence of such good communications.

Strengths were seen in the overall delivery of inspections of transportation and in the observation and evaluation of safety culture attributes at class I and IIA facilities.

While the methods of inspections are typical of inspection practices in other countries, the scope of coverage needs to be reviewed to consider a more focused verification of safety functions such as the availability of safety related systems and components. The team also determined that the use of risk arguments and a graded approach could help in guiding the frequency of minimum coverage of inspections.

Implementation of inspections in the field, with exceptions noted in the area of transportation, needs guidance with more specific and detailed acceptance criteria to ensure proper decision making, uniformity from inspector to inspector, fair delivery of the inspection and for knowledge transfer purposes.

9. REGULATIONS AND GUIDES

9.6. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

Belgium has established the following legislation pertaining amongst others to the safe transport of radioactive material: Law of 15 April 1994 and the implementation of this law in royal decree of 20 July 2001 (GRR-2001). In the Law of 15 April 1994, Article 18 specifically stipulates the responsibility of the FANC for the transport of radioactive material.

Article 57 of GRR-2001 requires that transport activities shall comply with the provisions laid down in international modal agreements and regulations governing the carriage of dangerous materials and that these may only be performed subject to a preliminary license. Since these modal agreements are transpositions of the IAEA transport regulations for each mode of transport (air, sea, road railway and inland waterways) the conclusion is that all provisions in IAEA TS-R-1 are fully addressed, including the responsibilities of the Regulatory Authority with respect to training of staff engaged in the transport of radioactive materials as described in articles 311 - 315 of TS-R-1.

The IAEA supporting guides TS-G-1.1 to TS-G-1.5 have not been directly implemented in the national legislation and regulation, but have been referenced where applicable (e.g. a reference to TS-G-1.1 occurs in document PDSR Guide (http://www.fanc.fgov.be/GED/00000000/2600/2632.pdf) published on the FANC website). The safety guide TS-G-1.2 is implemented through the royal decree of 17 October 2003, in which a national nuclear and radiological emergency plan for the Belgian territory was established, including transport accidents.

Training for staff involved in the transport of radioactive material is one of the cornerstones to ensure safety. Consequently, in many IAEA requirements documents it is emphasized that the Regulatory Authority provides for adequate training capacity commensurate with their individual responsibilities. Training courses can be distinguished in courses for ADR drivers of vehicles and courses for the ADR/RID Safety Advisor. The FANC has been appointed by the royal decree of 6 February to provide these training courses for drivers. The FANC offers basic training courses and refresher courses, the latter type for drivers whose certificate comes close to expiration (validity of certificate is 5 years). On the average 3 courses per year are held, both in the French and in the Dutch language. Training courses destined for the ADR/RID Safety Advisor are offered as a joint effort by recognized organizations (DGT and AIB Vinçotte-Controlatom). However, the exams are set up by the FANC as well as the issuing of the certificates after passing the test.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: FANC has established an inspection programme for carriers (document SP 007-02) for ensuring compliance with the regulations in the area of transport of radioactive materials. It is exemplary for the graded approach, which has been adopted for many regulatory functions exercised by the regulatory body in Belgium. It has also attracted the attention of regulatory authorities in other countries (e.g. in France, an overview was given in ASN's monthly journal CONTROLE nr.193).	
(1)	BASIS: GSR Part 1 para. 2.34 states that "As an essential element of the national policy and strategy for safety, the necessary professional training for maintaining the competence of a sufficient number of suitably qualified and experienced staff shall be made available."
(2)	BASIS: GSR Part 1 para. 2.41 states that "…If no suitable commercial or non-governmental provider of the necessary technical services is available, the government may have to make provision for the availability of such services."
(3)	BASIS: TS-R-1 para's 3.11-3.15 state that "Workers shall receive appropriate training concerning radiation protection, including precautions to be observed in order to restrict their occupational exposure and the exposure of other persons who might be affected by their actions."
S20	Suggestion: The government should consider making provision for parties other than the regulator to provide training courses for ADR drivers of vehicles carrying radioactive materials.

9.7. SUMMARY

All areas of the FANC's competence are covered by regulations with the exception of some specific cases that are identified in subchapters 9.1-9.6. Still under development are, for example, the specific safety requirements for waste disposal facilities, decommissioning, and storage of radioactive waste and spent fuel. In anticipation of license application for the near surface facility and the MYRRHA research reactor, the regulatory body has developed a suite of guides to be used by the applicant and the regulatory body.

Currently, there is no systematic process for evaluating and reviewing regulations and guides (including the assurance of coverage of relevant IAEA standards) and revising as appropriate. Drafting of a process for establishing generic guides has been initiated. The regulatory body should also consider consulting the public when developing new regulatory guides.

The FANC has taken an informal proactive approach to improve compliance with the regulatory requirements by holding various stakeholder meetings with the licensees. There has also been a FANC initiative to provide training courses for drivers of vehicles including radioactive material packages. The FANC should consider making provision for parties other than the regulator to provide training courses for ADR drivers of vehicles carrying radioactive materials.

A2.2 BULGARIA

IAEA-NS-IRRS-2013/01

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO BULGARIA

Sofia, Bulgaria, 8 to 19 April 2013

5. AUTHORIZATION

5.6. AUTHORIZATION OF TRANSPORT ACTIVITIES

According to ASUNE, a permit or licence is required for every transport of radioactive material. Permits are required for single shipments of radioactive or nuclear material and for transits through Bulgaria of radioactive materials (including radioactive waste, spent fuel, etc.). Licences are required for multiple shipments of radioactive material (excluding fissile material and radioactive waste) in Bulgaria.

There are relatively few transports of fissile material, all of which relate to Kozloduy NPP. In regard to the transport of non-fissile (or fissile-excepted) material, about 50 licensees and about 20 permits were issued during the last 5 years.

Adopting a single regime for transport licensing does not fully align with a graded approach, particularly for the transport or transit of very low level radioactive materials. The IRRS team therefore suggests that BNRA should consider whether it is appropriate to exempt very low radioactive materials from requiring a licence or permit for transport. Nevertheless, the IRRS team agrees that these transports should at least be subject to a notification process that would allow BNRA to act if it has particular concerns.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part 1 Requirement 23 states that “Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either exempted or approved by means of a notification process.”
(2)	BASIS: GSR Part 3 Para. 2.31 states that “The regulatory body shall adopt a graded approach to the implementation of the system of protection and safety, such that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation.”
S12	Suggestion: BNRA should consider exempting the transport of very low level radioactive material from an authorization in accordance with a graded approach.

All the types of authorization (i.e. “unilateral” and “multilateral” approvals) listed in IAEA’s transport regulation in Para. 802 of TS-R-1 are regulated by licence or permit for transport in Bulgaria.

There is ever no design, manufacturing or testing of packages, of special form of radioactive material, or of low level dispersible material in Bulgaria (to-date only foreign designed packages have been used). This means that Bulgarian unilateral approval does not yet exist, though IRRS team agree there is no urgent need for this at present.

Furthermore, according to the discussion with the BNRA staff, the responsibility for approval of package design has not been appointed to BNRA in the ASUNE if the package is not used in an actual transport of radioactive material.

While it is recognised that there is no current necessity for such an authorization process, The IRRS team suggests that the government should consider appointing a competent authority to address this gap.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: TS-R-1 Requirement 802 states that “Competent authority approval shall be required for the following: (a) Designs for: […] iii. Packages containing 0.1 kg or more of uranium hexafluoride (see Para. 805); iv. All packages containing fissile material unless exempted by Para. 417 (see Paras 812–814, 816 and 817); v. Type B(U) packages and Type B(M) packages (see Paras 806–811, 816 and 817); vi. Type C packages (see Paras 806–808). [...]”
(2)	BASIS: TS-R-1 Requirements 805, 808, 811, 814 state that “[...] The competent authority shall establish an approval certificate stating that the approved design meets the requirements [...] and shall attribute to that design an identification mark.”
(3)	BASIS: TS-R-1 Requirement 833 states that “Each approval certificate of the design of a package […] shall include the following information: [...].”
S13	Suggestion: The government should consider appointing a competent authority (e.g. BNRA) for approval of package design to address cases where such approvals cannot be included in a licence or a permit for transport.

5.7. SUMMARY

The legal and regulatory framework for the authorization of nuclear facilities and sources of ionizing radiation is available in ASUNE and “Regulations on the Procedure for Issuing Licences and Permits for Safe Use of Nuclear Energy”. The authorization issued by BNRA includes licences and permits which are issued during various stages of the authorization process. BNRA also issues licences to certain individuals working in certain positions and special training institutions for providing training in the area of nuclear safety and radiation protection. The chairman of BNRA has the authority to issue, amend, renew, suspend and revoke licences and permits. In addition, internal processes followed for issuing authorization are described in procedures and instructions issued under the management system of BNRA. In general the legal and regulatory framework for the authorization process of BNRA and the authorization stages established are in line with the IAEA Safety Standards. However, certain issues have been identified by the IRRS team. The issue of non-availability of a defined process for release of site and facility from regulatory control formed the basis for a recommendation. Some of the issues that led to suggestions are that public consultation is not made during licensing stage; conditions for the closure of a radioactive waste disposal facility are not clearly defined in the regulatory framework; objective, clear criteria and procedures on renewal of authorization for SIR including a validity period are not established; criteria to justify new practices and activities with SIR are not defined. The team observed that BNRA publishes incidents with SIR on its website which in the opinion of the team is a good practice.

6. REVIEW AND ASSESSMENT

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

Each transport of radioactive material has to be covered by a permit or a licence. The applications for such licences or permits are reviewed and assessed by BNRA staff from two separate departments depending upon whether fissile or non-fissile material is being transported.

The documentation needed in support of an application for a permit or licence for transport are clearly listed in the Regulation on the Procedure for Issuing Licences and Permits for Safe Use of Nuclear Energy.

These documents constitute the basis (in combination with inspection) for reviews and assessments to confirm compliance with the requirements stipulated in the relevant regulations. These requirements are based on, and globally in line with, the IAEA Safety Standards for transport.

The process for reviewing and assessing transport activities regulated by BNRA follows BNRA's generic approach to managing reviews and assessments. In particular, applying a single systematic approach to the regulation of all transport activities means that the review and assessment process for the transport of very low level radioactive material does not fully align with a graded approach.

The assessment and the review for the approval required by IAEA transport regulation are included in the process for the review and assessment of applications for licence or permit for transport activities. In Bulgaria, these approvals are almost exclusively related to the transport of fresh and spent fuel (i.e. fissile materials) to and from Kozloduy NPP. After the first assessments carried out several years ago, the assessments for these approvals have been limited to an endorsement of the assessment made by the competent authority of the country of origin of the package designs. TS-G-1.1 (Rev. 1) however states that such assessments should be made independently, primarily because of the nature of the criticality hazard and the importance of maintaining sub-criticality at all times during transport. The IRRS team therefore suggests that BNRA should independently and periodically assess the criticality safety of the package design used in Bulgaria to transport nuclear material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part 1 Requirement 25 states that "The regulatory body shall review and assess relevant information … to determine whether facilities and activities comply with regulatory requirements [...]."
(2)	BASIS: TS-G-1.1 (Rev. 1) Para. 802.2 states that "in the case where competent authority approval is required, an independent assessment by the competent authority should be undertaken, as appropriate, [...]."
(3)	BASIS: TS-G-1.1 (Rev. 1) Para. 810.1 states that "Information given by the applicant […] the design. Through the mechanism of multilateral approval the design of a Type B (M) package is independently assessed by competent authorities in all countries through or into which such packages are transported."
(4)	BASIS: TS-G-1.1 (Rev. 1) Para. 812.1 states that "Multilateral approval is required for all package designs for fissile material (IF, AF, B(U)F, B(M)F and CF) […]. It is therefore necessary that competent authorities independently assess and approve all package designs for fissile material."
S15	Suggestion: BNRA should consider undertaking independent and periodic reassessments, based on IAEA Transport Safety Standards for multilateral approval, of the design of transport packages in use in Bulgaria, and in particular the justification of sub-criticality.

6.7. SUMMARY

This IRRS team looked at review and assessment practices in Bulgaria for regulating a wide range of types of nuclear and radiological facilities and activities, focussing mostly on BNRA's review and assessment for nuclear facilities. BNRA is considered to have efficient processes for nuclear safety reviews and assessments applying standards strongly in line with IAEA Safety Standards.

In some cases however the IRRS team found review and assessment processes are not governed by formal, written procedures, leading to findings on the quality and consistency of the assessments performed. In the cases where there are written procedures, such as within BNRA, aspects were nevertheless identified where these procedures might reasonably be improved or, in the case of radioactive sources, implemented more effectively.

For example, the availability of technical guidance, either to inform licensees of how to meet legal requirements, or to provide assessors with advice on how to conduct their assessments, is limited or absent in many areas. Nevertheless, the regulations we reviewed are very detailed and align well with IAEA Safety Standards. In two areas however, relating to the topical coverage of NPP Periodic Safety Reviews and to criticality assessments performed for the transport of fissile materials, we noted omissions compared to IAEA guidance.

7. INSPECTION

7.7. INSPECTION OF TRANSPORT ACTIVITIES

BNRA staff from two separate departments is responsible for conducting inspections of transport activities, depending upon whether fissile or non- fissile material is being transported.

Every year, BNRA staff prepares an annual inspection plan including the transport activities for which inspections will be conducted. This annual plan is not defined on basis of a planned and systematic inspection program. According to the discussions with BNRA staff, it has been identified that the principal informal "decision making criteria" to define, in the annual inspection plan, which licensee or permit holder will be inspected is related to the level of radioactive risk. This process leads BNRA to conduct inspections every time for transport of spent fuel and for transport of fresh fuel, almost every time for transport of high level of radioactive material, and time to time for others transport radioactive material the occurrence depending on the radiation risk of radioactive material transported and on the numbers of the shipments made by the licensee.

In 2012, about ten planned (announced and unannounced) inspections and about the same number of unplanned (reactive) inspections were conducted for the transport of (non-fissile) radioactive material. Some of the unplanned inspections were carried out as a part of the assessment and review of applications fora licence or permit for transport.

BNRA's current practice for inspection of the transport of fissile material is to inspect almost every transport of fresh fuel (90%) and spent fuel (100 %), with the participation of resident inspectors of the Kozloduy NPP.

The IRRS team considers that the numbers of inspection of transport activities is appropriate to the extent of transport activities in Bulgaria.

7.8. SUMMARY

Based on the documents reviewed, on the interviews conducted, and three site visits to observe inspections, the IRRS team concludes that BNRA conducts extensive inspection activities, although the program lacks a planned and systematic inspection programme, as well as lacking written guidelines to inspectors that would ensure a systematic and consistent approach to inspection. BNRA and NCRRP inspectors conducted these inspections in a competent and professional manner. Based on the interactions between the inspectors and the licensees' and permit holders' staff, the communications between BNRA and NCRRP inspectors and the operators appeared to be open, frank, and safety-focused. The inspection at the Kozloduy NPP identified that inspections are used by BNRA as implementation of preventive regulatory control were not consistent with the IAEA Safety Standards for use of inspections to verify implementation following issuance of an authorization or permit. During the observation of the inspections at the SIR and Kozloduy, the team observed that the inspectors spent most of their time in desktop reviews or discussions with the licensee and not observing activities in the field.

The IRRS team acknowledges that BRNA's inspection practice is generally in line with the IAEA requirements but there is room for improvement. The recommendations and suggestions provided by the IRRS team are aimed to optimize the existing inspection processes, including development and implementation of a planned and systematic inspection program, in BNRA, and coordination of inspection activities across the responsible regulatory organizations.

9. REGULATIONS AND GUIDES

9.7. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

Extensive legislation regulating the transport of radioactive material is in force in Bulgaria. In particular, the "Regulation on the Conditions and Procedure of Transport of Radioactive Material" is based on the requirements of the IAEA transport regulation TS-R-1 (2005 Edition). The Regulation stipulates additionally that other more general regulations for the transport (e.g. by road) of dangerous goods issued by the Minister responsible for transport also apply to the transport of radioactive materials. These modal regulations are in line with international modal regulations for transport of dangerous good (ADR/RID/ICAO/IMDG/ADN) which are in line with the requirements of the IAEA transport regulation.

The IAEA transport regulation is reviewed and updated periodically. The IAEA Safety Standard on transport regulations TS-R-1 was updated in 2012 as SSR-6. However, the present IRRS mission is based on the 2009 edition of TS-R-1, because the IRRS self-assessment process preceded the issuance of SSR-6. The Bulgarian regulation for transport is not amended at each revision of the IAEA standards, but a review is carried out as part of wider processes aimed at keeping regulations up to date. BNRA has confirmed that a review of their transport regulations has been done and the implementation of the modifications of the regulations is being carried out (which will include the requirements of the Council Directive 2006/117/EURATOM and the Standard Document for the Supervision and Control of Shipments of Radioactive Waste and Spent Fuel).

In practice, the different schedules for revising the different regulations lead to duplications, conflicts and discrepancies between specific requirements of the transport regulations, requirements of the modal regulation and the IAEA transport regulations. The IRRS team points out, for example, the following discrepancies:

- there are no transitional arrangements;
- there is no specific notification process in case of non-compliance neither in the BNRA transport regulations) nor in the Regulation of the Conditions and Procedure for Notification of the Nuclear Regulatory Agency about Events in Nuclear Facilities and Sites with Sources of Ionising Radiation ;
- there is no specific requirement about undeliverable consignments ;
- there is no requirement for presence of a feature as a seal (as evidence that the package has not been opened) for industrial package for fissile material.

The IRSS team considers that, other than the absence of a requirement for a notification process in cases of non-compliance, these discrepancies are only of limited relevance to safety. However, for the notification process a Suggestion is made below.

<table>
<tr><th colspan="2">RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</th></tr>
<tr><td>(1)</td><td>BASIS: TS-R-1 Requirement 309 states that “In the event of non-compliance with any limit in these Regulations applicable to radiation level or contamination:

(a) the consignor shall be informed of the non-compliance by […]

(b) the carrier, consignor or consignee, as appropriate, shall: […]

(c) the communication of the non-compliance to the consignor and the relevant competent authority(ies), respectively, shall be made as soon as practicable and it shall be immediate whenever an emergency exposure situation has developed or is developing.”</td></tr>
<tr><td>S23</td><td>Suggestion: BNRA should implement a notification process in case of non-compliance in transport activities.</td></tr>
</table>

BNRA commissioned a TSO to undertake a full review of existing international guidance for transport in 2010. This review led to the preparation of a several national new guidance documents for transport (currently in draft). BNRA plans to review these documents in order to finalize this guidance. The documents include guidance on the following topics:

- planning and preparing for emergency response to transport accidents;
- radiation protection programmes for the transport of radioactive material;
- management system for the safe transport of radioactive material;
- compliance assurance for the safe transport of radioactive material.

BNRA has however issued a guide to applicants wishing to apply for a transport licence which clearly identifies all the information that needs to be supplied.

The IRRS team encourages BNRA to continue and finalise its guidance on transport activities. Completing this programme will address the recommendation of section 9.1 for transport activities.

9.8. SUMMARY

All areas of BNRA's competence are covered by regulations and a few regulatory guides. The need for each regulation is explicitly defined by ASUNE.

Regulations and guides reflect the IAEA Safety Standards and other relevant international requirements but in many cases do not provide detailed requirements and the associated criteria. It seems necessary to develop and introduce appropriate regulatory guides to describe and make available acceptable methods to fulfil the principles and requirements of the regulations. The need for new and more detailed regulatory guides is seen for many technical areas of the licensing process.

The procedures to develop, amend and revise regulations and regulatory guides are stringent and comply with the state of the art. Well-defined review periods trigger regular updates which are keeping regulations and guides up to date. A comprehensive renewal programme for all regulations is presently undertaken and already in an advanced stage.

A2.3 CROATIA

IAEA-NS-IRRS-2015/09

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO THE REPUBLIC OF CROATIA

Zagreb, Croatia, 8 to 17 June 2015

Note: There are no transport related chapters/subchapters in this report. The transport of radioactive materials is only mentioned in relation to radioactive sources.

A2.4 CZECH REPUBLIC

IAEA-NS-IRRS-2013/11

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO THE CZECH REPUBLIC

Prague, Czech Republic, 18 to 29 November 2013

5. AUTHORIZATION

5.7. AUTHORIZATION OF TRANSPORT ACTIVITIES

The transport of radioactive material in the Czech Republic is well established and an appropriate governmental, legal and regulatory framework for the safety of transport of radioactive material is in place.

Transports are typically undertaken by road, rail and air modes as required. A summary of these transports is given in the Annual Report (SÚJB, 2012). Transport is undertaken in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material (TS-R-1 2009) and the relevant Modal Instruments (ADR, RID, ICAO TI's etc. which are given effect to by the Ministry of Transport and Ministry of Foreign Affairs).

The regulatory responsibilities for the safety of the transport of radioactive material are primarily allocated to SÚJB through the Atomic Act, and as amended by a Decree detailing various areas (e.g. type-approval of packaging, ionizing radiation sources and shipment).

The Ministry of Transport has established SÚJB as the enforcement authority for class 7 transport by road and rail (ADR and RID). The Ministry of Foreign Affairs of the Czech Republic maintains up-to-date requirements of ADR and RID for road and rail transports of dangerous goods (including radioactive material) by issuing new Notifications every two years. These notifications contain English and Czech translations of Annexes A and B of the ADR agreement and Appendix C of the RID convention. For sea and air transports the general requirements are given in the appropriate modal regulations while the detailed requirements are stipulated in the current IMDG Code and ICAO-TI.

It is expected that the requirements of SSR-6 (2012) will be given effect in the revised ADR from 2014. In addition to the IAEA transport requirements approval is also required for nuclear material shipments and shipments of radioactive material with an activity greater than 3000A1 or 3000A2, as appropriate, or 1000TBq, whichever is the lower. The processing of approval applications is described in the Atomic Act and in an implementing Decree, on type-approval and shipment.

The work of SÚJB in the area of regulating transport of radioactive material among other items includes the assessment of applications and the associated technical documentation for licensing, assessment of applications and associated technical documentation for issuing of type approval certificates for packages type B(U), B(M) fissile material and Type S (for Storage), verification and validation of type approval certificates for different package types (Type IP-1,IP-2, IP-3,Type B(M), Type C, and fissile material), inspection of facilities and enforcement as required.

Assessments of package designs that do not require approval by the competent authority (such as Type A packages or industrial packages containing fissile-excepted radioactive material) are carried out by the appropriate organizations and the necessary evidence of such assessments is made available to the competent authority, if requested.

Prior to issuing an approval for a special arrangement shipment, SÚJB checks if all requirements stipulated in the Decree, on type-approval and shipment and also all requirements stated in the regulations which had not been met are replaced with special conditions (or technical or administrative) assuring that that the level of nuclear and radiation safety and physical protection during the shipment is at an identical or higher level. Such conditions are subject to approval by SÚJB.

All aspects relevant for the safety of the shipment must be included in the documents submitted in approval request. The documents are reviewed according to the Atomic Act, implementing decrees and internal guidance.

The process is regulated by Act No. 500/2004 Coll., Administrative Procedure Code. The SÚJB approvals are issued for up to 10 years.

5.8. SUMMARY

The authorization process for the regulation of nuclear installations, radioactive waste, ionising radiation sources and transportation is well established with a clear governmental, legal and regulatory framework, and an appropriate application of the graded approach.

SÚJB should consider strengthening the cooperation with the relevant competent authorities involved in the authorization process under the Construction Act. In addition, SÚJB should ensure that the regulatory criteria for the design and operation of operating and future NPPs are fully developed and take into consideration the safety requirements of the appropriate IAEA NPP safety standards. Concerning human resources, the systematic approach to analysing SÚJB's needs to address the siting assessment phase of new build was identified as a good practice.

For radiation sources, the SÚJB maintains a comprehensive and accurate regulatory data system for managing licensees and sources. To ensure up to date records, the SÚJB has made an arrangement through which the financial status of all licensees of radiation sources is regularly checked, this arrangement was also identified as a good practice.

To ensure that SÚJB has the knowledge and information to conduct review and assessment of the disposal of spent fuel, SÚJB should consider the arrangements for the development of independent research.

6. REVIEW AND ASSESSMENT

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

The national regulations for safe transport of radioactive materials are maintained up-to-date by the new Notification of the Ministry of Foreign Affairs of the Czech Republic every two years, which gives effect to the ADR and other modal instruments. Safety documentation submitted by an applicant is compared with legal requirements for the design of type-approval and shipment (Decree No. 317/2002 Coll).

Documents describing handling, storing and segregation of packages sufficiently from places occupied by transport workers and members of the public by consignors and carriers are a part of the documentation submitted to SÚJB by a consignor for a shipment approval (the Atomic Act).

The appointed inspector carries out the safety documentation assessment (including a comparison between described properties of the design and those prescribed) and prepares a draft of the type-approval if the safety documentation is satisfactory; otherwise a revised version is requested from the applicant. The assessment results are contained in the part "Reasons for the decision" of the draft approval. The head of Division of Radioactive Waste and Spent Fuel Management reviews the draft and modifies it as necessary and finally signs the Office Decision on type-approval as appropriate. Independent qualified experts / organizations such as relevant Faculties in the Czech Technical University of Prague and the University of West Bohemia may also be appointed to assist the Office in reviewing the documentation. A review of the compliance assurance programme for type approving packages, special form radioactive material, shipments etc. confirmed that these are being implemented in practice administratively and supported by inspections as appropriate. SÚJB is provided with adequate resources to perform its functions in the area or review and assessment. Various guidance documents are available on the SÚJB website to assist the applicant with the process.

6.8. SUMMARY

It can be stated in general that the review and assessment activities at SÚJB are carried out at a high quality level, with a well implemented graded approach, e.g. with a very detailed tool to assess currently the initial preliminary safety report submitted for Temelín 3/4 identified as a good practice. An appropriate governmental, legal and regulatory framework with respect to review and assessment for the safety of nuclear installations and transport activities as well as for the management of radioactive waste and use of radiation sources is in place.

However, the current organisation and management system of SÚJB for review and assessment still leave room for improvement. In order to ensure consistency and stability in the decision making, additional internal guidance and criteria for judging safety should be defined, and the considerations on TSO inputs should be better documented. In addition, SÚJB should ensure that it maintains technical competences in all the areas in which it engages advice from external experts.

7. INSPECTION

7.7. INSPECTION OF TRANSPORT ACTIVITIES

Transport inspections are planned, performed and assessed in compliance with the Atomic Act and implementing Decree No. 317/2002 Coll., on type-approval, shipment and internal guide VDMI 019/2001: Inspection manual for compliance checking of the shipment of nuclear materials and radionuclide emitters. The scope and frequency of the regulatory inspections corresponds to the potential risks posed by the shipment. All planned inspections are focused on the compliance of the shipment with the relevant provisions of the Decree No. 317/2002 Coll., on type-approval and shipment (and with the requirements of appropriate approval certificate). Reactive inspections are performed only if an abnormal occurrence requires immediate investigation or if there are concerns about the licensee's capability to perform any corrective actions in the event of an incident.

In 2012, SÚJB carried out 10 inspections of the transport of nuclear materials and radioactive substances. They included inspections of international transports of fresh nuclear fuel for the two nuclear power plants and inspections of the international transport of uranium concentrate and irradiated nuclear materials. SÚJB also inspects packages of foreign origin while in transit in its area of jurisdiction. A similar number of inspections have been taken up to November 2013 with similar results.

The compliance assurance programme of SÚJB includes the monitoring of handling and stowage of packages by consignors and carriers. Documents describing handling and stowage of packages by consignors and carriers are a part of the documentation submitted to the SÚJB by a consignor for shipment approval. The relevant aspects of these (e.g. radiation protection during transport (including dosimetry arrangements), emergency preparedness, physical protection arrangements, driver competence/training, stowage during carriage, segregation, verification of transport documents, etc.) are inspected by the SÚJB staff accompanying the shipment to see if they are in accordance with the legal requirements.

SÚJB ensures through inspections that the requirements for all modes of transport have been met in practice. Upon completion of the inspection, SÚJB provides the user's management with a summary of the results of the inspection, including any non-compliances noted. The inspection report is issued in a standard format known as the 'Protocol'. The Office keeps track of inspection findings as evidence of compliance and retains all official written materials concerning inspections for 15 years.

The SÚJB performs inspections, auditing and/or reviews of the management system established by the operator as well as checking the appropriate quality assurance programme. The audit is governed by internal guides VDS 080/2013 Quality systems assessment and VDMI 020/2001 Inspection manual for quality checking of packaging manufacturing. In the Czech Republic, there are two specialized manufacturers of packaging (UJP Praha and SKODA JS). The SÚJB performs inspections of the manufacturing activities and of the activities in the management system. The results of such inspections are recorded and communicated to the manufacturer.

A similar situation exists for the only testing facility in the Czech Republic (SÚRAO). Following the upgrade of the testing facility during 2005-2006 SÚJB conducted inspections including witnessing the tests and checked that the tests were carried out in accordance with the quality management system. On the basis of the inspection, the testing facility was approved to resume package testing. The results of such inspections are recorded and communicated to the testing facility management. While these inspections have been undertaken, the frequency of these would not be considered optimum, given the current staffing levels and administrative burden on the transport staff.

If an inspection reveals an unsatisfactory situation or a non-compliance, SÚJB follows up to determine the cause of the problem and initiates suitable action to prevent its recurrence (including additional education and training). Penalties for violation of a legal obligation are established under the Atomic Act. The inspection and enforcement programmes are applied to all activities that are important to safety irrespective of whether an approval certificate is required or not.

SÚJB is provided with resources to perform its compliance assurance programme for conducting inspections in the nuclear sector; however these resources in terms of staffing could be augmented. Inspections are undertaken throughout the country. The findings and lessons learned are analysed at regular meetings of the inspection assessment Commission and the results of the assessment are published in the Annual Report of the State Office for Nuclear Safety (see recommendation in Chapter 3.3).

The transport of radioactive material in the Czech Republic is well established and an appropriate governmental, legal and regulatory framework with respect to inspection functions for the safety of transport of radioactive material is in place. However, noting the current complement of two inspectors (one being trained) and the age profile in the Division of Radioactive Waste and Spent Fuel Management specializing in the work associated with the transport sector (review and assessment, issuing approvals, undertaking inspections, witnessing testing etc.) and the administrative burden associated with the implementation of existing EC Directives and the development of new ones, performing necessary regulatory functions and activities poses a constant challenge.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Noting the current complement of two inspectors (one being trained) and the age profile in the Division of Radioactive Waste and Spent Fuel Management specializing in the work associated with the transport sector (review and assessment, issuing approvals, undertaking inspections, etc.) and the administrative burden associated with the implementation of existing EC Directives and the development of new ones, performing necessary regulatory functions and activities poses a constant challenge.	
(1)	BASIS: GSR Part 1 para. 18 states that “The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities to be regulated, to perform its functions and to discharge its responsibilities.”
S15	Suggestion: SÚJB should consider more comprehensive and frequent training for regional inspectors undertaking inspections of the transport of radioactive material.

7.8. SUMMARY

SÚJB has a formal, graded inspection programme that carries out its functions to ensure its licensees and radiological facilities comply with legislation, regulations and the terms of their licenses.

While some improvement to the programmes can be made, the inspection process is utilized and documented in a structured and appropriate manner. SÚJB has self-initiated an action plan to ensure the programme covers all aspects of related IAEA guidance.

The IRRS team considered the inspectors observed to be trained, competent, and respected by their regulated entities. They conducted their inspections in accordance with internal procedures. The IRRS team considered the Committee for Evaluation of Inspections (CEI) that reviews each inspection report and its related findings as a good practice, as well as SÚJB’s new programme to assess nuclear power plant operator safety culture.

The IRRS Team noted that inspectors rarely exercise the right to conduct an unannounced inspection during non-routine working hours and that the planning for such unannounced inspections is not formalized. It was also noted that SÚJB resident inspectors are not directed to respond to the NPP site when an emergency arises or participate as a member of the SÚJB emergency response team.

The IRRS team acknowledges that SÚJB inspection practices are in line with the IAEA requirements. There is room for improvement and the suggestions and recommendations provided by the IRRS team are aimed to optimize the existing inspection process implemented by SÚJB.

9. REGULATIONS AND GUIDES

9.7. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

The development of a new version of the Atomic Act and new implementing regulations are at an advanced stage and take into account technical development, new knowledge resulting from membership of the Czech Republic in the European Union, membership in international organisations, staff experience and feedback.

The legal framework for shipment in the Czech Republic is clearly specified on the SÚJB website http://www.sujb.cz/en/nuclear-safety/radiation-material-transportation/legal-framework.

A comprehensive list of the UN and IAEA Transport Regulation and Safety Guides as well as a glossary of terms is also included.

A summary of the application for shipment approval as well as an overview of the safety documentation required and the items to be included in the emergency procedures are specified on the website http://www.sujb.cz in the nuclear safety section. A section on the safety of transport of radioactive material and the approvals required from SÚJB are also provided. A list of type approvals for Czech made packages, international packages and for radioactive material is also available. Safety Guide No. BN-JB-1.13 Transport of Radioactive Material, 2011 is a useful reference for users and relevant SÚJB staff.

The competent authority also provides training to its own personnel. The contents of such training is outlined in an Internal document – Directive No. 039 /2001 (rev. 3/2012) System of education, training and assessment for the employees of the State Office for Nuclear Safety. This training includes information on transport regulations and transport safety in general.

Additionally it is expected that relevant requirements of the new European Commission Basic Safety Standards Directive, the Directive 2006/117 on waste, the Directive on inland transport of dangerous goods and the main provisions of IAEA TS-G-1.4 (The Management System for the Safe Transport of Radioactive Material) and IAEA TS-G-1.5 (Compliance Assurance for the Safe Transport of Radioactive Material) will be incorporated in the new Atomic Act. It is anticipated that the planned provisions will provide a good basis for compliance with the transport safety standard and the aforementioned IAEA Guidance.

9.8. SUMMARY

The Czech Republic has a well-established legislative and regulatory framework for the use of nuclear energy, the uses of radiation sources and for the protection of people and the environment from the harmful effects of ionising radiation. In the Atomic Act main stages of radiation utilisation are addressed (siting, construction, commissioning, operation, reconstruction and decommissioning). The system of decrees and guides is enabled by the Atomic Act.

The IRRS Team recognized that the IAEA Requirements are not fully implemented in the current system of regulations. Where SÚJB regards the matter as appropriate, new IAEA Safety Standards are made obligatory through licence conditions. In addition there is no formalized process in place for reviewing and updating regulations.

SÚJB has clearly recognized that the Czech legislative and regulatory framework have to be updated. SÚJB has therefore started an intensive project to prepare and implement a new Atomic Act and its related decrees. The target of SÚJB is to implement the latest knowledge and experience from regulatory practice. As a result of a limited review of the draft of the new Atomic Act, the IRRS Team determined that the new Atomic Act is well designed, covers the main stages of activities and reflects the latest knowledge. Even aspects of on-going discussions within the EU are covered. The IRRS Team encourages SÚJB to complete this activity.

A2.5 FINLAND

IAEA-NS-IRRS-2012/04

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO FINLAND

Helsinki, Finland, 15 to 26 October 2012

IAEA-NS-IRRS-2015/08

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION TO FINLAND

Helsinki, Finland, 8 to 16 June 2015

5. AUTHORIZATION

5.7. AUTHORIZATION OF TRANSPORT

For nuclear material and nuclear waste, a licence for transport is required according to the Nuclear Energy Act, unless the transport involves small quantities exempted from the transport licence, in accordance of Section 17 of the Nuclear Energy Decree. STUK has YVL guides that establish requirements for safety (YVL 6.5) and security (YVL 6.21) of transport for this material. For nuclear material such as fresh fuel, a transport plan and transport security plan are mandatory in addition to the licence. These requirements for authorization of transport of nuclear material were seen to be in compliance with the requirements of the TS-R-1.The transport of non-nuclear radioactive material is exempted from licence under the Radiation Act (Section 17 of Act 592/1991), but is regulated according to national transport regulations on dangerous goods, based on IAEA safety standards. Therefore there is no authorization process in STUK for this practice. This issue is followed up in section 7.7 of this report.

STUK has produced a pamphlet with instructions for drivers (STUK OPASTAA / SYYSKUU 2012– Radioaktiivisten aineiden kuljetus, 36 pp) which is available for downloading from its web site.

5.8 SUMMARY

The team considers that, with the current exception of a process for authorization of decommissioning, STUK actually performs authorization consistent with requirements 23 and 24 of GSR Part 1 and other relevant safety standards.

The Government needs to establish a legal authorization process for decommissioning and closure.

STUK's approach in plant modification and safety class components approval are reflected in very broad and intensive authorization of all safety related items regardless to the other safety significance attributes of certain change. STUK may introduce some additional criteria to rearrange the load on graded way focusing more on safety significant items and less on less significant items.

STUK also should consider adopting formal authorization in spite that the inspecting of the dosimetry laboratory takes place regularly.

For its own uses of radiation, STUK should consider demonstrating, in a transparent manner, that it satisfies all the required regulatory conditions necessary for an authorization.

5.7. AUTHORIZATION OF TRANSPORT (FOLLOW-UP)

There were no findings in this area in the initial IRRS mission.

6. REVIEW AND ASSESSMENT

6.7. REVIEW AND ASSESSMENT OF TRANSPORT

In Finland, about twenty to thirty thousand consignments containing radioactive materials are transported annually. The majority of these is delivered to hospitals. Other users are research facilities and industry. Additionally, radiopharmaceuticals are produced in Finland for domestic use and for export. Fresh fuel is delivered to Finnish nuclear power plants (NPP) about four times per year. A container with used sources is transported under special arrangements once every 1 to 2 years to Olkiluoto. Spent nuclear fuel is planned to be sent in the future to a final repository also at Olkiluoto.

Applications for approvals of transport of nuclear material are reviewed according to STUK's internal guides, Guide YTV 5.3.1 and Guide SKV 5.2. Compliance with requirements for transport is assured by inspection and by approving operator's plans for safety, security and emergency preparedness. The transport of non-nuclear radioactive material is not subject to authorization and review by STUK, unless sent by special arrangements. There is no design, manufacturing or testing of transport packaging, special form material or low dispersible material in Finland so validation mainly involves approval of package designs by foreign manufacturers.

6.8. SUMMARY

Review and assessment processes in STUK are well established and controlled. Large number of guides related to safety assessment to be performed by the licensees, as well as well as those for control of internal review processes are available, thus providing adequate framework for review and assessment. For nuclear power plants this framework includes a comprehensive set of technical and radiological acceptance criteria and assessment conditions for all plant states, including severe accidents. STUK approach to promoting the use of the best available methods of safety analysis in the authorization process, special attention put on independent regulatory analytical and experimental assessment of the novel design solutions should be recognized as very good regulatory performance.

Systematic reassessment according the evolving STUK documents led to the safety improvements of existing facilities. Graded approach to review and assessment depending of associated risk is in place. In spite of good results achieved there are always possibilities for further improvements. Lessons learned from previously executed reviews provide an input to updating STUK guides. Examples of specific areas where further improvements are advisable include complementing the set of STUK guidelines by a guide on format and content of safety analysis report, continuing development of internal review guides for other technical areas and enhancing consistency of analysis of radiological consequences in different authorization documents.

6.7. REVIEW AND ASSESSMENT OF TRANSPORT (FOLLOW-UP)

There were no findings in this area in the initial IRRS mission.

7. INSPECTION

7.7. INSPECTION OF TRANSPORT

The transport of nuclear material is subject to inspection, unless the quantity is so low that it is below exemption limits for the transport licence. Inspection on the road is carried out with the cooperation of the police. The IRRS team was informed that there was a limited number of transports of fresh nuclear fuel, approximately four times per year. There used to be transport of spent nuclear fuel when it was returned to the Russian Federation. The transport of spent nuclear fuels will however increase considerably in the coming years when the final repository will be in operation, and STUK has recognized that this is a challenge to be met.

When transport is a part of a licensed practice (as in industrial radiography), the transport arrangements are inspected by STUK as a part of the inspection of the practice even though the transport as such is not subject to licence.

As the Radiation Act does not require a specific licence for transport of non-nuclear radioactive material, STUK has no detailed information on carriers. However, being the competent authority for the transport of radioactive materials, STUK is responsible for monitoring compliance with transport regulations and it assessed the doses due to transport several years ago, but there is no systematic process for it. STUK has identified this issue in its action plan. There are on-going discussions at the EU level to ensure consistency of the transport directive and the radiation protection directive, with a view to establish a system of notification for the carriers, so that national registers could be established. STUK is supporting this proposal to facilitate its regulatory control of radioactive material transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part 1 Requirement 27 states that "The regulatory body shall carry out inspections of facilities and activities to verify that the authorized party is in compliance with the regulatory requirements and with the conditions specified in the authorization."
(2)	BASIS: TS-R-1 Para 308 states that "The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the basic safety standards."
S14	Suggestion: STUK should consider initiating an inspection programme that includes periodic assessments of the levels of workers' doses in different types of transport activities in cooperation with the relevant regulatory agencies.

7.7. INSPECTION OF TRANSPORT (FOLLOW-UP)

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S14	Suggestion: STUK should consider initiating an inspection programme that includes periodic assessments of the levels of workers' doses in different types of transport activities in cooperation with the relevant regulatory agencies.

Changes since the initial IRRS mission

Suggestion 14: STUK has undertaken an assessment of the collective dose received by workers in Finland in the transport of radioactive material by road (the principal mode of transport in Finland) through a survey conducted in 2013 of the quantity of radioactive material transported in that year. The doses received were estimated applying methodologies used in similar surveys in Sweden and the UK, with the results showing a collective dose of around 12-13person-mSv. STUK has committed to repeat the survey every 5 years at the same time as a survey of dangerous goods transport by the Finnish Transport Safety Agency.

STUK has developed a plan for control of radioactive material in transport covering the period from 2015 to 2018 that includes a programme of inspections of transport hubs and major carriers, to be conducted in co-operation with other relevant authorities. Status of the finding in the initial mission

Suggestion 14 (S14) is closed on the basis of progress and confidence in effective completion as STUK has carried out a survey of estimated worker doses from road transport in 2013 and is committed to repeating the survey each 5 years. STUK has developed a plan for control of transport over the period 2015-2018 that includes a programme of inspections.

9. REGULATIONS AND GUIDES

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

The Ministry of Transport and Communications is responsible for the development of legislation and requirements for the transport of all dangerous goods. The requirements of TS-R-1 are incorporated into national regulations which are based on the ADR, RID, IMDG Code and ICAO-TI. In the Act on the Transport of Dangerous Goods (719/1994), STUK is defined as the competent authority for the transport of radioactive materials. STUK oversees the radioactive material transports in cooperation with police, Customs, Border Guard and the Defence Forces.

Regulatory requirements for the transport of nuclear material and nuclear waste are given in Guides YVL 6.4 (packages), 6.5 (transport safety) and 6.21 (transport security). STUK's regulatory requirements are currently being revised. STUK grants the licences for nuclear material and nuclear waste transports, for these a licence is needed with some exceptions (Section 17 of 161/1988) for small quantities.

The national regulations governing transport by road in Finland are based on the ADR regulations. The version in use agrees for the most part with TS-R-1, with the exemption of not using external markings on vehicles in some specific cases (excepted packages and medical unsealed sources). Even though the deviation from TS-R-1 is a minor one and of limit relevance for safety, the IRRS team is of the view that TS-R-1 should be implemented in the relevant Finnish legislation without any exemptions.

9.8. SUMMARY

All areas of STUK's competence are covered by regulations and guides with the exception of some specific cases that are identified in subchapters 9.2 to 9.7. Regulations and guides reflect IAEA and other relevant international recommendations. Regular updates are keeping regulations and guides up to date.

STUK needs to cooperate with relevant ministries in the legislative process to maintain an appropriate framework of binding regulatory principles and requirements relevant to its areas of competence. As STUK's authority in this legislative process is not clearly and unambiguously defined in existing law, the IRRS team recommends measures (see Section 1.3) that would align the situation in Finland in this area with IAEA requirements and best practices.

A comprehensive renewal programme for safety regulatory YVL guides is in advanced stage of implementation and will be finalized by end of February 2013, resp. by the end of August 2013 in case of those related to structures and components of nuclear facilities. When completed, STUK will have available a very well structured modern set of regulatory guidance coherent with most recent international standards and best practices.

STUK's Regulatory guides are updated in accordance with stringent review periods. This may be quite challenging for STUK with respect to the availability of resources, especially in the radiation safety area.

In the area of regulations and guides STUK reacted to Fukushima accident promptly. There is already a package of proposals for modification of legally binding legislation, and the regulatory guides are in advanced stage of implementation.

9.7. REGULATIONS AND GUIDES FOR TRANSPORT (FOLLOW-UP)

There were no findings in this area in the initial IRRS mission.

A2.6 FRANCE

IAEA-NS-IRRS-2014/09

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO THE REPUBLIC OF FRANCE

Montrogue, Republic of France, 17 to 28 November 2014

5. AUTHORIZATION

5.8. AUTHORIZATION OF TRANSPORT ACTIVITIES

The requirements of TS-R-1, Regulations for the Safe Transport of Radioactive Material, paragraph 802, state that the Competent Authority approval shall be required for special form of radioactive material, low dispersible radioactive material, packages containing 0.1 kg or more of uranium hexafluoride, packages containing fissile material unless excepted, Type B(U) packages, Type B(M) packages, Type C packages, special arrangements, certain shipments, radiation protection programmes for special use vessels and the calculation of radionuclide values that are not listed in Table 2 to TS-R-1. By Order, it is specified that ASN is the Competent Authority for the carriage of radioactive or fissile materials intended for civilian purposes. ASN identified that there are some types of authorization that are not in use in France and therefore have not been reviewed or authorized, specifically for low dispersible material or for civilian use of a Type C package. ASN is prepared to review these if an application is received. Authorizations for Type B and fissile packages, as well as special arrangements, are routinely issued and include the requirements of paragraphs 827 through 829 of TS-R-1. ASN has implemented provisions for Type B and fissile packaging that are more restrictive than TS-R-1, paragraphs 816 and 817, to phase out certificates of approval for package designs approved under the 1973 and 1985 editions of the IAEA Regulations for the Safe Transport for Radioactive Material. ASN has identified in the advanced review material the need to encourage applicants to develop new packages to replace those older designs. This is captured as Action Item 5.4 in the Self-Assessment Action Plan.

5.9. SUMMARY

ASN, being the nuclear regulatory authority in France, issues authorizations to BNIs, radiation sources and facilities, and transportation of fissile and radioactive materials. The authorization stages for BNIs include creation, commissioning, final shutdown and decommissioning (or final closure and transition to the surveillance phase for waste disposal facility) and de-licensing. The authorizations for creation, final shutdown, decommissioning and de-licensing are issued by the Government, whereas authorization for commissioning is issued by ASN. ASN also issued requisites (conditions to be met by the licensee) during all authorization stages. The licensees of BNIs are required to undergo a periodic safety review, even though this is not an authorization stage.

The facilities involving radioactive sources and radiation generators require authorization and notification; however, these can be exempted depending on their characteristics, use and potential exposure that these can cause. Authorizations for transport are in line with all requirements of the IAEA Regulations for Safe Transport of Radioactive Material, TS-R-1, and are routinely issued.

ASN has a well-defined authorization system covering the entire life cycle of facilities and activities. The authorization system is, in general, in line with IAEA safety standards whereas additional steps have been planned or are in the pipeline for further improvement. ASN has performed a thorough self-assessment based on IAEA's SARIS tool, providing the details on how they comply with IAEA safety standards, identifying areas for further improvement, and have drafted a detailed plan for the corrective actions for improvement.

The team has also identified certain areas for improvement in the authorization process (details are provided in sections 5.1 to 5.8 above) including implementation of a graded approach in the authorization of radiation sources and facilities, issuance of the authorization for radiation sources and facilities to the appropriate legal entity, and responsibilities of ASN with regard to the national sealed source database.

6.8. REVIEW AND ASSESSMENT FOR TRANSPORT ACTIVITIES

ASN's primary role for transport review and assessment is for authorization of packaging in accordance with TS-R-1. ASN can issue approvals for radioactive material in special form and low dispersible radioactive materials; packages containing 0.1 kg or more of uranium hexafluoride; packages containing fissile material; Type B and Type C packaging designs. The assessment process is described in ASN Guide No. 7, "Transport of Packages or Radioactive Materials for Civil Use on Public Roads." For a new transport package design, ASN has three main stages for their review process leading up to the issuance of a certificate of approval: the preliminary safety report; the test programme; and the design safety report. After each of these stages, ASN issues a letter stating the points that have been accepted, rejected or need completing. As described in the ASN-IRSN Framework Document, IRSN provides technical support to ASN for transport approvals, including all of the types listed above. ASN may also request an assessment by the advisory committee for transport before making a final conclusion regarding the acceptability of a transport application. Taking into consideration the IRSN assessment and advisory committee response, ASN issues the approvals.

Approval certificates are typically issued for a five-year period. As older packages are reviewed for renewal of the certificate, ASN evaluates the design against current regulatory requirements and incorporate enhanced assessment methods or any lesson learned during use of the package. An example is the review and assessment of the model TN-13/2. ASN required the applicant to consider a new drop orientation, which resulted in a revised cover design. ASN issued an interim approval to allow limited shipments with appropriate compensatory measure and a full renewal of the certificate for the design with the new cover plate. This example illustrates ASN's focus on continuous improvement and on ensuring compliance with the requirements of TS-R-1.

ASN reviews and approves the training organization and programme for certification of Class 7 drivers. Applications for approval of drop test targets (locations where the facility meets the requirements of TS-R-1, paragraph 717) are reviewed and ASN has issued letters for four test facilities that satisfactorily meet regulatory requirements. Currently, ASN provides review and assessment for implementation of radiation protection programmes for the transport through inspection. As noted in Section 9.8, ASN's authority to require notification from carriers of radioactive material is needed to enhance the review and approval of radiation protection programmes for transport.

6.9. SUMMARY

Review and assessment for BNIs is performed by ASN mainly within the frame of authorisation, plant modification, operating experience feedback and periodic safety reviews. The type of documents subject to review and assessment is very diverse in scope and content and the regulatory body applies a graded approach. ASN is supported by its main TSO, IRSN, with in-depth analyses on the major safety relevant issues. A second technical advice is the one provided by the various Advisory Committees of Experts (GPE).

The review and assessment process for evaluating the suitability of radiation source facilities has been examined and found to be essentially adequate, although the review team proposes a stricter documentation on how the assessment of such facilities is graded on a safety basis. A corresponding suggestion, to clarify the graded approach used in the regulations and guides for different facilities and activities, may be found in section 9.

With regard to the safety assessment performed for transport activities, the team concludes that it is fully consistent with the relevant IAEA requirements.

The team has also identified an area for improvement with regard to regulatory guidance for the applicants and licensees of BNIs, for example with respect to the content of a safety analysis report. ASN has initiated a project defining the scope and schedule for completing the regulatory framework. A corresponding recommendation from the review team, encouraging timely implementation of the ASN plan, may be found in section 9.

7. INSPECTION

7.8. INSPECTION OF TRANSPORT ACTIVITIES

ASN's responsibility for inspection of the transport of radioactive materials is specified in the Environmental Code. ASN's transport inspection activities encompass inspection of transport operations, package design testing, package manufacturing including fabrication and non-destructive testing, package maintenance, transport worker training, and radiation protection program requirements. ASN has developed a comprehensive set of guidance documents for inspection of transport, which cover a wide range of activities. Additional new guides are also under development. ASN completed 131 transport inspections in 2013. Transport inspections are performed by ASN headquarters Direction du transport et des sources (DTS) staff and regional Division staff.

Transport inspections can be announced or unannounced, and can be planned or reactive. An inspection plan is issued each year which identifies goals for the total number and priority topics for inspection. It was noted in the 2014 inspection plan that "During the course of 2014, two "transport" qualified DTS staff members are liable to leave ASN, which could affect the number of inspections run by DTS for the divisions (15 in 2013)." At present, the headquarters DTS staff responsible for transport includes the Director, Deputy Director, and six engineers, and the Divisions typically have one inspector each, who specializes in transport. Though some Divisions may have two inspectors, they would specialize, one for BNIs and the other for small scale nuclear activities. Transportation training is usually offered once per year, which can result in significant delays in completing the training. ASN identified maintaining inspector competence as action item 7.1 in the Self-Assessment Action Plan.

<table>
<tr><th colspan="2">RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</th></tr>
<tr><td colspan="2">Observation: In the Divisions, the number of inspectors for the transport program is limited. It was observed that due to the limited number of inspectors in a Division, the transport inspections can be significantly impacted when an inspector is ill or otherwise unavailable.

Additionally, there is a high turnover among the staff, which can lead to the Division having no inspector fully competent to inspect transportation at some times. Because the transport training is only offered about once per year, there can be a delay for getting the new inspector trained.</td></tr>
<tr><td>(1)</td><td>BASIS: TS-R-1, Para. 307 states that "The competent authority is responsible for assuring compliance with these Regulations. Means to discharge this responsibility include the establishment and execution of a programme for monitoring the design, manufacture, testing, inspection and maintenance of packaging, special form radioactive material and low dispersible radioactive material, and the preparation, documentation, handling and stowage of packages by consignors and carriers, to provide evidence that the provisions of these Regulations are being met in practice."</td></tr>
<tr><td>(2)</td><td>BASIS: TS-G-1.5, Para.2.13 states that "The competent authority should establish and maintain a programme for training its own employees. The training provided should be sufficient to ensure consistency in the application of the Transport Regulations."</td></tr>
<tr><td>S14</td><td>Suggestion: ASN should consider developing a more effective training to address the limited number of transportation inspectors and the turnover in the Divisions.</td></tr>
</table>

7.9. SUMMARY

The IRRS team concluded that there are sufficient legal basis and ASN internal documents to carry out regulatory inspections in accordance with relevant IAEA documents.

- ASN inspectors are well qualified, motivated to discharge their duties, and respected by inspected organisations. ASN has implemented a well-structured, systematic and effective system of inspectors' training,
- ASN inspections are planned and performed in such way that an acceptable level of assurance that regulatory requirements are met is achieved,

- Results of ASN inspections are recorded and communicated to the public, the inspected organisations and within the ASN, as appropriate.

The IRRS team identified several suggestions for improvement of ASN inspection programme and practices, for example the completion and updating of inspection guidance documents and the development of criteria for initiating reactive inspections.

9. REGULATIONS AND GUIDES

9.8. REGULATIONS AND GUIDES FOR TRANSPORT ACTIVITIES

The IAEA Regulations for the Safe Transport of Radioactive Material, TS-R-1, 2009 Edition, have been incorporated into the United Nations (UN) Recommendations on the Transport of Dangerous Goods, Model Regulations, and Eighteenth Revised Edition. The UN Model Regulations are then incorporated into the modal standards for road, rail, water, and air:

- European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);
- Regulations concerning the International Carriage of Dangerous Goods by Rail (RID);
- European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN);
- IMO International Maritime Dangerous Goods Code (IMDG); and
- Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions).

The Code of Environment, Legislative Part, Order no. 2012-6 of 5 January 2012 amending Books 1 and 5, is the underlying French law and identifies ASN's responsibility for the safety of the transport of radioactive materials. The modal standards, as identified above, which incorporate TS-R-1 are implemented in France through Orders.

TS-R-1 is very effectively incorporated into the French regulation with very little exception. The only area where some additional regulation was identified as being needed is to extend ASN's regulatory authority to transport carriers. It was identified that a decision required under the Public Health Code had been drafted but not yet adopted. The proposed decision would require notification of carrier's activities to ASN, making the radiation protection requirements of the Labour Code applicable to carriers of radioactive material. This was identified as action item 5.5 in the Self-Assessment Action Plan.

ASN has developed a comprehensive set of guidance documents, both for use by ASN staff and for applicants and licensees. As noted in Section 7.8, ASN has many guidance documents for inspection. These guides provide detailed information, for example text from the pertinent regulations, the agenda and common themes for the inspection, and detailed examples or checklists of items to be evaluated during the inspection.

For applicants and licensees, ASN makes key guidance documents available on the ASN website. Guides available on the website include Guide No. 7, for applications for shipment and package approval, and guidance for the reporting of transport-related incidents. ASN initial approvals and regulatory decisions are also publicly available on the website. ASN has appropriate regulations to include all requirements of TS-R-1 and adequate guides for implementation of the transport regulations by all modes of transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The decision to require notification to ASN for carriers of radioactive material which is needed to apply the radiation protection requirements of the Labour Code has not been adopted. This notification is important to ensure effective inspections of the radiation protection programmes for transport.	
(1)	BASIS: TS-R-1, Para. 302 states that “A radiation protection programme shall be established for the transport of radioactive material. The nature and extent of the measures to be employed in the programme shall be related to the magnitude and likelihood of radiation exposures. The programme shall incorporate the requirements of paras 301, 303–305, 311

	and 559. Programme documents shall be available, on request, for inspection by the relevant competent authority.”
(2)	BASIS: TS-G-1.3, Para. 5.14 states that “Certain requirements for protection and safety are so important that compliance with them should be independently verified. It is the principal role and responsibility of the competent authority to enforce compliance with all relevant requirements and standards, including those for the optimization of protection and safety in transport, by means of independent verification.”
S19	Suggestion: ASN should consider completing the process to implement the Public Health Code to require notification by carriers of radioactive material.

9.9. SUMMARY

The French regulatory system comprises a comprehensive framework of laws, decrees, orders, and ASN decisions and guidelines. In 2008, ASN defined a project for developing new regulatory resolutions and guides which clarify the decree and order setting out the general rules applicable to BNIs. Current goal is to finalize the project in 2015. Once completed, ASN resolutions and guides will cover all stages of the lifetime of BNIs and have a scope of a comprehensive set of topics related to safety. However, ASN should consider developing explicit criteria for radiological consequence analyses of incidents and accidents. ASN should also consider preparing a safety guide for sub-surface disposal facility if that facility will be proposed by Andra in 2015. In addition, ASN should consider further clarifying the graded approach used in the regulations and guides for different facilities and activities.

The process for developing and updating regulations and guides is quite generic. ASN has already recognized the need for a separate procedure for developing guidelines but a more detailed guidance for developing resolutions could also be considered. Currently, there is no systematic process for evaluating and reviewing regulations and guides (including the assurance of coverage of relevant IAEA standards), and revising them, as appropriate.

Currently, the Public Health Code does not define an administrative regime to apply radiation safety requirements specifically to carriers of radioactive material. ASN should complete the process to implement the Public Health Code to incorporate the notification requirement for carriers of radioactive material.

A2.7 GERMANY

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO THE GOVERNMENT OF GERMANY

Bonn and Stuttgart, Germany, 8 to 18 September 2008

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION TO GERMANY

Bonn and Stuttgart, Germany, 4 to 10 September 2011

Note: The transport of radioactive materials is not mentioned in either mission report.

A2.8 GREECE

IAEA-NS-IRRS-2012/02

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO GREECE

Athens, Greece, 20 to 30 May 2012

Content copying not allowed by document security settings!

IAEA-NS-IRRS-2017/11

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION TO GREECE

Athens, Greece, 20 to 24 November 2017

11. TRANSPORT OF RADIOACTIVE MATERIAL

11.1. REGULATIONS AND THE GLOBAL NUCLEAR SAFETY REGIME

There were no findings in this area in the initial IRRS mission.

11.2. Competent Authority There were no findings in this area in the initial IRRS mission.

11.3. RESPONSIBILITY FOR SAFETY

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
S9	Suggestion: The Government should consider revising its regulatory framework for the transport of radioactive materials to provide for a contemporary set of requirements which are fully consistent with the international regulatory framework.

Changes since the initial IRRS mission

Suggestion S9: In 2012, the IRRS team noted that the existing regulations (MD 5) only partially incorporated IAEA Regulations TSR-1 and contained an error in the definition of “Quality Assurance”. It was noted that in Greece, the review and revision cycle for radiation protection regulations differs significantly from that for IAEA Regulations SSR-6 (former TSR-1). In addition, the transposition of the revised UN Recommendations on the Transport of Dangerous Goods (that incorporate the SSR-6 revised requirements) involves other competent authorities and legislative considerations beyond the field of radiation safety.

In developing the new Radiation Protection Regulations (RPR) and specifically the Joint Ministerial Decision (JMD) on regulatory control, reference is made to the pertinent legislation for the transport of Class 7 material by any transport mode. By adopting this approach, definitions and requirements are not duplicated in the regulations.

In this context, the national regulatory framework for the transport of radioactive material (TRAM) provides for a contemporary set of requirements which are fully consistent with the international regulatory framework.

Moreover, TRAM is considered a practice that falls within radiation protection regulatory oversight (PD 15). Provisions for notification, registration and authorization of carriers and shipments, validation of package design approval certificates, assignment of responsibilities and accident reporting are included in the draft JMD on regulatory control.

JMD provides the legislative link between the new RPR and other relevant transport legislation. When it comes into force, the complete legislative framework for transport of radioactive material will be consistent with the international regulatory framework and will facilitate synchronising the revision cycle with the IAEA Regulations revision cycle.

Status of the finding in the initial mission

Suggestion S9 is closed on the basis of progress made and confidence in effective completion. The revised national regulatory framework for the transport of radioactive material (TRAM) provides for a contemporary set of requirements which are fully consistent with the international regulatory framework. Confidence is made that the legislative document will be approved by February 2018 and the secondary legislation and guidance 6 months thereafter.

11.4. Delivery and coordination of regulatory functions

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R22	Recommendation: GAEC should collaborate and coordinate with other Greek authorities with assigned competence for the transport of radioactive material to: facilitate the timely and effective exchange of information; and enable effective coordination of regulatory functions.

Changes since the initial IRRS mission

Recommendations R22: The IRRS team noted that while there is no formalised national process in place, in practice EEAE co-operates and collaborates efficiently and effectively with other national authorities with assigned competence for TRAM. Consequently, EEAE complies with the relevant IAEA requirements.

Status of the finding in the initial mission

Recommendations R22 is closed. EEAE co-operates and collaborates efficiently and effectively with other national authorities with assigned competence for TRAM.

11.5. Operational Activities and Compliance Assurance

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R23	Recommendation: GAEC should review, develop and strengthen its capacity for review and approval of package and material designs.

Changes since the initial IRRS mission

Recommendations R23: The IRRS team noted that package and material designs that require Competent Authority approval are not designed, tested or manufactured in Greece. The IRRS team were informed that in the past fifteen years, only one application for the multilateral approval of a Type B (M) package was submitted to EEAE.

The lack of capacity in this field was initially addressed by EEAE by joining the European Association of Competent Authorities (EACA) in 2014. EEAE intends to rely on the existing experience among EACA members and Competent Authorities for technical assistance in future, should the need arise.

Furthermore, EEAE participates in the Mediterranean Network for the safe transport of radioactive materials (MedNet) serving as the Chair since 2015. MedNet members, including EEAE, requested and received relevant training from IAEA in 2016. Arising from this training, EEAE developed and incorporated a number of guides and templates into its IMS including:

- internal guide for package design certificate validation according to ADR/RID;
- internal guide for package design certificate validation according to IAEA SSR-6;
- template for Validation Certificate of Package Design for the Transport of Radioactive Material.

In addition, EEAE's review and assessment for the validation of packaging and material design is conducted against the European PDSR Guide, issue 3, 2014 published by EACA.

The strategy and the actions put in place by EEAE, joining the EACA and participating in the activities of MedNet have developed and strengthened its capacity for the review and approval of package and material designs.

Status of the finding in the initial mission

Recommendations R23 is closed. EEAE capacity for review and approval of package and material designs is strengthened.

2012 MISSION RECOMMENDATIONS, SUGGESTIONS	
R24	Recommendation: GAEC and other transport competent authorities should implement appropriate, co-ordinated, compliance assurance programmes.
S10	Suggestion: GAEC and other transport competent authorities should consider using IAEA TS-G-1.5 in developing their compliance assurance programme(s).

Changes since the initial IRRS mission

Recommendations R24 and Suggestion S10: In the context of its participation in MedNet, EEAE conducted a review of its compliance management system against the IAEA Safety Guide TS-G-1.5. Moreover, the Strengths Weaknesses Opportunities Threats (SWOT) analyses was performed by EEAE. These compliance management system reviews triggered the development of the EEAE internal guides for the review and assessment of package designs and the use of the EACA inspection check lists. The IRRS team noted that while there is no formalised national process in place, in practice, EEAE co-operates and collaborates efficiently and effectively with other national authorities with assigned competence for TRAM, including in relation to compliance assurance programmes.

Status of the finding in the initial mission

Recommendations R24 and Suggestion 10 are closed. EEAE implements co-ordinated compliance assurance programmes. The other transport competent authorities were not involved in the review during the initial or follow up missions.

A2.9 IRELAND

IAEA-NS-2015/11

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO IRELAND

Dublin, Ireland, 30 August 2015 to 9 September 2015

5. AUTHORIZATION

5.4. AUTHORIZATION OF TRANSPORT

The authorization of some facilities includes, where relevant, aspects related to the transportation of radioactive material. Compliance with IAEA "Regulation for the Safe Transport of Radioactive Material" is included, as well as the modal transport regulations (ADR, RID, IMDG code and TI-ICAO), as a reference in the Authorization's condition. The carriers are also approved by the EPA. The license duration of these Authorizations (licenses) ranges from 1 to 3 years.

The EPA is the competent authority in respect of matters relating to the carriage by road of Class 7 radioactive materials, including, among others, the approval of specialization courses for the training of drivers of vehicles carrying radioactive material of ADR Class 7 and the examination of persons who have participated in those courses required under the relevant road transport statutory provisions.

Regarding road transport, the requirements concerning the training of the vehicle crew (drivers) is function specific and the training requirements and structure of the training is provided in Chapter 8.2 of the ADR for basic and specialization training. Basic courses are approved by the Health and Safety Authority and run by the Chartered Institute of Logistics and Transport. The one day Class 7 specialization course is run by a training company approved by the EPA.

For the approvals required by the SSR-6 para. 802 (and the modal transport regulations) the IAEA regulation includes a graded approach to safety by the application of activity limits for the content, dose rate limits for packages and conveyances, requirements on the design, operation and on the package maintenance, and the required administrative controls (e.g. the need for package design approval, inspections before each transport).

The functions of the EPA include issuing approvals; however, in practice the items listed in para. 802 of the IAEA Regulations are not currently applicable to Ireland. Only Shipment Approval Certificates are issued for Type B packages where required and where valid Competent Authority Certificates of Design (from the country of origin) are available.

Special form radioactive material, low dispersible radioactive material, fissile material, packages containing 0.1 kg or more of uranium hexafluoride, Type B(U), Type B(M) packages or Type C packages are not currently designed or manufactured in Ireland.

While there are a number of Competent Authorities involved in the transport of Dangerous Goods by Road, Rail, Sea and Air with respect to the implementation of the Modal Instruments (ADR, RID, IMDG and TI-ICAO), the EPA is the only Competent Authority that issues an Authorization for the transport of radioactive material. No applications for approvals for certain shipments, radiation protection programmes for special use vessels, approval for calculation of radionuclide values not listed in Table 2 (Section VIII of the IAEA SSR-6 Regulation) or approval for calculation of alternative activity limits for an exempt consignment of instruments or articles have been received to date.

More information was required during the IRRS mission in regard to the relationships between the different Competent Authorities. A meeting was organized by the EPA with representatives of the Maritime Safety Directorate, the Irish Aviation Authority and the EPA. Issues in relation to the process of authorization, assessment, inspection and enforcement actions were discussed at this meeting and these issues are included in chapters 6.4, 7.4 and chapter 8.

The Maritime Safety Directorate stated that they do not issue Authorizations.

The Irish Aviation Authority (IAA) issues approvals and undertakes on-going surveillance of compliance by airlines and organizations involved in the carriage of dangerous goods, including radioactive material, by air. IAA also issues the approval for training companies to conduct dangerous goods training in accordance with the requirement of the ICAO Technical Instructions.

5.5. SUMMARY

The Radiological Protection Act 1991, provides for the EPA to license facilities and practices. Within the EPA, the ORP has the delegated responsibility for the radiological licensing function.

Authorization of facilities and activities is through a one-level authorization system of licensing. The applicant is required to submit documentation to the EPA that includes Facility Design Plans, Risk Assessments, and Radiation Safety Procedures one month before commencement of any licensable practice.

The legislation does not provide for different types of authorization at different stages in the lifetime of a facility or the duration of an activity. Licenses are issued for periods ranging from one to four years, depending upon the activities carried out and risks involved.

The legislation as such does not provide for a graded approach for regulation. However, EPA implements a graded approach to its regulatory functions, including authorization and inspections, utilizing risk based categorization of practices and sources. Once a license has been granted, any modifications to practices, equipment or facilities require the licensee to seek authorization from the EPA in the form of an amendment (change) request to the license.

In regards to the transport of radioactive material, the Irish Aviation authority also issues approvals and undertakes on-going surveillance of compliance by Airlines and organizations involved in the carriage of dangerous goods by air.

EPA/ORP has recently introduced a computerized system, Graded Authorization Management Information System (GAMIS) that was developed through the EPA's Licensing Enforcement and Monitoring Application (LEMA). The system provides for online license applications, as well as, amendments and renewal of licenses through an online web portal EDEN (Environmental Data Exchange Network). However, written procedures for the authorization, review and assessment of license applications are not in place.

6. REVIEW AND ASSESSMENT

6.4. REVIEW AND ASSESSMENT FOR TRANSPORT

With regard to the transport of radioactive material by road, the review and assessment is undertaken by the EPA and includes both radiation protection and transport matters. The licensee is required to ensure that all the activities associated with the transport of radioactive material shall be conducted in accordance with the IAEA's regulation for the Safe Transport of Radioactive Material, the Modal Instrument and national transport regulations.

The Quality Management system for ORP inspection activities is accredited to the international standard ISO 17020 and relates to inspection activities with regard to radiological protection. However, there are no documented procedures regarding the assessment of applications for authorizations in relation to the transport of radioactive material. This is addressed in Recommendation 10 in Section 4.4.

A meeting was organized during the IRRS mission by the EPA with representatives of the Maritime Safety Directorate, the Irish Aviation Authority and the EPA. The Irish Aviation Authority indicated during this meeting that the review and assessments of airlines to transport dangerous goods (including Class 7) are undertaken using standard forms.

6.5. SUMMARY

An applicant for a license is required to submit documentation to the EPA that includes Facility Design Plans, Risk Assessments, and Radiation Safety Procedures. The EPA reviews and assesses this information to determine whether the facilities and activities comply with the regulatory requirements.

A graded approach to review and assessment is implicitly built into the process by the fact that the contents of the risk assessment and radiation safety procedures are expected to be more rigorous and comprehensive for high risk practices than for lower risk practices.

Review and assessment is carried out before issuing a license, upon receipt of a request for an amendment to a license, during regulatory inspections and at the license renewal stage. Usually review and assessment is carried out by an individual inspector but in the case of a high risk practice, or a new type of practice, a license review panel is established to assess the application. Advice may also be obtained from external independent experts during the review and assessment process.

The documents sent to EPA in support of the application are produced by the applicant in conjunction with a Radiation Protection Adviser (RPA). Especially in the case of high risk practices the comprehensiveness, quality and completeness of the documents for review and assessment by the EPA is highly reliant on the expertise provided to the licensees by the RPAs.

EPA has prepared generic safety assessments for specific types of practices in order to assess the possibility of authorizing them by registration, rather than by license which will be provided for with the implementation of the new EU BSS directive.

With regard to the transport of radioactive material by road, the review and assessment is undertaken by the EPA. The Irish Aviation undertakes the assessments of airlines to transport dangerous goods by air (including Class 7).

7. INSPECTION

7.4. INSPECTION OF TRANSPORT

The EPA is responsible for the inspection of radioactive material transported by road and rail (although in Ireland there is currently no transport of radioactive material by rail).

The frequency of the transportation of radioactive material by road within Ireland is currently approximately 5000 transports per year.

The vast majority of the packages transported are Excepted or Type A packages (mainly for medical uses). A small proportion of the packages are Type B packages (mainly cobalt radioactive sources used in industrial sterilization and iridium sources for industrial radiography). The number of inspections undertaken of radioactive material transported by road in a given year is based upon a risk analysis.

All inspection activities undertaken by the EPA are carried out within the framework of a Quality Management System [QM17020] This issue is addressed in Good Practice 1 in Chapter 4.1. The Quality Procedures Manual includes a set of forms where transport is considered. Nevertheless, audits to verify the user’s management system of transport organizations are not currently implemented.

<table>
<tr><th colspan="2">RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</th></tr>
<tr><td colspan="2">Observation: Transport organization’s management systems are not included in the Inspection Programme.</td></tr>
<tr><td>(1)</td><td>BASIS: SSR-6, para 306 states that “A management system based on international, national or other standards acceptable to the competent authority shall be established and implemented for all activities within the scope of the Regulations.”

SSR-6, para 307 states that “The competent authority shall assure compliance with these Regulations.”

Safety Guide TS-G-1.5 para 4.58 states that “The competent authority should put in place an auditing programme to verify that the user’s management system is implemented and followed correctly…” and “…However, the competent authority should also ensure by means of an ongoing audit or inspection programme that suitable management systems are implemented in the transport of packages of other types.”</td></tr>
</table>

R11	Recommendation: The EPA inspection program should be extended to verify that the user's management system relating to the transport of radioactive material is implemented and followed correctly.

With regard to the transport of radioactive material by sea, the number of transportations is significantly less than by road and it is undertaken infrequently. There are no transports of packages that require notification or multilateral approval on the territorial Sea in Ireland. Transport of radioactive material by sea utilizes the road-sea-road interface. The consignors and consignees involved in the transportation of radioactive material by sea are licensed by the EPA.

A meeting was organized during the IRRS mission by the EPA with representatives of the Maritime Safety Directorate, the Irish Aviation Authority and the EPA. The Maritime Safety Directorate representative stated that there is no specific programme for the inspection of radioactive materials. Furthermore, the training, in relation to IMDG Code, provided for inspectors does not include specific training in relation to radioactive material (Class 7). See Recommendation 5 in Chapter 1.5.

The majority of the radioactive sources transported by air are used for medical purposes. They are shipped from, or are delivered to, EPA licensed facilities within Ireland by road. Some of these radioactive sources are transported to Northern Ireland as transit shipments by road.

The Irish Aviation Authority representative stated that the inspections are performed based on an annual inspection programme and that the IAA inspectorate has dangerous goods training that meets the requirements of the ICAO Technical Instruction.

7.6. SUMMARY

The Radiological Protection Act empowers the EPA to appoint inspectors for the purpose of the Act and assigns a comprehensive set of powers to the inspectors.

EPA's inspection activities are accredited by the Irish National Accreditation Board (INAB) to the ISO 17020:2012 standard for inspection bodies.

EPA sets up an annual inspection programme which is approved by the Board of EPA. The inspection programme takes into account various factors including the target inspection frequency, reported incidents during the year, issues related to individual licensees, matters that may have arisen during the year and the available staff resources. During the year the programme may be adjusted, when deemed necessary. Inspection findings are reviewed regularly and the main findings are published annually.

The main purpose of inspections is to check the licensee's compliance with license conditions and relevant legislation and, while not yet incorporated into the audit form, to assess the licensee's safety culture.

With regard to the transport of radioactive material, the EPA is responsible for the inspection of radioactive material only by road and rail, though in practice no transport by rail takes place. Inspection of radioactive material by sea and air is the responsibility of the Marine Survey Office and the Irish Aviation Authority, respectively.

An inspection is normally conducted by one inspector but in the case of a complex facility more than one inspector may be involved. Inspections are carried out utilizing practice specific inspection audit forms that are followed during the whole inspection. A formal report of the inspection findings is forwarded within four weeks.

Most planned inspections are announced but some unannounced inspections are also conducted, for example, in the case of industrial radiography (NDT). This is facilitated by the fact the EPA receives from the licensee advance notices of any site radiography work. The programme includes also joint security inspections with An Garda Síochána, Ireland's national police.

The IRRS team followed the conduction of several inspections. The IRRS team observed that the EPA inspections are comprehensive, concentrated in matters relevant to safety and were conducted in a very professional manner. The IRRS team was convinced that the inspections contribute significantly to the improvement of safety and enhancing the safety culture at the regulated facilities.

9.5. REGULATIONS AND GUIDES FOR TRANSPORT

The EPA is not responsible for the publication and periodic review and revision of national regulations for the safe transport of radioactive material. Each mode of transport regulation is maintained by the relevant government departments that initiate national legislation that give effect to the Modal Instrument (ADR, RID, IMDG Code and ICAO TI). Nevertheless, the requirements regarding the transport of radioactive material, that are included in the modal instruments, comes from the IAEA SSR-6 Regulation. The modification of SSR-6 comes from the IAEA-TRANSSC committee in which the EPA is the representative of Ireland.

The EPA has a set of guides and protocols available in its website in which the transport activities are included. There are also some guides that are not yet published but they are available on request. Nevertheless, there is no formal policy in place regarding a review and revision of these guides, see Recommendation 12 in Chapter 9.1.

9.6. SUMMARY

The legally binding regulations setting out the basic criteria for regulatory compliance are established through the Orders issued by the Minister implementing the European Directives. It was noticed that the radiation protection regulations need to be updated in accordance with the latest IAEA safety requirements. It is expected that this will happen when the country implements the Euratom Basic Safety Standards Directive in 2018. In addition the regulatory framework for decommissioning and safe radioactive waste management needs to be developed.

EPA does not have the power to issued legally binding regulations. However, its functions prescribed in the Radiological Protection Act include the preparation and issuance of codes of practice dealing with radiation safety.

EPA has established a set of codes of practice and guidance. However, these do not provide for a systematic set of codes and guides covering all types of regulated practices but are rather set up for certain topical needs. There are no established policies and processes regarding establishing and amending guidance documents and codes of practice.

The EPA can impose additional regulatory requirements on licensees by the inclusion of specific conditions in the licenses granted. These conditions supplement legislative requirements and in many cases make explicit reference to the EPA’s codes of practice and guidance documents.

EPA has developed comprehensive sets of standard license conditions to be attached to all licenses. In this way, the EPA establishes many of its safety principles, requirements and associated criteria for safety as license conditions instead of establishing regulations, codes of practice and guides.

All the EPA issued guidance documents and Codes of Practice are accessible to interested parties through the EPA website.

A2.10 ITALY

IAEA-NS-IRRS-2016/09

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO ITALY

Rome, Italy, 21 November to 2 December 2016

5. AUTHORIZATION

5.6. AUTHORIZATION OF TRANSPORT

The transport of radioactive material is part of the transport of dangerous goods. The UN Model Regulations use a classification system in which each dangerous substance or article is assigned to a Class, depending on the nature of the danger that it presents. The radioactive material is assigned to Class 7. Approximately 200,000 packages containing radioactive material are transported in Italy each year that represent about 2% of the entire movement of dangerous goods.

The majority of the excepted packages, industrial packages and Type A packages, which are not subject to competent authority approval. Type B packages and packages for fissile material, which are subject to competent authority approval, are also in use. All of Type B packages transported are of foreign design.

The majority of the shipments are related to the use of radioactive material for medical purposes, industry (non-nuclear), for research and for transport of radioactive waste. The shipments in the nuclear fuel cycle are related essentially to the research reactors and to the decommissioning activities of the nuclear power plants. The spent fuel coming from the operations of NPPs was sent abroad during the last decade for reprocessing. A small number of spent fuel assemblies still stored in a facility will be sent for reprocessing in the next few years. A larger number of return shipments of high level vitrified waste to Italy will take place in the future, starting in about 2020.

The requirements of the IAEA Transport Regulations SSR-6 are fully implemented through the international model transport regulations for dangerous goods for Class 7 and must be applied by law in Italy for road, rail, inland waterway, sea and air transport (ADR, RID, ADN, IMDG-Code, ICAO-TI). Based on this, all approval requirements (“approval” is used in SSR-6 instead of “authorization”) for the transport of radioactive material in Italy are in compliance with SSR-6, for which ISPRA issues the appropriate approval certificates. The IRRS team noted that some procedures and guides are currently under development for the various approval types as part of the management system (see Section 9.6).

In addition, there is a requirement for authorization of carriers based on the Nuclear Energy Act and the Radiation Protection Act, which must also be observed for the transport of radioactive material in Italy. There is a link to SSR-6 in so far, that the provisions of the IAEA Regulations SSR-6 are taken into account during the process for the authorization of the carrier. The Ministry for Economic Development is designated as regulatory body (competent authority) to issue this authorization. ISPRA is involved as advisor as well as other ministries depending on the mode of transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: The authorization of carriers is required according to the Act on Peaceful Use of Nuclear Energy and the Radiation Protection Act in Italy for which the Ministry for Economic Development is designated as regulatory body. For this authorization ISPRA is involved as advisor as well as other ministries depending on the mode of transport. However, there is no clear assignment of responsibilities and tasks for the various involved parties. The advice from ISPRA includes some aspects of SSR-6 (Radiation Protection Programme, training, material classification).

(1)	BASIS: GSR Part 1 (Rev.1) Requirement 7 states that “Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provisions for the effective coordination of their regulatory functions, to avoid any omissions or undue duplications and to avoid conflicting requirements being placed on authorized parties.”
(2)	BASIS: GSR Part 1 (Rev. 1) Requirement 23 states that “Authorization by the regulatory body, including specification of the conditions necessary for safety, shall be a prerequisite for all those facilities and activities that are not either explicitly exempted or approved by means of a notification process.”
(3)	BASIS: GSR Part 1 (Rev. 1) Requirement 2 Para 2.6 states that “Where several authorities are involved, the government shall specify clearly the responsibilities and functions of each authority within the governmental, legal and regulatory framework for safety.”
R17	Recommendation: The Government should review and accordingly revise the authorization process for carriers regarding the: - legal responsibilities and needs of involved parties - specification of conditions for authorization - implementation of a graded approach - consistency with exemption requirements for authorization based on SSR-6 to achieve a transparent, effective and simplified authorization process for all modes of transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: Observation: There are no new manufactured packagings in Italy which are subject to competent authority approval, but there are many older packaging in use for which appropriate maintenance operations and inspections are very important. Such maintenance and service activities must be performed within a certain time frame to guarantee that the package design during its use still meets all applicable requirements as part of the quality assurance program. It is not requested by ISPRA that such dates for performing maintenance and service activities are indicated on the packaging itself.	
(1)	BASIS: TS-G-1.5 para 4.96 states that “It should be indicated on the packaging when the last maintenance or service operation was done or, preferably, when the next maintenance or service operation is due.”
S9	Suggestion: ISPRA should consider specifying in their Package Design Approval Certificates that the date of the next maintenance or servicing operation, according to the approved maintenance or servicing programme, should be indicated on the packaging.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: Based on the authorization procedure for carriers ISPRA has collected data on all performed shipments of radioactive material in Italy since 1987. A very comprehensive, web-based database has been developed (TRARADWEB) which contains not just statistical data (e.g., consignor, consignee, transport route, time, …) but also very detailed safety related information (e.g. package type, radionuclides, activity amount, dose rates, …) and which is updated regularly. This modern tool contains options for verification and control of transmitted data (identification of non-compliances) as well as for analyses necessary for statistical and also safety related purposes (e.g. dose assessments for workers and the public, regional information for emergency preparedness and planning).

(1)	BASIS: SSR-6 para 308 states that "The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the Basic Safety Standards."
(2)	BASIS: TS-G-1.5 para 4.51 states that "The competent authority is required to arrange for periodic assessments to evaluate the radiation dose to workers and to member of the public due to the transport of radioactive material. Data from consignors and carriers that need to assess the dose arising from their transport operations may be used in such assessments of radiation doses by the competent authority."
GP2	Good Practice: The development, maintenance and use of the comprehensive ISPRA web-based database (TRARADWEB) is considered to be a good practice because it goes beyond the collection of standard transport data by providing additional safety related data and corresponding analyses tools necessary to perform dose assessments due to transport, to identify non-compliances and to support the provincial emergency preparedness and planning.

5.7. SUMMARY

The system of authorization is rather complex in the Italian system, involving both national and regional authorities. Particular focus has been given to decommissioning, waste management and the planning of a waste repository, which constitute the main challenges for Italy. The IRRS team identified areas for improvements to better align authorization procedures with the IAEA safety standards and for taking into account international best practices. In the area of radiation sources and transport of radioactive material, definition of the responsible authorities, the application of a graded approach and the coordination between the authorities are among the issues the IRRS team has identified possible improvements. Finally, the development, maintenance and use of the comprehensive ISPRA web-based database (TRARADWEB) is considered to be a good practice.

6. REVIEW AND ASSESSMENT

6.3. REVIEW AND ASSESSMENT FOR TRANSPORT

ISPRA is able to independently review and assess technical data and the results of tests submitted by an applicant for the approvals requested by the IAEA Regulations SSR-6. The independent review and assessment in line with SSR-6 covers all aspects of criticality, heat transfer, radiation protection, structural analysis and all related measures of the management system of the applicant. In case of an application for approval of package design for which a prototype will be subject to the tests, established by the IAEA Regulations SSR-6, the preliminary tests program is discussed with the applicant and a management system is requested that addresses all the aspects of the testing.

There are no internal procedures and guides for review and assessment work available as part of the ISPRA management system (see module 9.6). Presently the technical resources for review and assessment seem to be acceptable due to the current situation that for the existing packages in use only limited review and assessment activities are necessary to prolong existing certificates and to validate foreign certificates. This is no longer the case for the future when new package designs will have to be approved and a full review and assessment work must be performed in compliance with the latest state of art.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: In the future, shipments of spent fuel and return shipments of vitrified waste from reprocessing to Italy are expected. Therefore it is essential to maintain and develop the skills of the staff of the competent authority to review, assess and approve package designs for these transports.	
(1)	BASIS: GSR Part 1(Rev. 1) Requirement 18 states that "The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and

	number of facilities and activities to be regulated, to perform its function and to discharge its responsibilities.”
(2)	BASIS: TS-G-1.5, para 2.13 states that “The competent authority should establish and maintain a programme for training its own employees.”
R21	Recommendation: The regulatory body should establish and maintain an appropriate training and qualification programme to assure that the future needs regarding the review, assessment and approval of package designs for transport of spent fuel and high level vitrified waste are met.

6.4. SUMMARY

ISPRA is performing the regulatory review and assessment of the safety assessment and other safety documentation provided by the operator in support to the licence application independently. To improve its regulatory functions related to review and assessment, ISPRA should (a) establish specific requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct appropriate safety assessments and (b) develop procedures to specify the principles, requirements and associated criteria for safety upon which its regulatory review and assessment is performed and for recording the results.

For the research reactors, a periodic review report as a licence condition is scheduled every 5 years. The review approach is based mainly on the monitoring of the facility conditions and evaluation of the plant safety in accordance with the Code of Conduct for Research Reactors. Since not all relevant safety factors are addressed in this review, ISPRA should require the operators of research reactors to perform periodic safety reviews of all factors of relevance for safety according to a graded approach.

In the future, shipments of spent fuel and return shipments of vitrified waste from reprocessing to Italy are expected. Therefore, it is essential to maintain and develop the skills of the staff of the competent authority to review, assess and approve package designs for these transports. The regulatory body should establish and maintain an appropriate training and qualification programme to assure that the future needs regarding the review, assessment and approval of package designs for transport of spent fuel and high level vitrified waste are met.

7. INSPECTION

7.6. INSPECTION OF TRANSPORT

The inspections are generally performed on the premises of the consignor or consignee during the operations of transport of fissile or non-fissile material. The basis for the inspection is usually the compliance with the relevant transport requirements based upon the IAEA Regulations SSR-6 and the modal regulations (ADR, RID, ADN, IMDG Code and ICAO TI). These inspections also include transport packages and transport operations. The inspections are also dedicated to the evaluation of the radiation protection programme of the consignor/carrier to verify compliance with the requirements both of IAEA Regulations SSR-6 and the Radiation Protection Act (Legislative Decree 17 March 1995, No. 230).

In particular due to the missing legal assignment to ISPRA as the competent authority for transport of radioactive material (class 7) for all modes of transport inspections during shipment cannot be performed (see Module 9.6). In this regard the draft action plan of the counterpart has identified already an appropriate action for road transport.

ISPRA has not sufficient human resources to perform all necessary inspections to ensure that all regulatory requirements that are important to safety are correctly fulfilled in practice. This issue is addressed in Recommendation R3 in Module 1, like

- manufacturing of packages which are not subject to competent authority approval (majority of packages in use in Italy),

- maintenance, repair and service activities for packaging,
- routine inspections during transport and measurement campaigns.

It was found out that for packages which are not subject to competent authority approval, compliance with the applicable requirements of SSR-6 is demonstrated by inspection, for which the consignor must provide documentary evidence. For this purpose the consignor is using a certificate of compliance, for which some important information is missing. This issue is addressed in Suggestion S12 below.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: For packages which are not subject to competent authority approval, compliance with the applicable requirements of SSR-6 is checked by inspection. In order to provide documentary evidence, the consignor is using a Certificate of Compliance. However, as observed by the IRRS team, some important information is missing in this certificate.	
(1)	BASIS: SSR-6, para 801 states that “For package designs where it is not required that a competent authority issue a certificate of approval, 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.”
(2)	BASIS: SSG-26, para 801.3 states that “In the case of packages that do not require competent authority approval, some form of ‘certificate of compliance’ should be applied. Such certificates of compliance should include the following information: (a), (b), (c), … , (m).”
S12	Suggestion: The competent authority should consider reviewing the consignor’s Certificate of Compliance for consistency with the IAEA safety standards.

7.7. SUMMARY

According to the Legislative Decree 230/1995, inspections are performed by ISPRA. Annual work plans are prepared to carry out inspections for facilities and activities. The regulatory body inspection staff is well knowledgeable. However, the human resource issues need to be addressed. The IRRS team found that the regulatory body should further develop procedures for inspection and an inspection programme.

9. REGULATIONS AND GUIDES

9.6. REGULATIONS AND GUIDES FOR TRANSPORT

Italy as contracting party of international agreements or conventions which apply for international transport of dangerous goods including radioactive material, the international regulations for the different modes of transport respectively ADR (road), RID (rail), ADN (inland waterway), IMDG Code (sea) and ICAO TI (air). The transport requirements of the IAEA Regulations SSR-6 are fully implemented into the international modal regulations and transposed into the national regulatory framework by appropriate Decrees and EC Regulations for land transport (road, rail, inland waterway), sea transport and air transport.

Other than the regulations for transport of dangerous goods the transport of radioactive material is also regulated by the legislative and regulatory framework for the peaceful use of nuclear energy and for the activities with the use of ionizing radiations mainly constituted by:

- Act on peaceful use of nuclear energy - Law 31 December 1962, No. 1860 (as modified);
- Radiation Protection Act - Legislative Decree 17 March 1995, No. 230 (as modified).

Article 5 of the Law No. 1860 establishes that transport of radioactive material for all modes of transport has to be carried out by authorized carriers. That authorization is issued by the Ministry of Economic Development and countersigned by the Ministry of Infrastructure and Transport. Article 21 of the Radiation Protection Act establishes that the carrier authorization has to be issued on the basis of a technical advice of ISPRA and of the Ministry of Interior, expressed after the review and assessment of the applicant’s documentation. The technical advice of ISPRA takes into account also some aspects of the IAEA Transport Regulations SSR-6.

It can be concluded that in Italy the regulations for safe transport of radioactive material as implemented in the dangerous goods transport regulations of class 7 are in full compliance with the requirements of SSR-6 for all modes of transport but that appropriate guidelines on how to implement these requirements in the various fields of transport are missing. The draft action plan of the counterpart has identified already an action to develop a technical guide on approvals.

Although ISPRA is acting as a competent authority as defined in SSR-6 there is currently no legal assignment to ISPRA to perform this function for all modes of transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: ISPRA acts as the competent authority for all functions as required by the IAEA Transport Regulations SSR-6, but these roles and functions are not assigned to it.	
(1)	BASIS: SSR-6 para 207 states that "Competent Authority shall mean anybody or authority designated or otherwise recognized as such for any purpose in connection with these Regulations."
(2)	BASIS: TS-G-1.5 para 2.6 states that "The responsibilities and duties of the competent authority (regulatory body) are required to be defined within the national legal framework of a State, in accordance with the requirements established in GS-R-1."
R27	Recommendation: The Government should assign the competent authority for all modes of transport of radioactive materials and define the responsibilities and duties in the national legal framework as required in the IAEA Transport Regulations SSR-6.

The IRRS team observed that a documented management system does not exist which is commensurate with ISPRAs functions and tasks to be performed as competent authority for transport to assure compliance with the IAEA Transport Regulations SSR-6 including the following areas:

- Procedures for package design and shipment approvals
- Conducting safety reviews and safety assessments
- Issuing approvals
- Carrying out regulatory inspections and any necessary enforcement actions (inspection programme, inspection checklist and enforcement programme)
- Development of technical guides for applicants for package design and shipment approvals
- Distribution and publication of information related to the safe transport of radioactive material

This issue is addressed in Section 4.2 Recommendation R11. This was also highlighted by the counterpart in the preliminary Action Plan for the IRRS Mission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: The IRRS team observed that a procedure at national level which allows a systematic review and revision of the transport regulations to keep them up to date, to take feedback from experience into account and to involve all interested parties is currently not in place.	
(1)	BASIS: GSR Part 1 (Rev. 1) Requirement 33 states that "Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and of relevant experienced gained."
R28	Recommendation: The Government should establish a systematic process for reviewing and revising transport regulations to keep them up to date, in which feedback is taken into account and interested ministries and competent authorities establish a consultation process with organizations representing applicants and users within the field of safe transport of radioactive material.
S14	Suggestion: The Government should consider establishing a national advisory committee to perform the review and revision processes.

9.7. SUMMARY

There is in general a lack of appropriate and up to date technical guides in various areas. The IRRS team was informed that some gaps are going to be filled through some guides under preparation on priority topics related to the national program (waste management and decommissioning). It is recommended that within the management system of the regulatory body procedures should be put in place which assure that in all areas relevant guides are developed, adopted, promoted and amended and reviewed as needed to keep them up to date and to take feedback from experience into account.

In the field of radiation sources, recommendations have been provided to enable regional authorities to have consistency in the regulatory control over category B sources and to develop technical guides for defining criteria for safety applicable to facilities using radiation sources.

For research reactors it is recommended to develop and implement requirements for an ageing management programme and operating experience feedback programme, which are not available so far.

The transport regulation, are fully consistent with the IAEA Transport Regulations SSR-6 but for its full implementation in practice a clear legal assignment to ISPRA as competent authority for all modes of transport in this field, is missing and must be put in place.

A2.11 LITHUANIA

IAEA-NS-IRRS-2016/03

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO REPUBLIC OF LITHUANIA

Vilnius, Lithuania, 17-29 April 2016

5. AUTHORIZATION

5.6. AUTHORIZATION OF TRANSPORT

The requirements for approval related to the design and shipment of packages are established through a range of legislative measures. The measures enact international agreements and apply to national as well as international transport of radioactive material. The international agreements include the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulation concerning the International Carriage of Dangerous Goods by Rail (RID), the Agreement on International Goods Transport by Rail (SMGS), the International Maritime Code for Dangerous Goods (IMDG Code) and International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air. The requirements apply to specific circumstances including special form radioactive material, fissile material (including fissile material excepted under para. 417(f) of SSR-6), packages of Types B(U), B(M) and C, packages containing more than 0.1 kg of uranium hexafluoride and certain shipments and transports under special arrangements.

RSC and VATESI are established by Government Resolution as the competent authorities for authorization (design or shipment approval) for the transport of radioactive material. However, their exact responsibilities are not defined in the Law on Nuclear Safety and the Law on Radiation Protection in all areas. VATESI has identified a corrective action for this in its action plan.

RSC has a written procedure for the validation of package designs approved by foreign countries. The procedure requires that documents supporting such applications have to include a detailed description of the packaging and content and a demonstration of compliance with the regulations. VATESI could improve the efficiency of its approval process by defining and publishing procedures for the main types of approvals it issues related to dangerous goods transport regulations. This is already included in VATESI's action plan.

Besides the above-mentioned approvals, carriers wishing to transport radioactive material other than in excepted packages in Lithuania need a licence (or a temporary permit) issued by RSC or VATESI. These licences are the basis for supervision of the operations. Procedures for application for and issuing of licenses are well-defined. Additionally, each shipment of radioactive material (other than for excepted packages) in, into or out of Lithuania requires a transport permit from RSC or VATESI. Depending on the assessment of safety and security of the proposed transport, this permit may place special conditions on the shipment.

<table>
<tr><th colspan="2">RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES</th></tr>
<tr><td colspan="2">Observation: The responsibilities of RSC and VATESI for approval required in SSR-6, para. 802 are not fully defined in the legal system of Lithuania.</td></tr>
<tr><td>(1)</td><td>BASIS: SSR-6, para. 802 states that "802. Competent authority approval shall be required for the following:
(a) Designs for:
(i) Special form radioactive material (…);
(ii) Low dispersible radioactive material (…);
(iii) Fissile material excepted under para. 417(f) (…);
(iv) Packages containing 0.1 kg or more of uranium hexafluoride (…);
(v) Packages containing fissile material, unless excepted by para. 417, 674 or 675 (…);
(vi) Type B(U) packages and Type B(M) packages (…);</td></tr>
</table>

	(vii) Type C packages (…). (b) Special arrangements (…). (c) Certain shipments (…). (d) Radiation protection programme for special use vessels (…). (e) Calculation of radionuclide values that are not listed in Table 2 (…). (f) Calculation of alternative activity limits for an exempt consignment of instruments or articles (…).”
(2)	BASIS: TS-G-1.5, para. 2.6 states that “ The responsibilities and duties of the competent authority (regulatory body) are required to be defined within the national legal framework of a State, … The responsibilities of the competent authority include: (b) Activities in connection with discharging these responsibilities for the safe transport of radioactive material, such as: (iii) Issuing approvals.”
R13	Recommendation: The government should revise the Law on Nuclear Safety and the Law on Radiation Protection to define all the responsibilities of VATESI and RSC for the transport-related approvals.

5.7. SUMMARY

The IRRS team found that the approaches to authorization followed by VATESI and RSC are generally in accordance with IAEA Safety Requirements.

There were however exceptions in a few areas, leading to recommendations and suggestions relating to the attaching of licence conditions; authorizations to ensure the suitability of spent fuel casks for post-storage transport; authorizing the closure of repositories; RSC’s application of a graded approach and omissions in the regulatory framework for transport-related approvals.

6. REVIEW AND ASSESSMENT

6.6. REVIEW AND ASSESSMENT FOR TRANSPORT

At present neither RSC nor VATESI assesses any package designs or materials for an approval under the dangerous goods regulations. This is because no packages are designed or shipped in Lithuania that would require competent authority approval of design or shipment according to these regulations.

RSC and VATESI have, related to their responsibilities, access to their own experts for dose rate and criticality safety assessments. For assessments in other areas, VATESI can contract external experts or technical support organizations who are independent of the applicant. In addition, RSC has contracts with external organizations for assessments not covered by its own experts.

6.7. SUMMARY

The IRRS team found that the approaches to reviews and assessments undertaken by VATESI and RSC are generally in accordance with IAEA Safety Requirements. This includes a Good Practice for the conduct of Periodic Safety Assessments for Category I, II and III radiation sources.

There were however exceptions in a few areas, leading to recommendations and suggestions relating to VATESI’s review and assessment processes. These related to the recording of reviews and assessments and their peer review; use of a graded approach; aspects of the “Oversight of Economic Entities process” and taking non-radiological risks into account.

7. INSPECTION

7.6. INSPECTION OF TRANSPORT

Inspections of carriers transporting radioactive material is done by inspectors from RSC or VATESI, depending on the information obtained in the licensing process. Inspections are based on internal procedures and, in case of RSC, on questionnaires. Inspections cover all important areas like condition of vehicles and packages, marking and labelling, compliance with radiation protection and training requirements for workers, status of emergency response arrangements, written instructions, radiation protection programme and security measures. Inspections are conducted once every three years. Inspections also include measurements of dose rates on the surface of the packages.

Further improvement of the inspection procedures is included in the VATESI action plan.

The result of the inspection is reported to the licensee, and for RSC the information about reports and non-compliances is recorded in the information system accessible by RSC and the licensee.

7.7. SUMMARY

In general the inspection programme, process and practice of the regulatory organizations are in line with the requirements of the safety standards. However in the legal circumstances there were shortcomings identified (legal framework for the unannounced inspections) and therefore one recommendation and one suggestion was formulated for both VATESI and RSC.

Suggestions related to the amendment of its inspection procedures were formulated by the IRRS team to enhance the effectiveness of inspections and to improve supervision of safety.

It was noted that in these fields there is an opportunity to improve graded approach in the planning of inspections by considering the frequency and necessity of inspecting low risk source facilities. The graded approach could also be considered in the context of the existing requirement to perform pre-licensing inspections in all facilities and for all changes to the licence thereof. Concerning these issues a recommendation was included in Section 5.

9. REGULATIONS AND GUIDES

9.6. REGULATIONS AND GUIDES FOR TRANSPORT

Lithuania applies to national as well as international shipments of radioactive material the regulations set in the international agreements for road, rail, sea and air transport that Lithuania has signed. Lithuania is member of IMO and ICAO and has signed ADR, RID and SMGS. This ensures that the regulations for safety of transport of radioactive material in Lithuania comply with SSR-6.

Review and revision of regulations regarding the transport of radioactive material includes drafting of text by RSC and VATESI, consultation with stakeholders and approval by the Ministry of Health and the Head of VATESI.

Based on the transport needs in Lithuania, RSC and VATESI have not yet issued extensive guidance for applicants for transport-related approvals. Taking into account potential transport needs arising from the existing nuclear installations and the possible renewal of the nuclear program, VATESI might benefit from making available such guidance. VATESI informed the IRRS team that it planned drafting some legislation defining application procedures and documents. As one basis for specifying application documents the international experience collected in the European PDSR guide could be used.

RSC and VATESI require training to workers of carriers according to ADR and check if this training is completed. In addition to the training required by ADR, radiation protection training and examination is required. Training centers and programs for this radiation protection training for RSC licensees are approved by RSC. The IRRS team was informed that VATESI would organize an equivalent function regarding VATESI licensees.

RSC and VATESI co-operate with other national organizations involved in the transport of dangerous goods, as the Ministry of Transport and Communication, the Border Guard Service and the Customs Department.

RSC and VATESI are involved in international cooperation projects. Nevertheless, both authorities would benefit from a more intensive and coordinated involvement in activities of Transport Safety Standards Committee (TRANSSC) and the European Association of Competent Authorities (EACA) for optimizing exchange of information and improving uniformity of the application of the IAEA transport regulations in all member states.

9.7. SUMMARY

In general, RSC and VATESI have established and implemented Regulations covering the areas under their regulatory oversight. There were however exceptions in a few areas, leading to recommendations and suggestions.

It is recognized that the updating of the legal and regulatory framework, taking into account the IAEA Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3 is timely.

For national and international transport of radioactive material, the regulations from the international agreements for road, rail, sea and air transport are applied. This complies with the IAEA standards.

VATESI regulations for radioactive waste management are not completely in line with the appropriate IAEA safety requirements (GSR part 5 and SSR 5), which were partly revealed in the self-assessment report and included in the action plan.

VATESI is drafting new safety rules on clearance of buildings and site to be used in the decommissioning of nuclear facilities; however, the criteria for clearance and the methodologies for the use of such criteria are to be established.

RSC rules on decommissioning of non-nuclear facilities need to be updated to comply with GSR part 6.

A2.12 MALTA

IAEA-NS-IRRS-2015/03

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO MALTA

Pietà, Malta, 22 February to 3 March 2015

Note: The transport of radioactive materials is not mentioned in the mission report.

A2.13 NETHERLANDS

IAEA-NS-IRRS-2014/07

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO THE NETHERLANDS

The Hague, The Netherlands, 3 to 13 November 2014

5. AUTHORIZATION

5.8. AUTHORIZATION OF TRANSPORT

The regulatory responsibilities for the safe transport of radioactive material are primarily allocated to the various ministries making up the Regulatory Body through the Nuclear Energy Act. Additional authorities and requirements are specified by various topical decrees including the Radiation Protection Decree; the Import, Export and Transit Decree; and, the Fissionable Materials, Ores and Radioactive Materials Transport Decree. The transport of radioactive materials by road, rail, air, and waterborne modes is regulated in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6) and the relevant modal instruments (ADR, RID, ICAO, ADN and IMDG).

Under the Ministry of Economic Affairs, NIV and RVO regulate the transport of radioactive material through the assessment of applications for transportation licences and the associated technical documentation for licensing. NIV licences transport associated with nuclear reactors including the transport of fresh and spent nuclear fuel as well as the transport of fresh and irradiated targets. Likewise, RVO licences radioactive material transport for nonnuclear activities and fuel cycle-related activities. Licences may be issued to the Consigner, the Carrier or the Consignee and any one of these licensed parties is required to be the licensee of record for a particular shipment taking sole responsibility for ensuring that the transportation of radioactive material is accomplished safe and in compliance with applicable regulatory requirements.

In general, the authorization process for licensing the transportation of radioactive material takes a graded approach. Specific authorization is required for the shipment of all fissionable materials, including fissile materials, radiopharmaceuticals, certain consumer goods, and shipments requiring special arrangements (regulatory exemptions). Other shipments of radioactive materials only require prior notification of the appropriate regulatory body depending on the form and quantity of radioactive material involved and the transport mode being used for the shipment. Two exceptions to the graded approach were noted where the transportation of depleted uranium requires a licence whereas the transport of a high activity sealed source only requires notification. It was noted that the latter example will soon change so that all high activity sealed source shipments will require a licence, rather than notification.

Both RVO and NIV make transport licence applications and supporting guidance material publically available to prospective applicants via the internet. All aspects relevant for the safety of the shipment must be included in the documents submitted in approval request. The transport application documents are reviewed for conformance with the requirements of the Nuclear Energy Act, topical decrees and review guidance. NIV provides guidance describing the information to be submitted with the application on line and as appropriate is incorporated in the application. Some guidance for completion of RVO transport licences applications is contained in the application form and an additional guidance brochure is under development by RVO and NIV staff and is scheduled for publication in 2015. Applications can be made electronically using dynamic PDF or PDF forms. Safety documentation submitted by an applicant is compared with legal requirements for the design of type-approval and shipment. Licences incorporate documents and procedures submitted with the application as a legally binding component of the licence. Radioactive transport licences are processed in accordance with the Netherlands General Administrative Act.

Regulatory provisions exist and are implemented by NIV to license special arrangement shipments of radioactive material when unique circumstances exist that would prevent compliance with existing transportation requirements. NIV reviews the justification for exemptions from specific regulatory requirements and, taking the form and quantity of radioactive material involved into consideration, issues a new short term transport licence with special conditions to provide an equivalent level of nuclear and radiation safety during the shipment.

Independent interviews of the RVO and NIV licensing staff as well as of KFD inspection staffs revealed the existence of organisational policy barriers that prohibit technical discussions at the staff level between the inspection and licensing groups. Recommendation 7 in Section 3 addresses this issue.

5.9. SUMMARY

The IRRS team concludes that the authorization process in the Netherlands covers all the major life stages of nuclear installations and is supported by a comprehensive legal framework. It implements a graded approach and benefits of an extensive transparency policy. The administrative bodies involved in delivering authorization are related to their domain of competency provided by the regulatory framework.

Due to the small number of nuclear facilities and their variety the regulatory body has chosen not to develop a general regulatory framework and prefers to specify precise safety requirements in the individual licences (so-called "Dutch approach"). The IRRS team recommends the regulatory body to enhance the consistency of different operating licences by using similar reference documents in the licences of all nuclear facilities. The regulatory body has been pro-active by organising an informal pre-licensing phase with applicants of nuclear facilities, which is considered a commendable practice by the IRRS team.

A programme that identifies the necessary steps for research, site selection, design, construction, commissioning, operation, closure and post-closure of the disposal facility would facilitate the further implementation of the national waste management strategy. This would contribute to avoiding undue burdens on future generations and to making effective use of the current knowledge about radioactive waste management in the Netherlands.

Decommissioning is seen as a distinct phase in the facility lifecycle and requires authorisation by the regulatory body. This is effected as a modification/amendment of the operating licence.

For radioactive sources, a graded approach is applied through the concepts of exemption, notification and authorization. The IRRS team suggests to extend the national register to include all authorized radiation sources in the Netherlands. The regulatory body should also consider extending the scope of authorisation to include the Import/Export of high activity sealed radiation sources.

The IRRS team concludes that transport of radioactive material in the Netherlands is well established and an appropriate governmental, legal and regulatory framework for the safety of transport of radioactive material is in place.

6. REVIEW AND ASSESSMENT

6.8. REVIEW AND ASSESSMENT FOR TRANSPORT

The review and assessment of transport activities in the Netherlands is carried out using mode specific requirements found in the appropriate regulations. These regulations implement the applicable IAEA TS-R-1 modal (ADR, RID, ICAO and IMDG) requirements.

Currently, radioactive material packages in use in the Netherlands that require review are designed and manufactured in other countries, and accordingly are approved by the Competent Authority in that country. No application for a new-package design review, for a package of Dutch origin, has been received in the past ten years. In 2013, RVO validated 17 package designs for radioactive shipments that originated from non-ADR states. NIV performs the design review of foreign packages for use within the Netherlands, but there is limited experience in conducting new-package design reviews. In 2013, NIV validated five package designs for radioactive shipments that originated from non-ADR states.

The NIV is aware of the plans of a Dutch reactor operator to submit the design of a new nuclear package for design approval in the near future, and it is developing procedures for the submission and review of the new-package design. NIV is also working to identify a competent technical support organization (TSO) to assist with the detailed design and engineering review should a new-package design be submitted for approval.

Under the Nuclear Energy Act, NIV is responsible for maintaining national regulations for the safe transport of radioactive materials and ensuring they remain up-to-date. NIV consults with the appropriate mode-specific policy makers within the Ministry of Infrastructure and Environment in the development and review of proposed revisions. The final publication of new and revised rules is the responsibility of the Ministry of Infrastructure and Environment.

Applications for a transport licence can be created electronically using dynamic PDF or PDF forms. NIV provides guidance describing the information to be submitted with the application on line and as appropriate is incorporated into the application. Some guidance for completion of RVO transport licence applications is contained in the application form. An additional guidance brochure is under development by RVO and NIV and is scheduled for publication in 2015.

Safety documentation submitted by an applicant is compared with legal requirements for the design of type-approval and shipment. Licences for the shipment of radioactive materials are processed and issued in accordance with the Netherlands General Administrative Act.

6.9. SUMMARY

The NIV and KFD are both involved in review and assessment within their administrative field of competency. The inclusion of new requirements for existing installations is done through licence updates which entail a complete review of the requirements or through licence modifications that deal with updating requirements related to what might be encompassed by a given modification of licence conditions.

Some licence requirements are not fully consistent across the different installations due to the infrequent licence revisions and differences in the availability of regulatory reference documents for the different nuclear installations.

Proposed modifications in facilities are categorized according to their safety significance. The prioritization is made by the management of KFD, the general goal is to manage demands in predefined periods as far as practicable. Each significant activity is organized and managed on a project based approach.

Deliverables of the review and assessment are verified by the use of the “four eye principle” which requires that a document compiled by one person is validated by another. The quality will be further improved if the regulatory body finalizes and publishes the “Dutch Licensing Policy”, “Organisational Review Plan” and “Technical Review Plan”. It should also cover all types of facilities and all stages in the life time of facilities.

Review and assessment of research reactors, fuel cycle facilities, waste management facilities and radiation sources facilities follows the general review and assessment practices. The regulatory body should consider that the regulatory framework for decommissioning includes consideration of requirements related to safety aspects and financial resources if deferred dismantling has been selected.

7. INSPECTION

7.8. INSPECTION OF TRANSPORT

Radioactive material transport inspections are planned, performed and assessed to determine transport licensee compliance with the Nuclear Energy Act and the appropriate topical decrees.

The ILT exercises regulatory oversight over for Class 7 (Radioactive Materials) transport. These ILT inspection departments have the following roles in the oversight effort:

Inspection Departments	Role
Nuclear Safety, Security, and Safeguards (KFD)	Public & Environmental Protection
The Rail and Road Transport Inspectorate	Road (ADR)
The Rail and Road Transport Inspectorate	Rail (RID)
The Netherlands Civil Aviation Authority	Air (ICAO)
The Netherlands Shipping Inspectorate	Maritime & Inland Water (IMDG/ADN)

In addition, ISZW has the authority for inspecting the occupational radiation protection component of radioactive materials transport licensee programs. However, radioactive material transport is viewed as a low risk activity and consistent with a graded approach, ISZW does not routinely inspect radioactive material transport occupational exposure programs.

In general, the scope of the regulatory inspections corresponds to the potential risks posed by the shipment. All planned inspections are focused on the compliance of the shipment with the relevant provisions of the transport licence and with the appropriate mode-specific regulations. Reactive inspections are performed when, in the judgment of the cognizant inspection component, an abnormal occurrence requires immediate investigation or if there are concerns about the licensee's capability to implement the appropriate corrective actions in response to an event.

In 2013 and 2014, the KFD met or surpassed its goal for the number of completed Class 7 inspections. The mode-specific transport inspection departments surpassed their goal in 2013, however in 2014, the mode-specific transport inspection departments only accomplished 20% of the number of planned Class7 inspections.

However, the Netherlands Shipping Inspectorate component of ILT has not conducted any inspections of maritime Class 7 (Radioactive Materials) transport shipments since sometime in 2011 or 2012. Several factors contributed to the decision to not perform any maritime Class 7 and to perform less mode-specific transport inspections than planned inspections including a shortage of operational transportation inspectors qualified and available to perform Class 7 inspections and exigent circumstances that diverted the qualified Class 7 maritime inspection staff to perform other inspections.

The IRRS team observed that the ILT inspection program evaluates the licensee's compliance with the conditions of their licence, including emergency preparedness specific to transportation, physical protection arrangements, driver fitness for duty, stowage during carriage, and the possession of required transport documents. The extent of the ILT inspection program is not based on a systematic analysis of the target group of authorised parties and number and type of transport operations. These issues are addressed in recommendation 14 in subsection 7.1.1.

Upon the completion of a transportation inspection, ILT inspectors provide the licensee's management with a summary of the results of the inspection, including any violations noted. KFD inspection records are maintained in the HOLMES registration system whereas other ILT inspection records are maintained on other various data systems.

The KFD began to use detailed inspection procedures in July 2014. These procedures have to be completed (see suggestion 9 in subsection 7.1.1). Inspector feedback on the new inspection guidance is gathered during periodic inspection staff meetings. RID and ADR inspectors that conduct transportation inspections on rail and road modes are provided a ruggedized computer loaded with inspection guidance and documentation software and equipped with remote wireless access to various databases.

Some delays in the production of inspection reports were reported by KFD.

If an inspection should identify one of more violations, ILT inspectors document the findings and notify the licensee of the violation in writing. Licensees are required to notify the ILT of the actions taken to correct the violations and to prevent their future recurrence. Inspectors (only so-called BOA's) are authorized to issue citations including fines. All inspectors have the authority to suspend a shipment and prevent its movement until violations have been corrected.

7.9. SUMMARY

The regulatory body has a large scope of inspection responsibilities given the diversity of nuclear and radiation facilities and activities. As a result of its review, the IRRS Team identified items that led to recommendations and suggestions as summarized below:

– The regulatory body should implement an inspection planning process that will include prioritization of planned inspections, cover adequate sample of regulated activities and facilities, type of inspections (scheduled and reactive, and announced and unannounced), frequency of inspections and areas and programmes to be inspected.

- KFD has general inspection guidance which defines the basic inspection process. However, this guidance is not plant or inspection theme/scope specific and it did not provide sufficient detail guidance to enable a systematic and consistent approach to inspection.
- KFD has the HOLMES system to capture and track inspection data. However, the ARM and the IRRS team found that use of this system is inconsistent. The IRRS team noted that this issue is partially addressed by the KFD action plan.

Overall, there are potential improvements identified by the IRRS team and by the regulatory body via its self-assessment. The regulatory body has proactively developed an action plan that addresses many of the issues.

9. REGULATIONS AND GUIDES

9.6. REGULATIONS AND GUIDES FOR TRANSPORT

Requirements of IAEA Transport Regulations (TS-R-1 / SSR-6) are implemented in the Dutch legislation. The Netherlands is represented in the IAEA Transport Safety Committee (TRANSSC), the UN committees responsible for the UN Model Regulations (Orange book) and the committees for the Modal Transport Regulations. IAEA advisory material for the IAEA Transport Regulations and guidance material are used for emergency response for incidents/accidents occurring during the transport. The use of the Package Design Safety Report Guide, established by the European Association of Competent Authorities is promoted. In the Netherlands, like other European countries, the international transport regulations are applied to the transport of all radioactive sources covering all modes of transport.

9.7. SUMMARY

The regulatory framework of Netherlands is in general structured at the higher level to provide a legal basis to its processes. However, absence of detailed regulatory guides make the regulatory body rely heavily on the licensing requirements. The regulatory body does not have detailed guides for its other processes also like inspection, etc. The regulatory body does not have a policy in place for the periodic revision of its existing regulations, which it intends to do in future every 5 years.

The regulatory framework for decommissioning needs to be strengthened specifically related to making financial provisions decommissioning of radiation facilities, requirements on the end state of decommissioning, termination of the authorization for decommissioning and on the release of the facility and/or site from regulatory control etc.

A2.14 POLAND

IAEA-NS-IRRS-2013/02

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO POLAND

Warsaw, Poland 15-25 April 2013

11. TAILORED MODULE FOR COUNTRIES EMBARKING ON NUCLEAR POWER (SSG-16)

11.2 CONSIDERATION OF ELEMENTS OF SSG-16

11.2.18 SSG-16 Element 19 Transport Safety

With respect to transport safety, PAA already had established the requirements for transport as contained in the ALA and implementing Regulation of the Council of Ministers of 20 February 2007 on the terms for import into the territory of the Republic of Poland, export from the territory of the Republic of Poland and transit through this territory of nuclear materials, radioactive sources and equipment containing such sources. Further, Poland has implemented into the national legal system, transport regulations in TS-R-1 through the ADR, RID, IMDG, and ICAO technical instructions. In addition, PAA participates in international activities such as being a corresponding member of IAEA TRANSSC committee. PAA also attends meetings of the Standing Working Group on Safe Transport of Radioactive Material (SWG).

The IRRS team concluded that Poland appears to be consistent with the expectations of SSG-16.

A2.15 ROMANIA

IAEA-NS-IRRS-2011/01

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO ROMANIA

Bucharest, Romania, 17 to 28 January 2011

Note: There was a follow up mission in 2017, but this mission report has not yet been published

11. TRANSPORT OF RADIOACTIVE MATERIAL

11.1. INTRODUCTION AND BACKGROUND

The transport of radioactive material in Romania is well established and a legislative infrastructure is in place to protect people and the environment. The main categories of radioactive materials transported in Romania are: a) radioactive waste, treated, packaged and transported to the National Repository, Baita b) uranium ore from the Crucea Mine to the Processing Uranium Ore Plant, Feldioara; c) uranium concentrate from Feldioara to the CANDU Nuclear Fuel Plant, Pitesti; d) fresh CANDU nuclear fuel from Pitesti to the NPP CANDU Cernavoda; e) spent nuclear fuel (SNF) from NPP Kozloduy (Bulgaria) to Ukraine (Russian Federation) and WWER fresh nuclear fuel from Russian Federation to Kozloduy NPP (Bulgaria),via the River Danube, trans-boundary transport; f) radioactive sources used for industrial purposes for example in irradiation facilities, industrial radiography, well-logging and in portable gauges ; g) radioactive sources used in nuclear medicine facilities (diagnostic and therapeutic) and for educational and research purposes.

The activity of the radioactive sources ranges from very low quantities to large quantities which are shipped by various modes of transport, i.e. road, rail, air (no internal flights), and inland waterways (Danube River). There has been no transport by sea and none is scheduled in the near future. Radioactive material is shipped in excepted packages, industrial packages, Type A packages and Type B packages which are of Romanian or external origin.

The National Commission for Nuclear Activities Control - CNCAN (Comisia Nationala pentru Controlul Activitatilor Nucleare) - is the nuclear safety authority of Romania, responsible for the regulation, licensing and control of nuclear activities, ensuring the peaceful use of nuclear energy and the protection of the public and workers from the harmful effects of ionising radiation. CNCAN elaborates the strategy and the policies for regulation, licensing and control with regard to nuclear safety, radiological safety, non-proliferation of nuclear weapons, physical protection of nuclear installations and materials, transport of radioactive materials and safe management of radioactive waste and spent fuel, as part of the National Strategy for the development of the nuclear sector. CNCAN reports to the Prime Minister, through the General Secretary of the Government.

The work of the CNAN in the area of transport of radioactive material among other items includes the assessment of applications and the associated technical documentation for licensing, assessment of applications and associated technical documentation for issuing of type approval certificates for packages type B(U), B(M) and fissile material, verification and validation of type approval certificates for different package types (Type B(M), Type C and fissile material), inspection of facilities and enforcement as required.

The review undertaken for transport safety as part of this IRRS mission was based upon the information provided by CNAN staff through the IAEA Self Assessment Tool, presentations, reports, interactions, discussions and visits to representative facilities. It is a follow-up mission to a previous IRRS mission held in January 2006 where transport was also included in the scope.

11.2. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES IN TRANSPORT

A comprehensive and sound legislative/governmental regulatory structure clearly exists defining the responsibilities of CNCAN in regulating the safe transport of radioactive material in Romania.

CNCAN Controls the implementation of the provisions of international treaties and agreements in force, with regard to safeguards, physical protection, illicit trafficking, transport of nuclear and radioactive materials, radiation protection, quality assurance in the nuclear field, nuclear safety, safe management of spent fuel and radioactive waste, and the intervention in case of nuclear accident.

The principal regulations for the safe transport of radioactive material in Romania are:

- Law No. 111/1996 which is the fundamental law regarding the safe deployment of nuclear activities; and Order No. 357/ 2005 published in the Official Bulletin of Romania No. 1152 of 20 December 2005 (NTR-01) approving the Norms on the transport of radioactive materials.
- Order No. 443/2008 published in the Official Bulletin of Romania No.797 of 27 November 2008 (NDR-06) approving the Norms on the supervision and control of international shipments of radioactive waste and spent fuel involving the Romanian territory.

This norm applies to the transport of radioactive materials by all transport modes: on road, water and in the air and which involve radioactive materials, including transport which is incidental to the use of the radioactive material. Transport comprises all operations and conditions associated with and involved in the movement of radioactive material. These include the design, manufacture, maintenance and repair of packaging, the preparation, handling, loading, shipment, transport including temporary storage, unloading and receipt at the final destination of radioactive material and packages. Romania has legally adopted the various conventions and thereby the corresponding modal agreements for the safe transport of dangerous goods (ADR, RID, ICAO-TI, and the IMDG-Code). The Standard document for the shipment of sealed sources between Member States of the European Union pursuant to Council Regulation No. 1493/93 is also used in practice. There is also evidence that there is co-operation regarding regulator to regulator consent for the shipment of IAEA Category 1 and 2 sources under the IAEA Code of Conduct for the shipment of these sources. The European Directive 2006/117 Euratom on shipment of radioactive waste and spent fuel is also applied in practice.

Noting recommendation R62 from the IRRS Mission 2006 that the cooperation with the Ministry of Transport and Infrastructure should be enhanced and formalized it acknowledged that steps to enhance the co-operation with the Ministry of Transport, Buildings and Tourism have been initiated by CNCAN.

Conclusion

Based on a review on the information provided, the legislative and statutory framework established to regulate the transport of radioactive material is comprehensive and covers the relevant modes of transport.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part 1 Section 2, 2.18 states that “The government shall ensure that there is appropriate coordination of and liaison between the various authorities concerned in areas such as: safety in the transport of dangerous goods, including nuclear material and radioactive material.”
R34	Recommendation: CNCAN should enhance and rejuvenate co-operation with the Ministry of Transport and Infrastructure at the highest level.

11.3. REGULATORY BODY RESPONSIBILITIES AND FUNCTIONS

For an introduction to the regulatory body responsibilities and functions, please refer to section 1.3 and section 3.0 of this report. Radiological safety standards applicable to the transport of radioactive material in the State are issued by CNCAN, in accordance with the provisions set in Article 5 of the Law. CNCAN is responsible for the publication and periodic revision of national regulations for safe transport of radioactive material. National regulations are revised and updated in consultation with relevant stakeholders as appropriate, when the international regulations (TS-R-1) are revised.

CNCAN is responsible for assuring compliance with the regulations for safe transport of radioactive material. The compliance assurance programme developed and implemented includes:

- the assessment of technical documentation in order to issue the validation of the type approval certificate for a particular package design
- the assessment of technical documentation and the inspection of the design and testing of the packages in order to issue the type approval certificate

- the assessment of technical documentation and inspections in order to issue the transport authorization
- the assessment of technical documentation and inspections in order to issue shipment certificates
- the assessment of technical documentation and inspections in order to issue the shipment certificate for special arrangements
- the assessment of technical documentation and inspections in order to approve the radiation protection programme for special use vessels

The key functions of CNCAN includes the issue of approvals required in TS-R- 1 (2005) and the inspection of premises and conveyances associated with the safe transport of radioactive material.

In the area of international cooperation and exchange of information, CNCAN maintains relations with a number of nuclear regulatory authorities and organisations worldwide, through bilateral arrangements and commitments under international conventions in the nuclear field. The international activities in which CNCAN is involved include the participation in the activities of WENRA and its technical working groups, the annual meetings of the Senior Regulators from countries that operate CANDU NPPs, the biannual meetings of the European High Level Group on Nuclear Safety and Waste Management (ENSREG) and its working groups, the contribution to the initiatives at European Union level and the participation in various IAEA activities. CNCAN also participates, as observer, in the annual session of the Nuclear Law Committee (NLC) of the NEA/OECD (Nuclear Energy Agency of the Organisation for Economic Co-operation and Development). Since 2010, CNCAN has been accepted as an observer in the CNRA (Committee of Nuclear Regulatory Activities) and CSNI (Committee on the Safety of Nuclear Installations) committees of NEA/OECD.

CNCAN liaises with regulatory bodies in other countries and takes part in the meetings of the European Association of Competent Authorities for the Safe Transport of Radioactive Material. Experts from Romania have also attended IAEA TRANSSC meetings in the past and this should be continued. There are general collaborations between CNCAN and similar bodies of other countries particularly the Russian Federation that also affect the activities carried out by CNCAN regarding transport. There are no exclusive formal agreements on transport-related subjects. Nevertheless, CNCAN has collaborated in a case-by-case basis with the regulatory bodies of other countries in transport package approval processes.

A review of NTR-01 indicates that the practical methodologies/guidance is available in the annex; however no supporting guidance documents are available or have been adopted with respect to the transport of radioactive material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part 1, Section 4, Paragraph 4.61 states that “The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides.”
S15	Suggestion: CNCAN should consider adopting international best practice safety guidance relating to the transport of radioactive material.

11.4. ORGANIZATION OF THE REGULATORY BODY

For detailed information on the organizational structure of the regulatory body and allocation of resources, reference should be made to section 3.1 of this report. The staff members working on transport of radioactive material are in the Unit (compartment) for Radiological Protection and Radioactive Waste Management (one staff member) (duties relate to fresh and spent fuel, high activity sealed radioactive sources and carriers) and in the Unit for Safeguards, Transport and Physical Protection (one staff member) (mining), both of which are part of the Nuclear Fuel Cycle Division. This Division is one of three Divisions part of the General Division for the Regulation, Licensing and Inspection of Nuclear Activities. There are two staff members covering transport (industrial, medical, and many other responsibilities) in the Radiological installations and source Licensing/ inspection Division. Recommendation R63 from the IRRS Mission 2006 „CNCAN should evaluate its responsibilities it has for transport safety, define an appropriate staffing level and if necessary adjust the distribution of staff among the division/branch in order to ensure the specialist transport staff work in one team.. It was also reported that currently the resources for transport of radioactive and nuclear material are considered appropriate. The proposed suggestion in this area has been incorporated in the general recommendation on resources in section 3.1.

11.5. AUTHORIZATION PROCESS, REVIEW AND ASSESSMENT

The licensing system is administered by CNCAN in cooperation with other governmental authorities (ministries and agencies) in such areas as environment, health, transport, labour, security, etc. The issues raised by these authorities are taken into account before licenses are issued by CNCAN, providing that there is no conflict with the provisions of the Law and CNCAN regulations. All other licenses granted by other governmental authorities are prerequisites to the CNCAN licenses. An exception would be the environmental authorisation issued by the Ministry of Environment and Forests after the issuance of the operation license by CNCAN. The environmental agreement, issued by the same Ministry is however a prerequisite to the siting license issued by CNCAN.

The Law gives a list of authorities having attributions in controlling various aspects related to nuclear activities. Although their attributions and responsibilities are established by the legislation, CNCAN has also signed formal Memoranda of Understanding with each of these organisations, for ensuring the prevention of potential gaps and overlaps in the implementation of their respective duties and responsibilities. For ensuring transparency of its activities and decision making process, CNCAN routinely consults with and ensures information of all the organisations that have an interest in its regulatory activities, including licensees and other nuclear industry representatives, governmental, local and municipal authorities, departments and agencies as well as interest groups and individual members of the public.

The approval/authorisation requirements for transport activities are clearly specified in Chapter VIII of Order No 357/ 2005 (NTR-01). General provisions are outlined in Article 801, 802 and 803. CNCAN approval / authorization is required for the following:

a) The transport activity for the radioactive materials (see Articles 804, 805, 806)

b) Designs for:

  i. Special form radioactive material (Articles 807, 808 and 818);

  ii. low dispersible radioactive material (Articles 807 & 808);

  iii. packages containing 0.1 kg or more of uranium hexafluoride (see Articles 810, 811)

  iv. all packages containing fissile material unless excepted by para. 672 (see Articles 813, 816, 817, 820)

  v. Type B(U) packages and Type B(M) packages (see Articles 810, 813, 816, 817, 820)

  vi. Type C packages (see Article 812);

c) Special arrangements (see Articles 822-823)

d) Certain shipment of radioactive materials (see Articles 820, 821)

e) Radiation protection programme for special use vessels (see Article 575 a))

f) Calculation of radionuclide values that are not listed in Table I (see Article 402).

The request for approvals/authorizations to CNCAN is undertaken in accordance with the provisions included in Annex No. 2 to norm NTR-01. CNCAN issues five types of approval certificates: for special form radioactive material, for low dispersible radioactive material, for special arrangement, shipment and package design. It also indicates in the package design approval certificate that the design meets the specific requirements and gives it an identification mark according to Article 825.

A detailed authorization methodology of the transport activity is provided in Annex No 2 of NTR-01. These articles present what information is required to be submitted to CNCAN and in what format. Details of the technical documentation and specific information required for various scenarios (for example, special arrangements, package design, shipment authorization, re-authorization or extension of validity etc) are also presented.

Guidelines on the content of the transport authorization and of approval certificates are provided in Annex No. 3 of NTR-01. This includes specific details of what each authorization includes, for example, identification mark, list of regulations, date of entry into force and expiry, conditions imposed and any potential restrictions on modes of transport, personnel with responsibilities, UN numbers, design specifications etc.

The authorization process as outlined essentially reflects the IAEA Regulations for the Safe Transport of Radioactive Material. It is clear that the requirements and controls for transport as specified in NTR-01 generally reflect the requirements specified in the relevant provisions of the IAEA TS-R-1.

Based on the information provided, the review and assessment process of the regulatory body to regulate the transport of radioactive material is in general satisfactory. Any suggestions other than those presented have been incorporated into sections 5.1 and 6.1 of this report.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: TS-R-1 2009 Edition, 308 states that "The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the Basic Safety Standards."
S16	Suggestion: CNCAN should consider performing a periodic assessment of the radiation doses received by persons involved in the transport of radioactive material, to ensure that the system of protection and safety complies with the provisions within the Fundamental Norms on Radiological Safety and of the applicable relevant norms on nuclear safety as well as the IAEA TS-R-1.

11.6. INSPECTION AND ENFORCEMENT

For background information on inspection and enforcement, refer to section 7.1 and 8.1.

The transport related inspections performed by CNCAN include:

- Scheduled inspections, planned and performed either by each of the technical divisions;
- Pre-authorization / licensing inspections;
- unscheduled and/or unannounced inspections, some of these being reactive inspections, in response to incidents;
- Transit inspections at the borders only.

Recommendation R65 from the IRRS Mission in 2006 indicated that .CNCAN should develop and implement a systematic inspection plan for the transport, in order to assure compliance with the relevant transport regulations.. The subsequent reported analysis of this showed that the establishment of an inspection plan was more efficient if undertaken in accordance with the varied schedule of transports, and authorization requests received. Recommendation R63 from the IRRS Mission 2006 indicated that .CNCAN should evaluate its responsibilities it has for transport safety, define an appropriate staffing level and if necessary adjust the distribution of staff among the division/branch in order to ensure the specialist transport staff work in one team.. It was also reported that currently the resources for transport of radioactive and nuclear material are considered appropriate.

While there is no specifically planned inspection programme, inspections are undertaken based on the number of transport authorizations received. It is also a licence or authorization condition that the licensee must notify CNCAN at least 72 hours in advance of the date of entry into Romanian territory of any shipment of high activity sealed radioactive material, fresh or spent fuel so that CNCAN experts can escort the shipments. There are typically up to 10 of these escorts per year. Twenty transport related inspections were undertaken in 2010 covering new authorizations (industrial, pharmaceutical, foreign carriers, and fresh nuclear fuel), modifications to existing authorizations (industrial ¡V relating to personnel and vehicles), inspection of fresh fuel transport by inland waterway and an in-transit inspection of high activity radioactive sources being transported across Romania. Inspections typically take about 1 day but some regarding inland waterway shipments can take several days.

During a site visit to and observation of a partial inspection of the Oncological Institute, it was noted from discussions with staff that arrangements in place for the transport of sources used in brachytherapy, nuclear medicine, iodine therapy and teletherapy are consistent with requirements of IAEA TS-R-1 and the Romanian Transport Norm NTR-01.

A second inspection was also observed at the National Institute for Physics and Nuclear Engineering. The Waste Management department facilitates the packaging and transport of disused radioactive sources from industrial and medical licensees to the storage facility in Magurele. The inspection of the relevant authorizations, documentation and vehicles approved for transport was well structured using a standard control check-list. All documentation was readily available by the facility and the designated drivers. Overall, the inspection was undertaken in a professional manner covering all the required items under the ADR and the transport NORM.

Any suggestions raised in this section have been incorporated into section 7.1 (Inspections). While there is an enforcement system in place, it has not been necessary to undertake any enforcement measures in the transport area to date. Further information on enforcement is presented in section 8.1.

11.7. DEVELOPMENT OF REGULATIONS AND GUIDES

CNCAN is empowered by Law to develop regulations in order to detail the general legal requirements as well as any other regulations necessary to support the licensing and control activities. The ordinary Law 24/2000, republished in 2010, on "Legislative technique for elaboration of the normative acts" and the Governmental Decision HG 561/2009 on the approval of the Regulation regarding the procedures for elaboration of public policy documents, establish the general provisions, technical rules and administrative procedures for the development of all Romanian regulations (normative acts). All the regulations issued by CNCAN are mandatory and enforceable. The regulations are developed in observance of relevant international standards and good practices. Various sources of information relevant for updating the system of regulations and guides are used, including international cooperation as well as feedback from the operators and from CNCAN inspectors based on their experience from the enforcement of the regulations.

While the definition of „regulations. in the Law (definition 24) includes „the technical, methodological rules, guidebooks, instructions, procedures or technical-organizational conditions concerning the authorization and control of nuclear activities, that are mandatory in the nuclear field, issued by the competent authority under Article 5 of the law. and noting that methodologies for authorization for various transport activities are given in Annex 2 of NTR-01, there are no specific guidance documents for example on compliance assurance for the safe transport of radioactive material, the management system for the safe transport of radioactive material, radiation protection programmes applicable to transport, approval of packages not requiring competent authority approval, security in the transport of radioactive material, planning and preparing for emergency response to transport accidents involving radioactive material etc for CNCAN staff, licensees, or stakeholders.

Any suggestions or recommendations arising from this section have been incorporated into section 9.1.

11.8. EMERGENCY PREPAREDNESS FOR TRANSPORT

For detailed background information on emergency preparedness refer to section 10.1. The Ministry of Transport and infrastructure has issued an emergency guide through the Romanian Road Authority regarding the intervention in case of a transport accident involving dangerous goods. This guide considers all nine classes of dangerous goods including radioactive material, i.e. Class 7. The guide covers the first measures after an accident. Accidents/incidents have to be reported to the Emergency Center.

It is also noted in Article 10 of NTR-01 that a radiation protection programme (including and intervention plan) applicable to the transport activity must be submitted as part of the technical documentation associated with the authorization. This requirement is also included in shipment certificates.

In the event of accidents or incidents during the transport of radioactive material, emergency provisions are in place to protect persons, property and the environment in accordance with the provisions of NTR-01, Articles 308-310. Adequate preparations have been established and maintained at a local and national level to respond to emergencies relating to the transport of radioactive material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	TS-R-1(2009), 305 states that "Emergency procedures shall take into account the formation of other dangerous substances that may result from the reaction between the contents of a consignment and the environment in the event of an accident."
S17	Suggestion: CNACN should consider establishing in consultation with relevant licensees a systematic method for conducting transport emergency drills or exercises periodically.

11.9. MANAGEMENT SYSTEMS FOR REGULATORY BODIES

CNCAN has established and implemented a Management System in accordance with the EN ISO 9001:2008 requirements and is currently revising it in order to implement the requirements in the IAEA GS-R-3 standard. The Management Manual of CNCAN describes the policies with regard to the regulation, licensing and control activities, the strategic objectives and plans, the interfaces at national and international level, the responsibilities of the organisational units of CNCAN, the mechanisms for measuring, evaluating and improving the effectiveness and efficiency of the regulatory activities, etc. It also provides a set of general requirements applicable to the performance of activities within all organisational units and the specific requirements applicable to the assessment and inspection activities performed by the technical divisions. The more detailed requirements and criteria are set in the procedures defining the various regulatory processes. In order to ensure the adequate implementation and improvement of the management system, the relevant procedures are sent for review and approval to all the divisions and departments. The Management Manual and all the internal procedures are available in electronic format on the local area network.

The management system manual of CNCAN is currently being reviewed and revised with external support from experts contracted under the IAEA Extra Budgetary Programme funded by CNCAN and NRPA (the regulatory body of Norway) in order to provide for alignment with the requirements in the IAEA GS-R-3 safety standard.

While for the most part a compliance assurance programme based on international, national or other standards acceptable to the competent authority has been established and implemented for Type A, Industrial, Type B(U) and fissile packages to ensure compliance with the relevant provisions of the regulations, there are no such programmes in place for the testing, inspection and documentation in respect of all special form radioactive material, low dispersible radioactive material and packages; use, maintenance and inspection of all packages; transport and temporary storage operations;

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part 1, Requirement 19 states that “The regulatory body shall establish, implement and assess and improve a management system that is aligned with its safety goals and contributes to their achievement.”
S18	Suggestion: The revision of the current management system should also take into account the topics set out in the current IAEA Safety Guide on the Management System for the Safe Transport of Radioactive Material (IAEA No TS-G-1.4) and the current IAEA Safety Guide on Compliance Assurance for the Safe Transport of Radioactive Material (IAEA No TS-G-1.5).

A2.16 SLOVENIA

IAEA-NS-IRRS-2011/05

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO THE REPUBLIC OF SLOVENIA

Ljubljana, Republic of Slovenia, 25 September to 4 October 2011

IAEA-NS-IRRS-2014/04

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION TO THE REPUBLIC OF SLOVENIA

Ljubljana, Republic of Slovenia, 9 to 16 September 2014

11. TRANSPORT OF RADIOACTIVE MATERIALS

The 29th of July 2011 the Ionizing Radiation Protection and Nuclear Safety Act (ZVISJV) articles 9 and 11 was amended so that transport of radioactive substances now is regulated and controlled as a practice requiring notification and licensing. This is a follow-up of action #27 - #29 in the Self-assessment action plan (Chapter 4 of the Self-Assessment Report, April 2010)

The IRRS team recognises the work still to be done by SNSA to fully integrate transport practices in their licensing and supervision processes but considers this to be a task proving little difficulties taken into account the high performance of their register for practices and support from the licensing process used for licensing of other practices.

The IAEA requirements for the safe transport of radioactive materials as found in TS-R-1 2009 Edition TS-R-1 is implemented in Slovenia through article 3 of the Transport of Dangerous Goods Act, which basically states that applicable international modal regulations shall apply.

These model regulations are internationally harmonized and give little room for “improvisation” on the side of requirements that the consignor, carrier and consignee must follow. However the TS-R-1 also set forth a number of tasks that the Competent Authority (CA) in each country are responsible for and should to be able to do.

Examples of such tasks are (TS-R-1 paragraph in parenthesis): (302) inspection of radiation protection programmes; (306) quality assurance programmes for manufacturing of packaging; (307) establish programmes for compliance assurance; (308) arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material; (309) be part of investigations in instances of non-compliance with the requirements on radiation and contamination levels; (310) approval of transport under special arrangement; (554) receive notification on first shipment of a package requiring CA approval; (555) receive notification for shipments of Type B(U) packages containing radioactive material with an activity greater than 3000A1 or 3000A2, as appropriate, or 1000 TBq, whichever is the lower, Type B(M) packages, shipments under special arrangement; (576) approve radiation protection programmes for Slovenian flagged vessels; (579) be informed and give advice on undeliverable consignment; (802) approve certain types of package designs, (827) issue approval certificates; (834) validate certificates requiring multilateral approval.

The IRRS team found that some of these tasks, notably the requirement on periodic assessment of doses to persons and compliance assurance in general, are shared by other authorities like SRPA, the police and transport authorities. The IRRS team considers it a useful exercise for SNSA together with other concerned authorities to go through the list of CA tasks and clarify, when needed, which authority is responsible for what task, and to find means to communicate this to consignors, carriers and consignees, including updating the list of appointed competent authorities as given in annexes to the international modal regulations.

Being a small organisation with limited resources SNSA benefits from close contact and sharing of information with other CAs within e.g. the European Union and the IAEA. In doing so, the results from other IAEA assessments, like the TRANSAS, can be used for mutual identification of competence and as a reference to establish bilateral agreements which are beneficial for all parties for tasks that involve, e.g. more complex assessments of package designs that have to be validated in many countries. The IRRS team encourages SNSA to continue the cooperation undertaken so far in this area.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: TS-R-1 para. 207 states that “Competent authority shall mean any body or authority designated or otherwise recognized as such for any purpose in connection with these Regulations.”
S28	Suggestion: SNSA should take initiative, together with other concerned authorities, to go through the list of CA tasks and clarify, when needed, which authority is responsible for what task, and to find means to communicate this along with relevant contact information to consignors, carriers and consignees.

11. TRANSPORT OF RADIOACTIVE MATERIALS

2011 mission RECOMMENDATIONS, SUGGESTIONS	
S28	Suggestion: SNSA should take initiative, together with other concerned authorities, to go through the list of CA tasks and clarify, when needed, which authority is responsible for what task, and to find means to communicate this along with relevant contact information to consignors, carriers and consignees.

Changes since the initial IRRS mission

Suggestion 28: Transport of radioactive material is regulated mainly through the Transport of Dangerous Goods Act (ZPNB). ZPNB in Article 3 refers to international regulations and conventions on transport of dangerous goods such as ADR. The Slovenian Ionising Radiation Protection and Nuclear Safety Act (ZVISJV) also covers transportation of nuclear and radioactive materials, which is defined in this Act as a “radiation practice”, therefore requiring licensing and inspection by either SNSA or SRPA (based on their respective jurisdiction).

In response to the suggestion, SNSA, together with the Ministry of Infrastructure and Spatial Planning (in charge of transport), reviewed the allocation of responsibilities assigned by ZPNB and ADR. The agreed outcomes of this review are:

- The assignment of responsibilities in ZPNB is clear, with no overlap and no gap. Unless otherwise specified, the competent authority is the Ministry of Infrastructure and Spatial Planning;
- There is no need to modify significantly the distribution of responsibilities but the roles played by SNSA and SRPA should be emphasized in the ZPNB;
- The only change in responsibilities needed, is the transfer of package approval from the Minister responsible for environment to SNSA, as this responsibility is formally assigned to the Minister responsible for environment, but in practice is discharged by SNSA.

Amendments to ZPNB (articles 7 and 52) have been drafted and agreed by interested parties to reflect these clarifications and changes. These amendments were presented to the IRRS team. It is expected that these amendments will be enacted in the course of 2015.

Licensees performing transport of nuclear and radioactive materials are already informed of these coming amendments. Once enacted, the amended ZPNB will be published in the Official Gazette and the list of Competent Authorities according to ADR will be updated, to better reflect the main roles of SNSA and SRPA, as “other competent authorities”, the “main competent authority” remaining the Ministry of Infrastructure and Spatial Planning. Status of the finding in the initial mission

Suggestion 28 is closed on the basis of progress made and confidence in effective completion as clarifications have been made in the responsibilities of the different competent authorities for transport of radioactive materials, and these clarifications will be reflected within a year through the amendment of the Transport of Dangerous Goods Act.

A2.17 SWEDEN

IAEA-NS-IRRS-2012/01

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION TO SWEDEN

Stockholm, Sweden, 6 to 17 February 2012

IAEA-NS-IRRS-2016/05

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) FOLLOW-UP MISSION TO SWEDEN

Stockholm, Sweden, 25 April-3 May 2016

10. TRANSPORT OF RADIOACTIVE MATERIAL

The transport requirements of IAEA (TS-R-1) are fully implemented in Swedish legislation, although the arrangements are complex.

The Swedish Act on the Transport of Dangerous Goods (2006:263) and its associated Ordinance (2006:311) assigns responsibility to the three main regulatory agencies. The Swedish Transport Agency are responsible for the regulations covering air and sea transport of all dangerous goods including radioactive materials, the Swedish Civil Contingencies Agency are responsible for the regulations for road and rail (they produce a Swedish translation of the European ADR and RID regulations) and the Swedish Radiation Safety Authority are the competent authority for the transport of radioactive material.

The overall structure is shown in the diagram below:

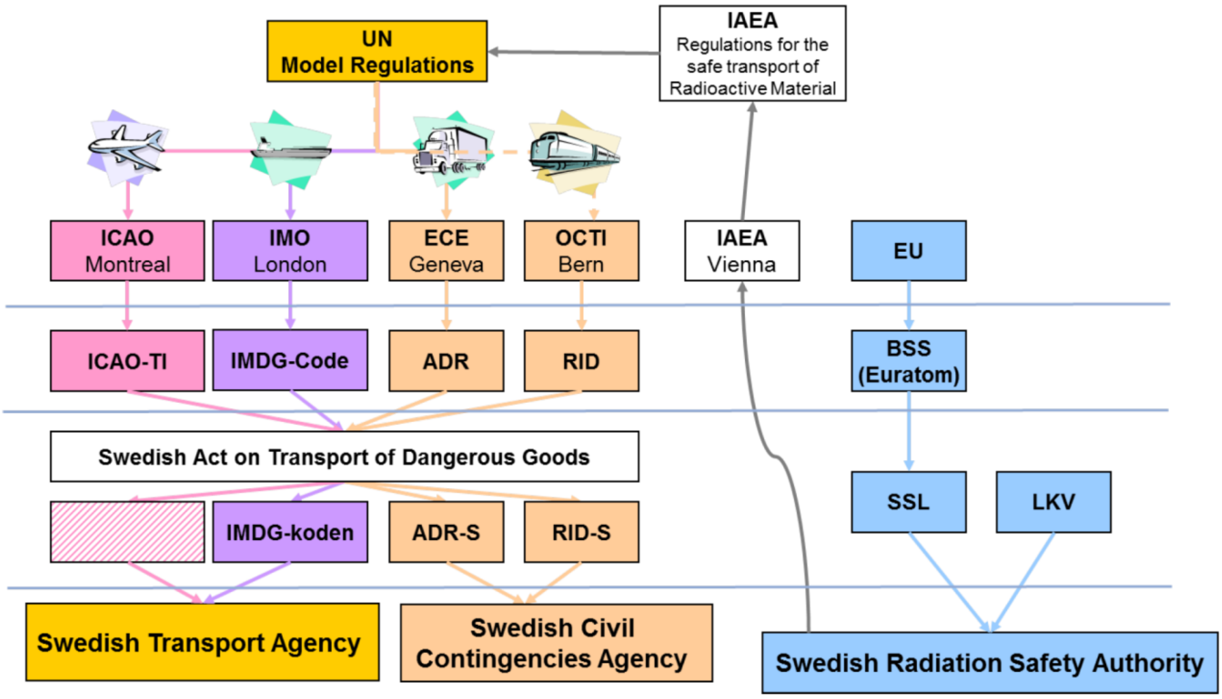


Figure 1
[SSL – Radiation Protection Act (1988:220) / LKV – Act on Nuclear Activities (1984:3)]

The complete list of regulations is:

- Act (1984:3) and Ordinance (1984:14) on Nuclear Activities
- Radiation Protection Act (1988:220) and Ordinance (1988:293)
- Transport of Dangerous Goods Act (2006:263) and Ordinance (2006:311)

- Regulations on transport of dangerous goods by road (MSBFS 2011:1ADR-S) and railway (MSBFS 2011:2 RID-S), sea (TSFS 2009:91 IMDG code) and air (Regulation EC/859/2008 ICAO-TI), i.e. the modal regulations.
- The Act on Nuclear Activities (1984:3) and the Radiation Protection Act (1988:220) require radiation protection and safety in all dealings with such material.

The Radiation Protection Act requires transporters of radioactive material to be licensed when radioactive materials are transported on Swedish territory, or when transiting Swedish territory, or when transporting radioactive materials on a Swedish flagged vessels. LKV requires transporters of nuclear materials to be licensed. Licences are required for radioactive or nuclear materials with SSM being responsible for issuing these licenses. Before a licence is issued SSM reviews the transporter's radiation protection programme and QA arrangements.

SSM are the Competent Authority for package assessments and compliance assessment, which includes inspection work and assisting in emergencies involving transport packages.

SSM are also members of the European Association of Competent Authorities.

10.2. OVERVIEW

The Swedish legislation and regulatory structure is comprehensive but complex, nonetheless there is a clear understanding regarding scope of responsibilities in each authority regarding transport.

Assessment of package designs, as required by TS-R-1, is carried out by SSM. They use a two tier system where packages that come from France, Germany and the UK are given a simplified review, unless the package contains fissile material. For fissile packages from these countries, the fissile aspects are independently verified. For packages from Sweden, or countries not part of ADR, a full review is carried out. The review process follows the IAEA TS-R-1 requirements and uses a safety report format developed with other EU countries. The SSM two tier process is novel and takes full advantage of work carried out by other Competent Authorities, without any reduction in overall safety. This graded methodology could be advantageously used by other competent authorities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: GSR Part 1 Requirement 14 Paragraph 3.2(e) states that "Multilateral and bilateral cooperation that enhances safety by means of harmonized approaches as well as increased quality and effectiveness of safety reviews and inspections."
GP8	Good Practice: SSM assessment of packages takes account of work done by other Competent Authorities. This approach is novel, not widely used elsewhere, helps where resources are limited and maintains safety levels.

For a small number of packages SSM has issued Special Arrangements to allow for their continued use as the certificates of approval are out of date. The required Package Design Safety Reports were not provided to SSM in time by the applicant. Despite issuing a Special Arrangement, SSM did not ask for any compensatory safety measures as required by the IAEA transport safety regulations TS-R-1 and associated guide TS-G-1.1. In similar situations other Competent Authorities issue time limited extensions, provided no significant change has occurred to the overall safety of the package.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	BASIS: TS-R-1 Paragraph 310 states that "Provided the competent authority is satisfied that conformity with the other provisions of these Regulations is impracticable and that the requisite standards of safety established by these Regulations have been demonstrated."
(2)	BASIS: TS-G-1.1 Paragraph 238.1 states that "The use of the 'special arrangement' should not be taken lightly. This type of shipment is intended for those situations where the normal requirements of the Regulations cannot be met."

(3)	BASIS: TS-G-1.1 Paragraph 312.2 states that "… alternative safety measures effectively equivalent to those prescribed in the Regulations."
R16	Recommendation: SSM should only use Special Arrangements as defined in TS-R-1.

All the approval certificates are signed by the Head of the Control and Protections Section but there is no formal authorisation for him to carry out this function. SSM should change its management system to designate the Head of Control and Protection as being the signatory for Competent Authority functions. This suggestion is part of the Recommendation in Module 3.6

The current management system covers the required scope for the regulations but only about half of the working documents have been produced. The remaining documents that describe the processes of the Transport Competent Authority should be completed to ensure a consistent and correctly graded approach is taken. This is now part of the Recommendation in Module 9.4.

The transporters of radioactive packages are aware of the requirement to report incidents/accidents to SSM and the evidence is that this reporting is comprehensive. There are no clear reporting criteria defined by the regulator. SSM should produce clear reporting criteria for transporters of radioactive materials. This is now part of the recommendation discussion documented in Module 9.4.

Compliance inspections are carried out by SSM. The overall process is well documented and thorough using check lists that ensure the appropriate weight is given to the correct regulatory requirements. Intervention reports are produced that record the main outcomes of the inspection. The numbers of inspections completed are low (6-8 per year). SSM are aware of this issue and are trying to introduce more inspections. This is now part of the Recommendation in Module 7.2.1.

10.3. VISIT TO WESTINGHOUSE FUEL FACTORY AT VASTERAS ON 9 FEBRUARY 2012

An IRRS team member accompanied two SSM inspectors to the Westinghouse Fuel Fabrication Plant at Vasteras. This inspection was a paper based review of the Westinghouse QA procedures dealing with the requirements of Paragraph 1.7.3 of ADR on QA arrangements and some other ADR requirements relating to documentation.

The team had a pre-meeting at SSM that involved using documentation that was based on information from the EU Association of Competent Authorities. This document provided a schedule of issues that were dealt with methodically and ensured the inspection team had reviewed all issues before the inspection.

The inspection went well and by adopting a methodical approach the inspectors covered all areas. They identified two work processes where there were no procedures or the ones available were considered inadequate. There was a de-brief meeting with Westinghouse who were made aware that the overall system was considered adequate but work processes required improvement.

This inspection will be followed up with a workplace inspection at a later date.

The inspection was well conducted and covered the relevant areas of the regulations.

5. AUTHORIZATION

5.4. TRANSPORT

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
R16	Recommendation: SSM should only use Special Arrangements as defined in TS-R-1.

Changes since the initial IRRS mission

Recommendation 16: SSM has established new internal guidance STYR2012-6 to address the management of applications for Special Arrangements. This guidance requires compensatory safety measures in case of special arrangements as defined in TS-R-1.

Status of the finding in the initial mission

Recommendation 16 is closed. SSM established guidance, STYR2012-6, on the review of applications for Special Arrangements as defined in TS-R-1.

A3 QUESTIONNAIRES

Due to the size of this section only the blank questionnaire is presented, the completed responses are provided as a separate consolidated file.

Comprehensive examination and analyses of the situation of transport of nuclear materials

Questionnaire to Member States

Introduction

The questionnaire is developed as a “protected” MS Word document that allows answers to be typed only into the designated fields.

Please enter the name (and the communication details) of contact person(s) who could be contacted in case further contacts would be needed and/or to provide any clarifications of the answers.

For some of the questions, a text-field is provided where the answers could be typed in. Please note that the size of the field will increase as the answer is typed.

For some of the questions, a tick box is provided. Clicking on the box will add a tick into the box (another click will remove the tick).

This set of questions is designed not only to gather information from Member States, but also to identify areas where information is not readily available. As a result it is expected that the response in several cases will at best be difficult, and it is acceptable to respond with **N/K (Not Known)** in these cases.

Additional documents may be added to the questionnaire as attachments.

Individual replies will be treated in confidence and will not be shared with third parties.

For any further information and/or clarification related to the questionnaire or any other questions, please contact the team leader of the study Jim Stewart (Transport@class7.info) or Bojan Tomic (b.tomic@enco.eu).

We would very much appreciate if you could return the completed questionnaire as soon as convenient, but not later than by **September 30th, 2017**.

Many thanks in advance for your cooperation.

MEMBER STATE:	

IDENTIFICATION OF THE PERSON(S) COMPLETING THE QUESTIONNAIRE:

Organisation:	
Responsibility:	
Name	
Position:	
E-mail address:	
Telephone No.:	

Organisation:	
Responsibility:	
Name	
Position:	
E-mail address:	
Telephone No.:	

Organisation:	
Responsibility:	
Name	
Position:	
E-mail address:	
Telephone No.:	

ACRONYMS

To aid simplicity, if there is a reference or organisation that is used often in the completion of the form you may wish to provide a shortened version here:

ACRONYM	REFERENCE or ORGANISATION

DATA SOURCES

Sources used by ENCO for pre-fill:

QUESTION	SOURCE

1. Industry and Transport Infrastructure

1.1 Material Transported

1.1.1 Number of Packages and Consignments per year (now, 10, 20 years projection)

		2016	2026	2036
1	How many packages were consigned in your country in			
2	How many packages do you believe will be consigned in your country in			

		2016	2026	2036
3	How many consignments took place in your country in			
4	How many consignments do you believe will take place in your country in			

Which areas do you see the major change occurring in? (Please elaborate)

5	

1.1.2 Types of Packages Type A/B(U)/B(M)/C and in particular excepted packages

Please provide a breakdown of the package types consigned in 2016 by %

	Package Type	%
1	UN 2908; UN 2909; UN 2910; UN 2911; UN 3507 Excepted Packages	
2	UN 2912; UN 3321; UN 3322 LSA non-fissile	
3	UN 3324; UN 3325 LSA fissile	
4	UN 2913 SCO non-fissile	
5	UN 3326 SCO fissile	
6	UN 2915; UN 3332 Type A non-fissile	
7	UN 3327; UN 3333 Type A fissile	
8	UN 2916; UN 2917 Type B non-fissile	
9	UN 3328; UN 3329 Type B fissile	
10	UN 3323; UN 3330 Type C	
11	UN 2919; UN 3331 Special Arrangement	
12	UN 2977; UN 2978 Uranium Hexafluoride	

1.1.3 Modes of transport

Please provide a breakdown of the modes of transport used for packages in 2016

	Mode	%
1	Road	
2	Rail	
3	Air	
4	Sea	
5	Inland waterways	

1.1.4 Carrier type

Please provide a breakdown of the carrier types for packages in 2016

	Carrier Type	%
1	Carried by owner	
2	Scheduled carrier	
3	Contract freight carrier	
4	Specialist RAM carrier	

1.1.5 End use of material

Please provide a breakdown of the end use of material for packages in 2016

	End Use	%
1	Industry	
2	Medicine	
3	Research and education	
4	Agriculture	
5	Nuclear	
6	Minerals	
7	Recycling	
8	Disposal/storage of waste	
9	Other	

1.1.6 Transboundary shipments

	Type of shipment	%
1	Incoming only from EU (intra-community shipment)	
2	Outgoing only to EU (intra-community shipment)	
3	Transit through your state from an EU state and to another EU state (intra-community shipment)	
4	Import to EU (extra-community shipment)	
5	Export from EU (extra-community shipment)	
6	Transit through your state where either the state the consignment comes from or goes to is not an EU state (extra-community shipment)	

1.1.7 Consignors, Consignees, Owners, Users

How many people were involved in radioactive material transport in the state in 2016?

	Activity	Total number
1	Consignors	
2	Consignees	
3	Package owners	
4	Package users	

What is your best estimate of the change in industry experience (in terms of sum of the number of person years available)?

	Activity	Decreasing a lot	Decreasing a little	Staying the same	Increasing a little	Increasing a lot
5	Designers	☐	☐	☐	☐	☐
6	Consignors	☐	☐	☐	☐	☐
7	Package owners	☐	☐	☐	☐	☐
8	Package users	☐	☐	☐	☐	☐

1.2 Transport Enterprises

		#
1	Number of road carriers that carry radioactive material	
2	Number of rail operators that carry radioactive material	
3	Number of aircraft operators carrying radioactive material	
4	Number of sea transport enterprises carrying radioactive material	
5	Number of inland waterways enterprises carrying radioactive material	

1.3 Route Restrictions

		#
1	Number of major airports that permit radioactive material transport	
2	Number of major sea ports that permit radioactive material transport	
3	Number of major inland waterway ports that permit radioactive material transport	

		YES	NO
4	Any restrictions on road routes for transport of radioactive material	☐	☐

If YES, please describe:

5	

		YES	NO
6	Any restrictions on rail routes for transport of radioactive material	☐	☐

If YES, please describe:

7	

1.4 Allowable Border Crossing Points (both EU and non EU)

		#
1	Border crossings rail	
2	Border crossings rail where radioactive material can cross	
3	Border crossings road	

		#
4	Border crossings road where radioactive material can cross	

2 Regulatory Infrastructure (regulations and oversight)
(include both safety and security where appropriate)

2.1 Regulation development and implementation

Transit is included in order to capture any specific legislation and practices that may exist (although this is unlikely).

2.1.1 Road, Rail, Inland waterways, Air, Sea, Transit

Please provide references to the regulations governing the transport of radioactive material and the associated regulatory bodies.

	Mode	Regulations	Regulator
1	Road		
2	Rail		
3	Air		
4	Sea		
5	Inland waterways		
6	Transit		

2.1.2 Reference to ADR, RID, ADN, ICAO TI, IMDG, SMGS

Please provide details of direct references to international agreements in your regulations.

	International Agreement	References
1	ADR	
2	RID	
3	ADN	
4	ICAO TI	
5	IMO IMDG	
6	SMGS	
7	IAEA SSR-6	

2.1.3 Variations and Prohibitions

Please detail any way your regulations <u>vary</u> from international agreements, and any <u>prohibitions</u> on the transport of radioactive material that are not in the international agreements.

2.1.3.1 Road

1	Variations:	
2	Prohibitions:	

2.1.3.2 Rail

1	Variations:	
2	Prohibitions:	

2.1.3.3 Inland waterways

1	Variations:	
2	Prohibitions:	

2.1.3.4 Air

1	Variations:	
2	Prohibitions:	

2.1.3.5 Sea

1	Variations:	
2	Prohibitions:	

2.1.3.6 Transit

1	Variations:	
2	Prohibitions:	

2.1.4 Enforcement powers

What enforcement powers (e.g. prohibition, improvement) and penalties (e.g. fine, imprisonment) are there for each mode of transport, and who is the enforcing body?

	Mode	Powers	Penalties	Enforcement Body
1	Road			
2	Rail			
3	Air			
4	Sea			
5	Inland waterways			
6	Transit			

2.1.5 Review and update process

What process do you have for reviewing the suitability of your national regulations? (Please elaborate)

1	

What process do you have for updating your regulations when necessary? (Please elaborate)

2	

2.1.6 Input to international regimes

How do you (Class 7 expert) provide suitable input to the international regimes (e.g. UNECE Orange Book, IMO IMDG Code, ICAO TI, ADR, RID, ADN) to ensure they continue to provide an acceptable level of control of the radiation, criticality and thermal hazards to persons, property and the environment that are associated with the transport of radioactive material? (Please elaborate)

1	

2.2 Emergency planning and exercises

2.2.1 Regulations and procedures

Are there any regulations requiring emergency <u>planning</u> for transport of radioactive material for each mode of transport, and who is responsible for responding?

	Mode	Regulations		Responder
		YES	NO	
1	Road	☐	☐	
2	Rail	☐	☐	
3	Air	☐	☐	
4	Sea	☐	☐	
5	Inland waterways	☐	☐	
6	Transit	☐	☐	

Are there any regulations requiring <u>exercising</u> of emergency plans for transport of radioactive material for each mode of transport, and who is responsible for exercising?

	Mode	Regulations		Exerciser
		YES	NO	
7	Road	☐	☐	
8	Rail	☐	☐	
9	Air	☐	☐	
10	Sea	☐	☐	
11	Inland waterways	☐	☐	
12	Transit	☐	☐	

2.2.2 Review of plans

Who is responsible for <u>reviewing</u> emergency plans for transport and how many did they review in 2016?

	Mode	Reviewer	Number of plans reviewed
1	Road		
2	Rail		
3	Air		
4	Sea		
5	Inland waterways		

	Mode	Reviewer	Number of plans reviewed
6	Transit		

2.2.3 Witnessing of exercises

Who is responsible for <u>witnessing</u> emergency exercises for transport and how many did they witness in 2016?

	Mode	Witness	Number of exercises witnessed
1	Road		
2	Rail		
3	Air		
4	Sea		
5	Inland waterways		
6	Transit		

2.2.4 First Responder Training

Who is responsible for ensuring first responders are trained to deal with radioactive material in transport? (Please elaborate)

1	

How many were trained in 2016?

		#
2	First responders trained in 2016	

2.3 Enforcement and Investigation

2.3.1 Regulation and registration

Do you have a requirement to report non-compliance to an enforcement authority?

	Mode	Reporting of non-compliance	
		YES	NO
1	Road	☐	☐
2	Rail	☐	☐
3	Air	☐	☐
4	Sea	☐	☐
5	Inland waterways	☐	☐
6	Transit	☐	☐

What powers of investigation are established in regulation?

	Mode	Powers
7	Road	

	Mode	Powers
8	Rail	
9	Air	
10	Sea	
11	Inland waterways	
12	Transit	

2.3.2 Trans-boundary powers

What powers are there to investigate an incident outside your state that has an influence on your state? (Please elaborate)

1	

What powers are there to investigate within your state when an incident occurs outside your state that may have a root cause within your state? (Please elaborate)

2	

2.3.3 Enforcement actions

		2012	2013	2014	2015	2016
1	How many enforcement actions were completed in					

2.3.4 Investigations

		2012	2013	2014	2015	2016
1	How many investigations of non-compliances were completed in					

2.3.5 Penalties

What penalties were applied as a result of enforcement in 2012 to 2016? (Please tick)

	Year	Imprisonment	Monetary	Prohibition	Improvement	Withdrawal of approval	Other
1	**2012**	☐	☐	☐	☐	☐	☐
2	**2013**	☐	☐	☐	☐	☐	☐
3	**2014**	☐	☐	☐	☐	☐	☐
4	**2015**	☐	☐	☐	☐	☐	☐
5	**2016**	☐	☐	☐	☐	☐	☐

2.4 Inspection of Transport Operations

2.4.1 Regulation and registration

Do you have a registration scheme for transport of radioactive material in regulation?

	Mode	Carrier Registration		Consignor Registration	
		YES	NO	YES	NO
1	Road	☐	☐	☐	☐
2	Rail	☐	☐	☐	☐
3	Air	☐	☐	☐	☐
4	Sea	☐	☐	☐	☐
5	Inland waterways	☐	☐	☐	☐
6	Transit	☐	☐	☐	☐

What powers to inspect transport operations are established in regulation?

	Mode	Powers
7	Road	
8	Rail	
9	Air	
10	Sea	
11	Inland waterways	
12	Transit	

How has COUNCIL DIRECTIVE 95/50/EC of 6 October 1995 on uniform procedures for checks on the transport of dangerous goods by road been implemented? Please provide copies of reports for 2012-2016 if available.

13	

2.4.2 Consignment witnessing

		2012	2013	2014	2015	2016
1	How many consignment operations were witnessed in					

2.4.3 Carrier witnessing

		2012	2013	2014	2015	2016
1	How many carriage operations were witnessed in					

2.4.4 Contamination monitoring

		2012	2013	2014	2015	2016
1	How many packages were independently monitored for contamination by or on behalf of the regulatory body in					

2.5 Witnessing of Manufacture

2.5.1 Regulation and registration

Do you have a registration scheme for package manufacturers for radioactive material in regulation?

	Mode	Manufacturer Registration	
		YES	NO
1	Road	☐	☐
2	Rail	☐	☐
3	Air	☐	☐
4	Sea	☐	☐
5	Inland waterways	☐	☐
6	Transit	☐	☐

What powers to inspect manufacture of packages are established in regulation?

	Mode	Powers
7	Road	
8	Rail	
9	Air	
10	Sea	
11	Inland waterways	
12	Transit	

2.5.2 Serial Number Register

		#
1	How many different designs are on the register of radioactive material transport packages?	
2	How many packages are on the register of radioactive material transport packages?	

		2012	2013	2014	2015	2016
3	How many serial numbers were added to the register in					

2.5.3 Evidence of manufacture

		2012	2013	2014	2015	2016
1	How many manufacturing operations were inspected in					

2.5.4 Non-CA approved package manufacture

		2012	2013	2014	2015	2016
1	How many packages not subject to CA approval had manufacture witnessed in					

What alternative methods other than witnessing are used to verify the manufacture of packages not subject to CA approval? (Please elaborate)

2	

2.6 Witnessing of Testing

2.6.1 Regulation and registration

Do you have a registration scheme for package tests for radioactive material in regulation?

	Mode	Manufacturer Registration	
		YES	NO
1	Road	☐	☐
2	Rail	☐	☐
3	Air	☐	☐
4	Sea	☐	☐
5	Inland waterways	☐	☐
6	Transit	☐	☐

What powers to inspect testing of packages are established in regulation?

	Mode	Powers
7	Road	
8	Rail	
9	Air	
10	Sea	
11	Inland waterways	
12	Transit	

2.6.2 International powers

Where packages are tested in another state and due to be approved in your state are there regulatory powers to permit review of testing in another state? (Please elaborate)

1	

2.6.3 Evidence of Test Witnessing

		2012	2013	2014	2015	2016
1	How many package tests were witnessed in					

2.6.4 Non-CA Approved Package Witnessing

		2012	2013	2014	2015	2016
1	How many packages not subject to CA approval had testing witnessed in					

What alternative methods other than witnessing are used to verify the testing of packages not subject to CA approval? (Please elaborate)

2	

2.7 Examination of Maintenance and Servicing Arrangements

2.7.1 Regulation and registration

Do you have a registration scheme for package maintenance for radioactive material in regulation?

	Mode	Maintainer Registration	
		YES	NO
1	Road	☐	☐
2	Rail	☐	☐
3	Air	☐	☐
4	Sea	☐	☐
5	Inland waterways	☐	☐
6	Transit	☐	☐

What powers to inspect maintaining of packages are established in regulation?

	Mode	Powers
7	Road	
8	Rail	
9	Air	
10	Sea	
11	Inland waterways	
12	Transit	

2.7.2 International powers

If packages owned in the state are maintained in another state what powers exist to allow you inspect the maintenance operations?

1	

If packages are owned in another state but maintained in your state what powers exist to allow you inspect the maintenance operations?

2	

2.7.3 Examination of records

		2012	2013	2014	2015	2016
1	How many maintenance records were examined in					

2.7.4 Examination of activities

		2012	2013	2014	2015	2016
1	How many maintenance operations were examined in					

2.8 Assessment

2.8.1 Timescales for assessment

Reflecting the most recent experience how long would it take between receipt of a submission to issuing a certificate of approval?

	Submission Type	Time to issue certificate
1	Type B(U) new design	
2	Type B(U)F new design	
3	Type B(U) minor update (e.g. additional nuclide)	
4	Type B(U)F minor update (e.g. fissile material density)	

Assuming a fully complete and accurate submission, how long would it take between receipt of a submission to issuing a certificate of approval?

	Submission Type	Time to issue certificate
5	Type B(U) new design	
6	Type B(U)F new design	
7	Type B(U) minor update (e.g. additional nuclide)	
8	Type B(U)F minor update (e.g. fissile material density)	

2.8.2 Assessment of Non-CA approved packages

		2012	2013	2014	2015	2016
1	How many non-CA approved packages have been reviewed to confirm a design assessment has been carried out in					
2	How many non-CA approved packages were re-assessed by the regulator in					

2.8.3 Assessment of Shipments

What checks are made during the assessment of shipments? (Please elaborate)

1	

		2012	2013	2014	2015	2016
2	How many shipments were assessed in					

		2012	2013	2014	2015	2016
3	How many of these shipments were limited to the EU in					

2.9 Audits of Management Systems

2.9.1 Regulation and registration

Do you have a registration scheme for management systems of users for radioactive material in regulation?

	Mode	Management System Registration	
		YES	NO
1	Road	☐	☐
2	Rail	☐	☐
3	Air	☐	☐
4	Sea	☐	☐
5	Inland waterways	☐	☐
6	Transit	☐	☐

What powers to audit management systems are established in regulation?

	Mode	Powers
7	Road	
8	Rail	
9	Air	
10	Sea	
11	Inland waterways	
12	Transit	

2.9.2 Audit Programme

		YES	NO
1	Is there a national audit programme?	☐	☐

		2012	2013	2014	2015	2016
2	How many management systems were audited by the regulator in					

2.9.3 Third Party Accreditation

What part does third party accreditation play in the state? (Please elaborate)

1	

2.9.4 Audits of RPPs

Do you have a registration scheme for Radiation Protection Programmes of users* for radioactive material transport in regulation?

	Mode	Management System Registration	
		YES	NO
1	Road	☐	☐
2	Rail	☐	☐
3	Air	☐	☐
4	Sea	☐	☐
5	Inland waterways	☐	☐
6	Transit	☐	☐

*a 'user' is a person who or an organization that designs, tests, assesses, manufactures, services, maintains, consigns, carries or otherwise uses a package in connection with the transport of radioactive material

What powers to audit Radiation Protection Programmes are established in regulation?

	Mode	Powers
7	Road	
8	Rail	
9	Air	
10	Sea	
11	Inland waterways	
12	Transit	

		2012	2013	2014	2015	2016
13	How many Radiation Protection Programmes were audited in					

2.10 Liaison and Cooperation

2.10.1 Regulators relevant to transport

Who are considered the lead/main/primary regulators for each mode of transport (for all issues, not just transport of radioactive material)?

	Mode	Lead Regulator
1	Road	
2	Rail	
3	Air	
4	Sea	
5	Inland waterways	
6	Transit	

Please provide a list of regulators with powers related to the transport of radioactive material and their scope.

7	

How do the regulators liaise with each other on issues of mutual interest? (Please elaborate)

8	

2.10.2 Regulators in other states

What means have been established to liaise with relevant regulators in other states?

1	

2.10.3 Joint activities

What joint activities typically take place between regulators either within the state or external to the state? (Please elaborate)

1	

2.11 Issuing of Approvals

2.11.1 Country of Origin Approvals

Who is responsible for issuing package and shipment approvals?

	Mode	Approval body
1	Road	
2	Rail	
3	Air	
4	Sea	
5	Inland waterways	
6	Transit	

		2012	2013	2014	2015	2016
7	How many country of origin approvals were issued in					

2.11.2 Multilateral Approvals by Re-certification

		2012	2013	2014	2015	2016
1	How many multilateral approvals by re-certification were issued in					

2.11.3 Multilateral approvals by Validation

		2012	2013	2014	2015	2016
1	How many multilateral approvals by validation were issued in					

2.11.4 Non-EU packages and shipments

		2012	2013	2014	2015	2016
1	How many re-certifications or validations of non-EU package or shipment certificates were issued in					

2.11.5 Recognition of certification by other EU states

		YES	NO
1	Is there any agreement to recognise certificates issued by other EU states?	☐	☐

If YES, please elaborate.

2	

2.11.6 Recognition of certification by non-EU states

		YES	NO
1	Is there any agreement to recognise certificates issued by non-EU states?	☐	☐

If YES, please elaborate.

2	

2.12 Training and Information Distribution

2.12.1 National Training Regimes

Is there a national training regime established related to the transport of radioactive material?

	Persons	Is there a national training scheme?	
		YES	NO
1	Carriers	☐	☐
2	First Responders	☐	☐
3	Police	☐	☐
4	Customs	☐	☐
5	Consignors	☐	☐
6	Regulators	☐	☐

Are there any regulatory requirements for training?

	Persons	Is training required by regulation?	
		YES	NO
7	Carriers	☐	☐
8	First Responders	☐	☐

	Persons	Is training required by regulation? YES	NO
9	Police	☐	☐
10	Customs	☐	☐
11	Consignors	☐	☐
12	Regulators	☐	☐

2.12.2 Numbers of trained people

How many people were trained 2012-2016?

		2012	2013	2014	2015	2016
1	Carriers					
2	First Responders					
3	Police					
4	Customs					
5	Consignors					
6	Regulators					

2.12.3 Recognition of training in other states

		YES	NO
1	Is training that was carried out in other states recognised?	☐	☐

2.13 Capacity (Regulator and Industry, -5yrs, Present, +5yrs)

Please estimate the number of people from the regulator (including any TSO) in full person years that are required to support the regulatory activities in the following areas, and what is the current resource level?

Where a person works in several areas assign a fraction to each area.

The resource level is requested in two units, number of people and total years of experience for those people

		2012 (#)	2016 (#)	2020 (#)	Current Resource (#)	Current Resource (Person-Years of Experience)
1	Regulation development and implementation					
2	Emergency planning and exercises					
3	Enforcement and Investigation					
4	Inspection of Transport Operations					
5	Examination of Maintenance and Servicing Arrangements					
6	Witnessing of Manufacture					
7	Witnessing of Testing					
8	Design Assessment					
9	Audits of Management Systems					
10	Liaison and Cooperation					

		2012 (#)	2016 (#)	2020 (#)	Current Resource (#)	Current Resource (Person-Years of Experience)
11	Issuing of Approvals					
12	Training and Information Distribution					

3 Effectiveness Measures

3.1 Normal Transport

3.1.1 Worker Exposures

What reviews of worker exposures have been carried out?

1	

How frequent are they carried out?

2	

Please provide a summary of any findings.

3	

3.1.2 Public Exposures

What reviews of public exposures have been carried out?

1	

How frequent are they carried out?

2	

Please provide a summary of any findings.

3	

3.1.3 Regulatory Costs

What direct charges are made to industry by the regulator?

1	

3.2 Accidents

3.2.1 Records of Accidents

		YES	NO
1	Is there a regulatory requirement to report accidents?	☐	☐
2	Are there national records of accidents collected?	☐	☐

		YES	NO
3	Is the INES system used?	☐	☐

		2012	2013	2014	2015	2016
4	How many accidents have there been in					
5	How many INES 2 and above events have there been in					

Please provide any references to reports.

6	

3.2.2 Reviews of Accidents

		YES	NO
1	Are accidents reviewed for the purpose of learning?	☐	☐

Please provide any references to reports.

2	

3.2.3 Historical Documentation

If you have any historical reports on accidents, please provide references.

1	

3.3 Image

3.3.1 Government Perception

What is the governments perception of the transport of radioactive material? (Please tick)

	Negative	Neutral	Positive
1	☐	☐	☐

3.3.2 Worker Perception

What is the perception of transport workers regarding the transport of radioactive material? (Please tick)

	Negative	Neutral	Positive
1	☐	☐	☐

3.3.3 Public Perception

What is the perception of the public regarding the transport of radioactive material? (Please tick)

	Negative	Neutral	Positive
1	☐	☐	☐

3.4 Reports

3.4.1 Regulator reports on non-compliance

Please provide any references to reports of non-compliances by the regulator.

1	

3.4.2 Radioactive Industry Reports

Please provide any references to reports of non-compliances by end users.

1	

3.4.3 Carrier Reports (e.g. DGSA reports)

Please provide any references to reports of non-compliances by carriers.

1	

Please provide references to where DGSA reports can be obtained.

2	

3.5 Historical Documents/ Technical Basis

3.5.1 IAEA review process

		YES	NO
1	Do you participate in the IAEA review process for SSR-6?	☐	☐

4 General Background

4.1 International Reports

4.1.1 IRRS missions- transport module results

Please provide reference to the results of any IRRS transport module results.

1	

4.1.2 ICAO state audits

Please provide any relevant feedback from ICAO state audits.

1	

4.1.3 IMO state audits

Please provide any relevant feedback from IMO state audits.

1	

4.1.4 ADR/RID/SMGS state audits

Have any audits been carried out under the auspices of:

		YES	NO
1	ADR	☐	☐
2	RID	☐	☐
3	SMGS	☐	☐

5 Specific Issues

5.1 Waste and exclusion

5.1.1 Waste Definition

What is the definition of radioactive waste?

1	

		YES	NO
2	Does this definition relate to the transport of radioactive material regulations in any way (e.g. exemption levels)?	☐	☐

5.1.2 Exclusion, exemption and clearance values

How are exclusion, exemption and clearance values used in the transport of radioactive material? (Please elaborate)

1	

What are the exclusion, exemption and clearance values in the state (do they have an international reference)? (Please elaborate)

2	

On occasions activities that incidentally involve radioactive material may result in concentration of the material such that the material falls within regulations (e.g. the generation of scale on pipework in the oil industry).

Please list any activities you are aware of that meet this description.

3	

What methods are or could be used to identify such activities? (Please elaborate)

4	

5.1.3 Arrangements related to radioactive waste, decommissioning waste shipments

What requirements apply to waste shipments in your state? (Please provide a summary)

1	

5.1.4 Recycling activities

		YES	NO
1	Is material destined for recycling considered to be waste?	☐	☐

		YES	NO
2	Are there recycling facilities in the state?	☐	☐

If YES, where does source material originate? (Please elaborate)

3	

5.2 Ageing Issues

5.2.1 Input to IAEA standards on ageing

What input has been made to the introduction of aging in transport at the IAEA?

1	

		YES	NO
2	Is there any gap in the IAEA proposals?	☐	☐

If YES, please elaborate.

3	

5.2.2 National regulation of ageing

How is aging of transport packages managed in national regulation? (Please elaborate)

1	

5.3 Denial of Shipments

5.3.1 Identification of problems

		YES	NO
1	Is there a problem with denial of shipment that you are aware of?	☐	☐

If YES, please elaborate.

2	

5.3.2 Promotion of industry

Which government body is responsible for promotion of the radioactive material transport industry?

1	

5.4 Good Practices

5.4.1 Reviews of Regulatory Burden

		YES	NO
1	Has there been any review of regulatory burden?	☐	☐

If YES, what was its findings, please provide a reference to the outcome?

2	

5.4.2 Safety enhancements

		YES	NO
1	Have there been any non-regulatory safety enhancements introduced?	☐	☐

If YES, please describe.

2	

5.4.3 Other concepts

		YES	NO
1	Are there any other good practices that should be noted?	☐	☐

If YES, please elaborate.

2	

5.6 Documentation and Information Requirements

5.6.1 Documents required for transport safety

What safety documents and approvals are required in order to consign or carry radioactive material?

1	

5.6.2 Documents required for transport security

What security documents and approvals are required in order to consign or carry radioactive material?

1	

5.6.3 Notifications Required for transport safety

What safety notifications are required in order to consign or carry radioactive material?

1	

5.6.4 Notifications Required for transport security

What security notifications are required in order to consign or carry radioactive material?

1	

5.7 Costs

5.7.1 Costs of Registration

What charges are made for registrations necessary for the shipment of radioactive material?

1	

5.7.2 Costs of Approvals

What charges are made for approvals necessary for the shipment of radioactive material?

1	

5.7.3 Registration of other EU actors

What charges are made for registrations necessary for the shipment of radioactive material for actors from other EU states?

1	

Follow-up Questionnaire to Member States

Introduction

The questionnaire is developed as a "protected" MS Word document that allows answers to be typed only into the designated fields.

Please enter the name (and the communication details) of contact person(s) who could be contacted in case further contacts would be needed and/or to provide any clarifications of the answers.

For some of the questions, a text-field is provided where the answers could be typed in. Please note that the size of the field will increase as the answer is typed.

For some of the questions, a tick box is provided. Clicking on the box will add a tick into the box (another click will remove the tick).

This set of questions is designed not only to gather information from Member States, but also to identify areas where information is not readily available. As a result it is expected that the response in several cases will at best be difficult, and it is acceptable to respond with **N/K (Not Known)** in these cases.

Additional documents may be added to the questionnaire as attachments.

Individual replies will be treated in confidence and will not be shared with third parties.

For any further information and/or clarification related to the questionnaire or any other questions, please contact the team leader of the study Jim Stewart (Transport@class7.info) or Bojan Tomic (b.tomic@enco.eu).

We would very much appreciate if you could return the completed questionnaire as soon as convenient, but not later than by **March 9th, 2018**.

Many thanks in advance for your cooperation.

MEMBER STATE:	

IDENTIFICATION OF THE PERSON(S) COMPLETING THE QUESTIONNAIRE:

Organisation:	
Responsibility:	
Name	
Position:	
E-mail address:	
Telephone No.:	

Organisation:	
Responsibility:	
Name	
Position:	
E-mail address:	
Telephone No.:	

Organisation:	
Responsibility:	
Name	
Position:	
E-mail address:	
Telephone No.:	

ACRONYMS

To aid simplicity, if there is a reference or organisation that is used often in the completion of the form you may wish to provide a shortened version here:

ACRONYM	REFERENCE or ORGANISATION

1. EPR

1.1 Please supply details of the person with PRIMARY responsibility for

		Planning for emergencies	Testing of emergency plans	Responding to an emergency
1	Consignments by road originating in your state			
2	Consignments by air originating in your state			
3	Shipments transiting your state by road			

2. Guidance

2.1 Please supply details of any simple guidance that could be developed that would facilitate compliant transport

1	
2	
3	
4	
5	

3. Costs

3.1 Please supply your estimate of costs (in Euros) for

1	A licence to carry	
2	A licence to consign	
3	A new B(U) package approval where the application is full and complete (including witnessing testing etc)	

4. Denial of shipment

4.1 Please provide details of concrete examples of denial of shipment

1	
2	
3	
4	
5	

5. Public perception

5.1 Please provide a list of items (documents etc) that can be shared which would assist with understanding of the transport of radioactive material, noting the requirements of Article 77 of the Basic Safety Standards Directive

1	
2	
3	
4	
5	

6. Open market

6.1 Please supply details of the states which have had dual-purpose casks (i.e. states including your own and any states that have been provided with them by your industry)

	Cask identity	States provided with the cask
1		
2		
3		

6.2 Please supply details of any dual purpose casks approved in your state

	Cask identity (state of origin)	Approved for transport (Y/N)	Approved for Storage (Y/N)
1			
2			
3			
4			
5			

6.3 Please provide information on where gamma radiography devices in your state are maintained and the state where spare parts are obtained from

	Device identity	State where maintenance is carried out	State where spare parts are obtained from
1			
2			
3			
4			
5			

7. Transposition of BSSD

7.1 Please clarify the details of transposition of the BSSD in relation to transport, and in particular the responsibilities of carriers and consignors in relation to the following articles

	Article	Consignor responsibility	Carrier responsibility
1	24		
2	25		
3	26		
4	27		
5	28		
6	29		
7	68		
8	69		
9	87		
10	88		
11	98		

8. Policy for review and revision of regulations

8.1 Please provide details of the basis used to decide whether regulations require updating and in particular

1	What are your regulations required to achieve?	
2	How do you identify whether your regulations achieve this?	
3	How do you decide if changes are justified?	

9. Training

9.1 Please supply a list of training providers in your state that could provide community wide training, particularly of regulators

1	
2	
3	
4	
5	

A4 QUESTIONNAIRE RESPONSE — INDUSTRY INFRASTRUCTURE

In order to understand the compliance assurance needs of an MS, a prerequisite is the prior understanding by the MS of the activities carried out by the industry — an aspect strongly emphasized by the SWG members. As such, the first section of the questionnaire was aimed at collecting readily available information from each MS. The information requested was consistent with the information that the IAEA recommends should be collected as an initial basis towards the development of compliance assurance systems. The amount of readily available information doubled as a performance indicator for the regulatory body.

In terms of accuracy, the graphs in this report have been restricted to those MS which provided an answer and should not be considered as absolute. The lack of an answer may not be an issue in itself — MS may measure packages consigned, or consignments and/or transport operations.

INDUSTRY AND TRANSPORT INFRASTRUCTURE

The first area examined is the industry, with particular reference to transport. While the transport of radioactive materials is often viewed as part of the industry, it is essential that it is mainly viewed in relation to the transport industry. The reason is that a significant safety aspect is embodied in the mode of transport (e.g. the accident rate of trucks and related accident severity is a key input to the safety standards for packaging). Also related to this area: safety requirements for vehicles, including vehicle standards, vehicle testing, safety equipment, operator training and operator licensing.

Q 1.1.1NUMBER OF PACKAGES AND CONSIGNMENTS PER YEAR (NOW, 10, 20 YEARS PROJECTION)

How many packages were consigned in your country in 2016, how many packages do you believe will be consigned in your country in 2026 and 2036

The purpose of this question was to establish the current volume of radioactive material transport and to establish a rough estimate of the potential increase/decrease over the next 20 years. This question was answered by 16 out of the 25 MS who responded to the questionnaire: AT, BG, HR, DK, DE, IE, NL, SK and ES provided no numbers, while EE, LU and MT provided data only for 2016 (**Figure 8**). The total number of consigned packages reported is in the region of 2,250,000 per year (taking into account gaps in reporting, this is more likely to be above 3,000,000 in reality). As expected, the number of consigned packages varies greatly within MS, by more than three orders of magnitude.

In order to provide a measure that was transferrable between MS, the number of packages consigned was divided by the population of the State. **Figure 9** examines the number of packages consigned for 100,000 persons in 2016. In this case, BE stands out above other States. The most likely reason for this is the location of the radionuclide production facilities. Other than this, FR and UK also have relatively high results. FR has a higher proportion of industrial use of radioactive material, while UK also has a significant medical isotope production facility.

Generally speaking, there are around two packages consigned per year for every 1000 people (excluding BE, FR and UK). Including all MS reporting results would give around 7 packages consigned per year for every 1000 people.

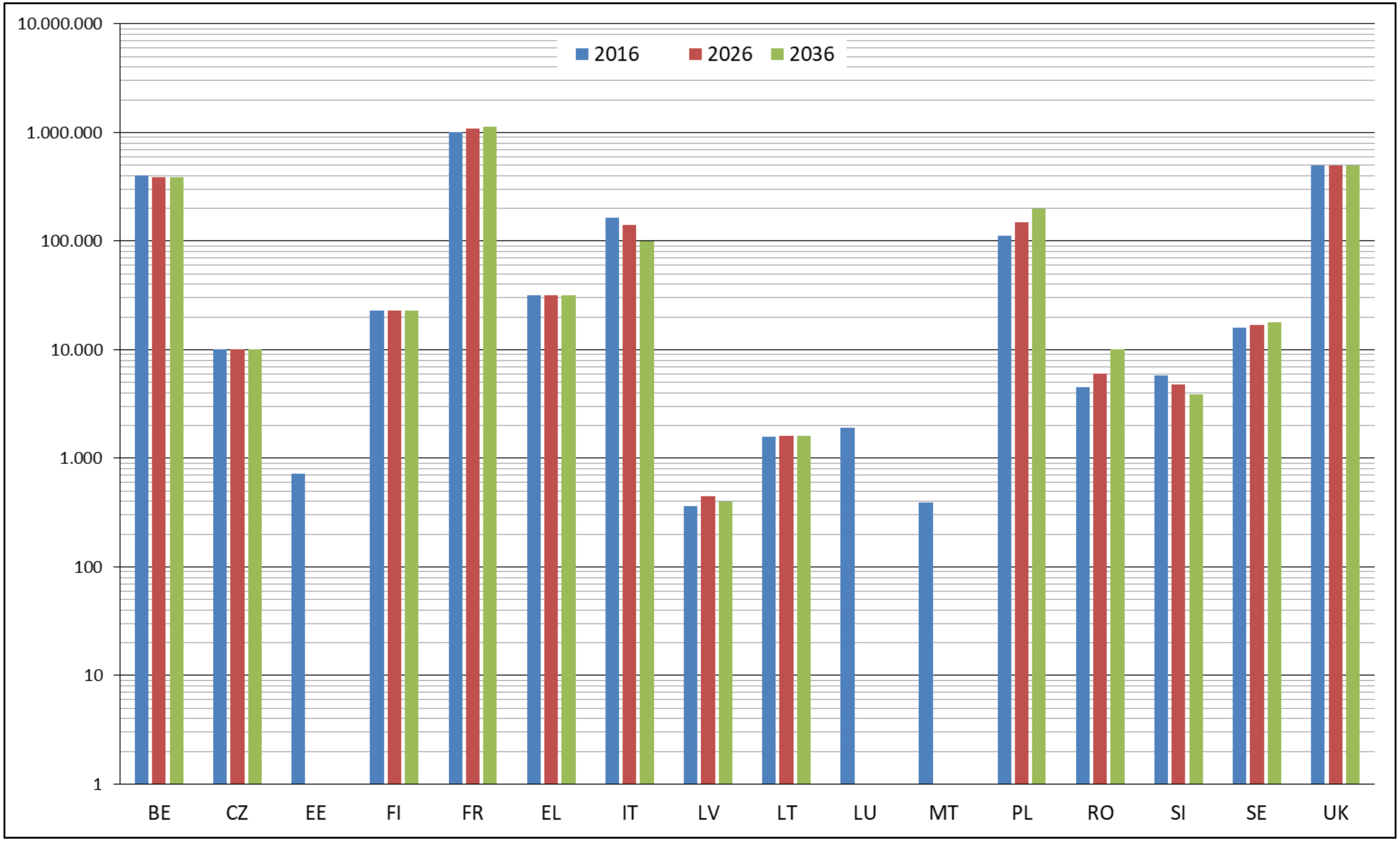
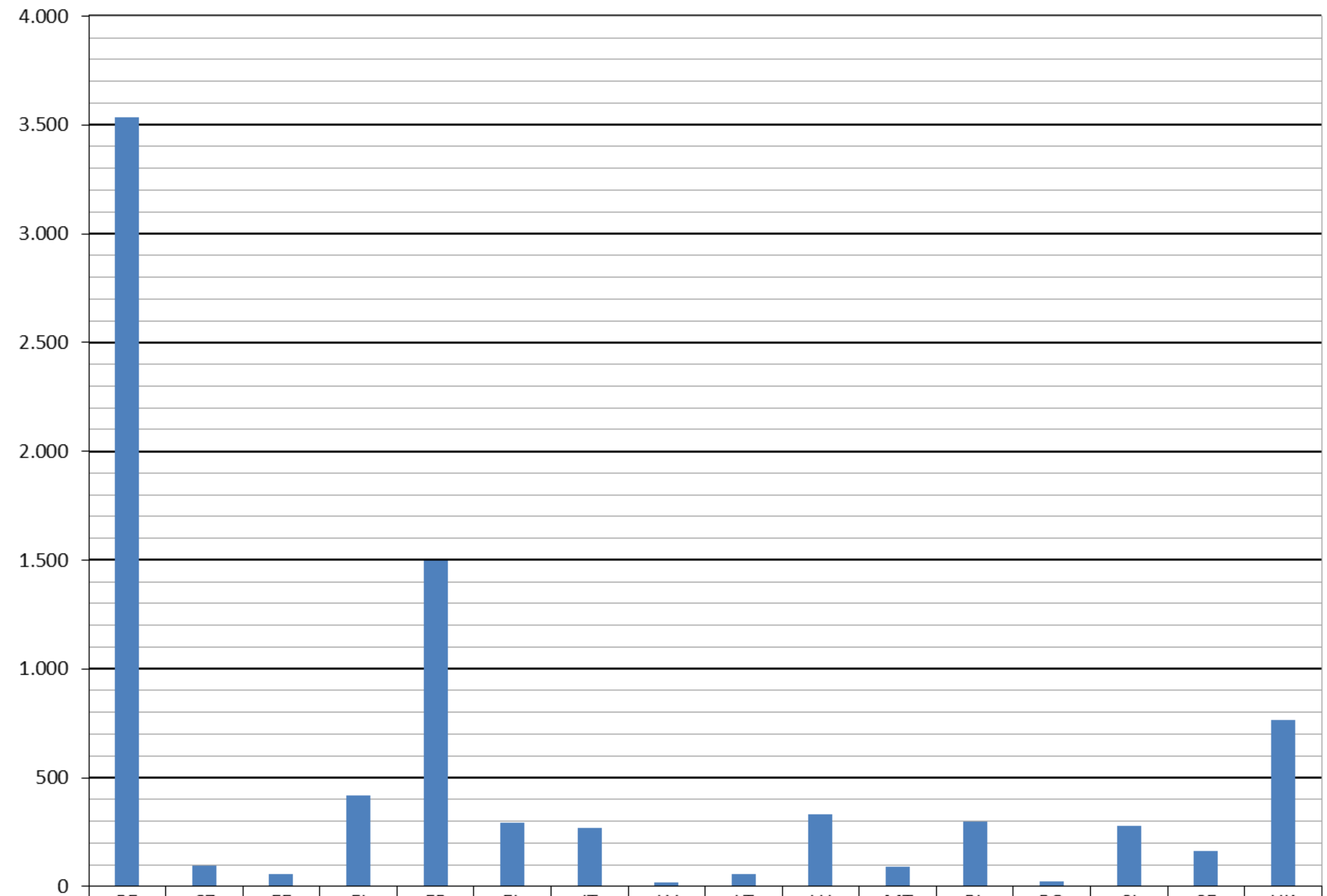


Figure 8: Number of packages consigned per year by MS (2016/2026/2036)



	BE	CZ	EE	FI	FR	EL	IT	LV	LT	LU	MT	PL	RO	SI	SE	UK
Packages 2016 per 100.000 persons	3.536	95	55	419	1.498	292	270	19	55	330	89	297	23	281	162	765

Figure 9: Number of packages consigned in 2016 per 100,000 persons*

*Population numbers from Pocketbook 2017 [1]

How many consignments took place in your country in 2016, how many consignments do you believe will take place in your country in 2026 and 2036?

A total of 17 out of 25 MS answered this question; AT, BG, HR, DK, DE, NL, ES and UK provided no numbers, while EE, IE, LU and MT provided numbers only for 2016 (**Figure 10**). The total number of consignments reported is in the region of 1,000,000 per year (again, taking into account the gaps in reporting this is also more likely to be between 25 and 50% higher in reality). Eurostat's transport database (file road_go_ta_dg) for 2016 reports 44,000 shipments for road transport in the EU. Clearly the reports providing statistical information to the EU are significantly in error (this study was related to the Community, while the Eurostat data was related to the EU — in effect these are the same in relation to statistics on shipments).

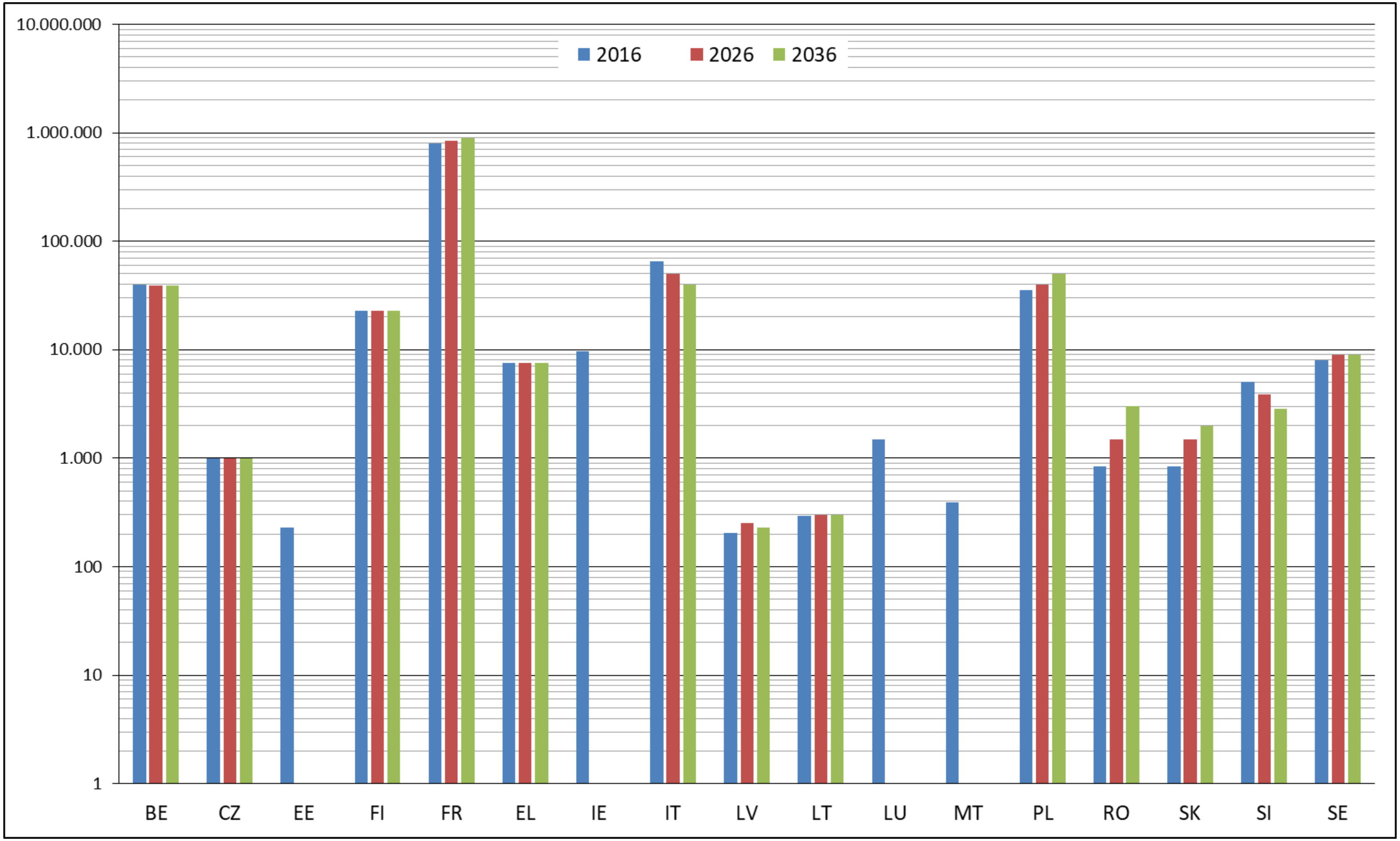


Figure 10: Number of consignments per year by MS (2016/2026/2036)

The calculated values for the number of packages per consignment are in the range of 1 to 10. The mean value for the 15 MS considered is 3.5 packages per consignment (**Figure 11**). The Consultant is aware of routine consignments in the tens and hundreds of packages, which does not seem consistent with the average value of 3.5 packages per consignment. The larger consignments tend to be of excepted packages and industrial packages (IP), so it is possible that the collection of data for these resulted in an underestimate.

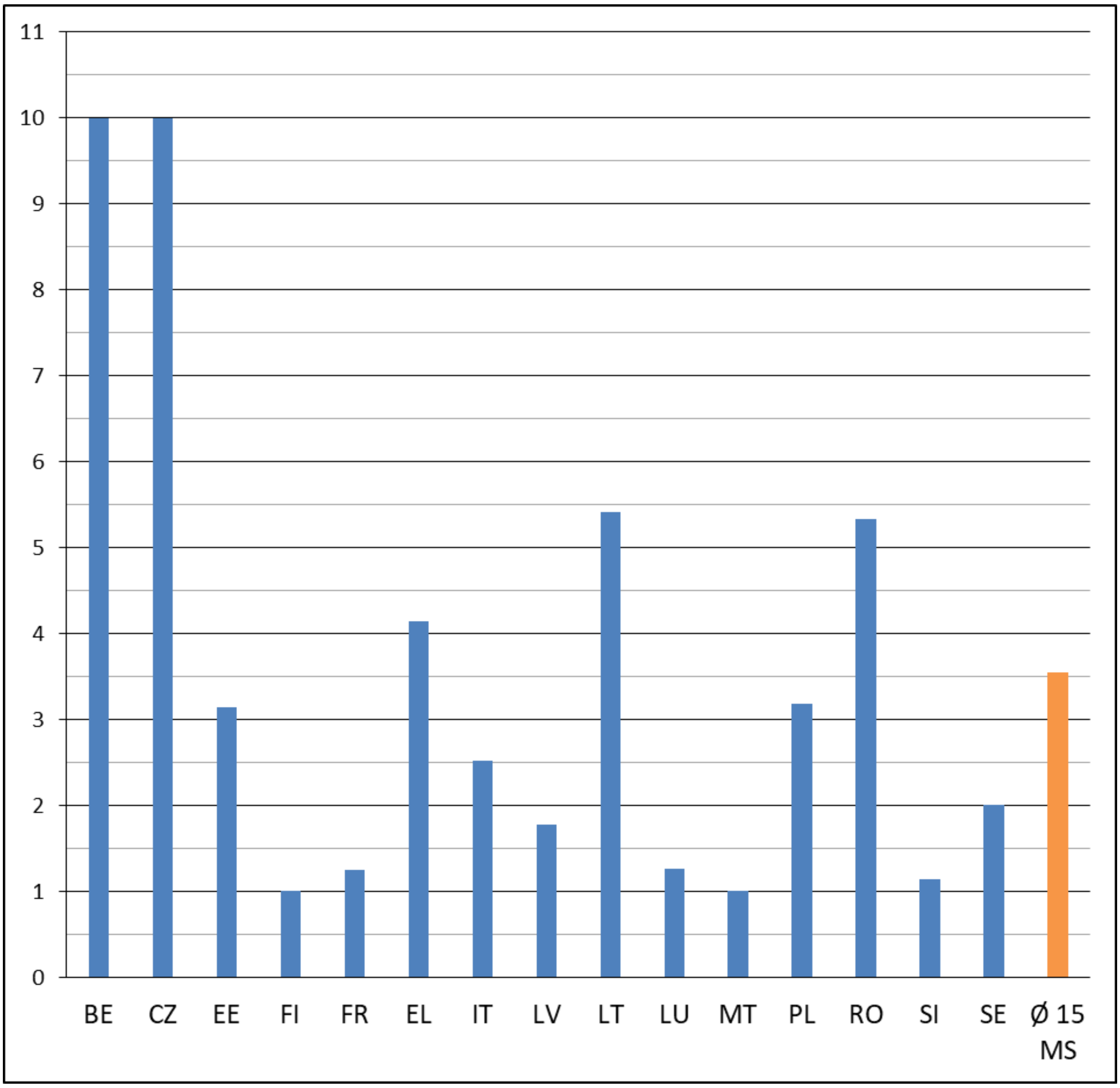


Figure 11: Number of packages per consignment by MS in 2016

The total number of packages per consignment for all MS for 2016 and projections for 2026 and 2036 are presented in **Figure 12**.

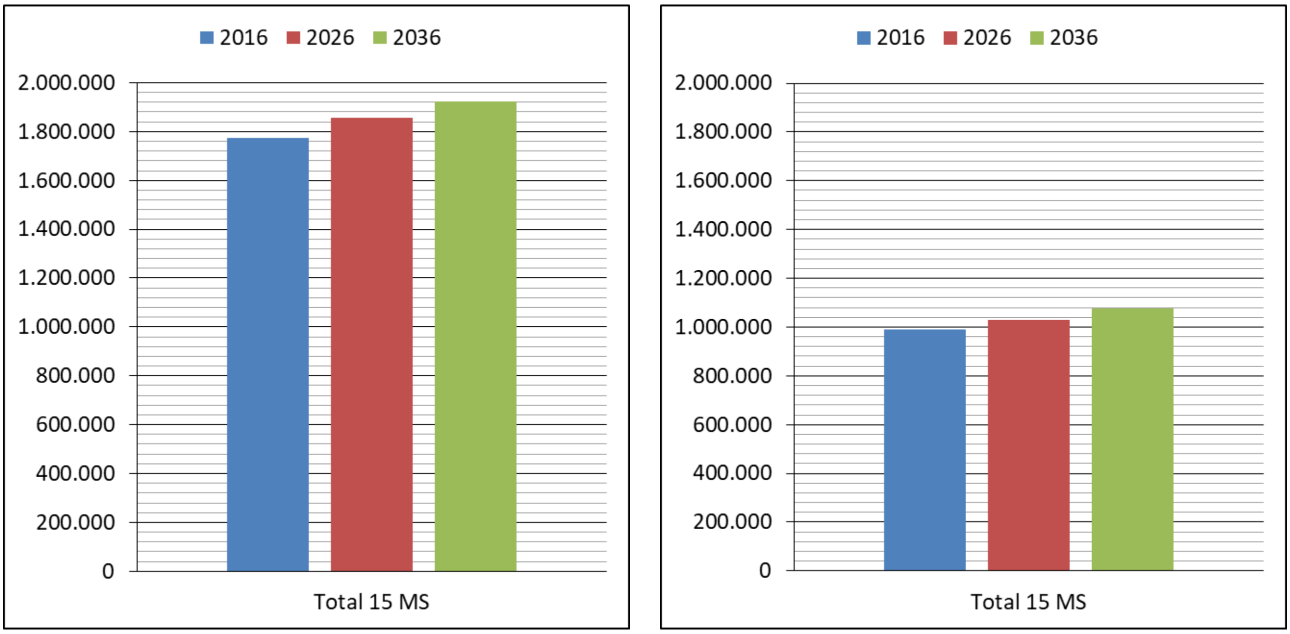


Figure 12: Total packages/consignments for all MS 2016/2026/2036

With regard to the expected changes for the number of packages and consignments within the next 10 and 20 years, a small increase is expected overall (approximately 7% over 20 years). Different MS view the development in their countries differently: the changes expected by 13 MS are presented in **Table 17**, **Figure 13** and **Figure 14**.

Table 17: Expected changes for packages/consignments compared to 2016

	Packages			Consignments	
	2026	2036		2026	2036
BE	0	0		0	0
CZ	0	0		0	0
FI	0	0		0	0
FR	+	+		+	+
EL	0	0		0	0
IT	-	-		-	-
LV	+	-		+	-
LT	0	0		0	0
PL	++	++		++	++
RO	++	++		++	++
SK	N/C	N/C		++	++
SI	-	-		-	-
SE	+	+		+	0
UK	+	+		N/C	N/C

Legend: 0: no changes to previous period, +/-: small increase/decrease to previous period, ++/--: large increase/decrease to previous period, N/C: not calculated

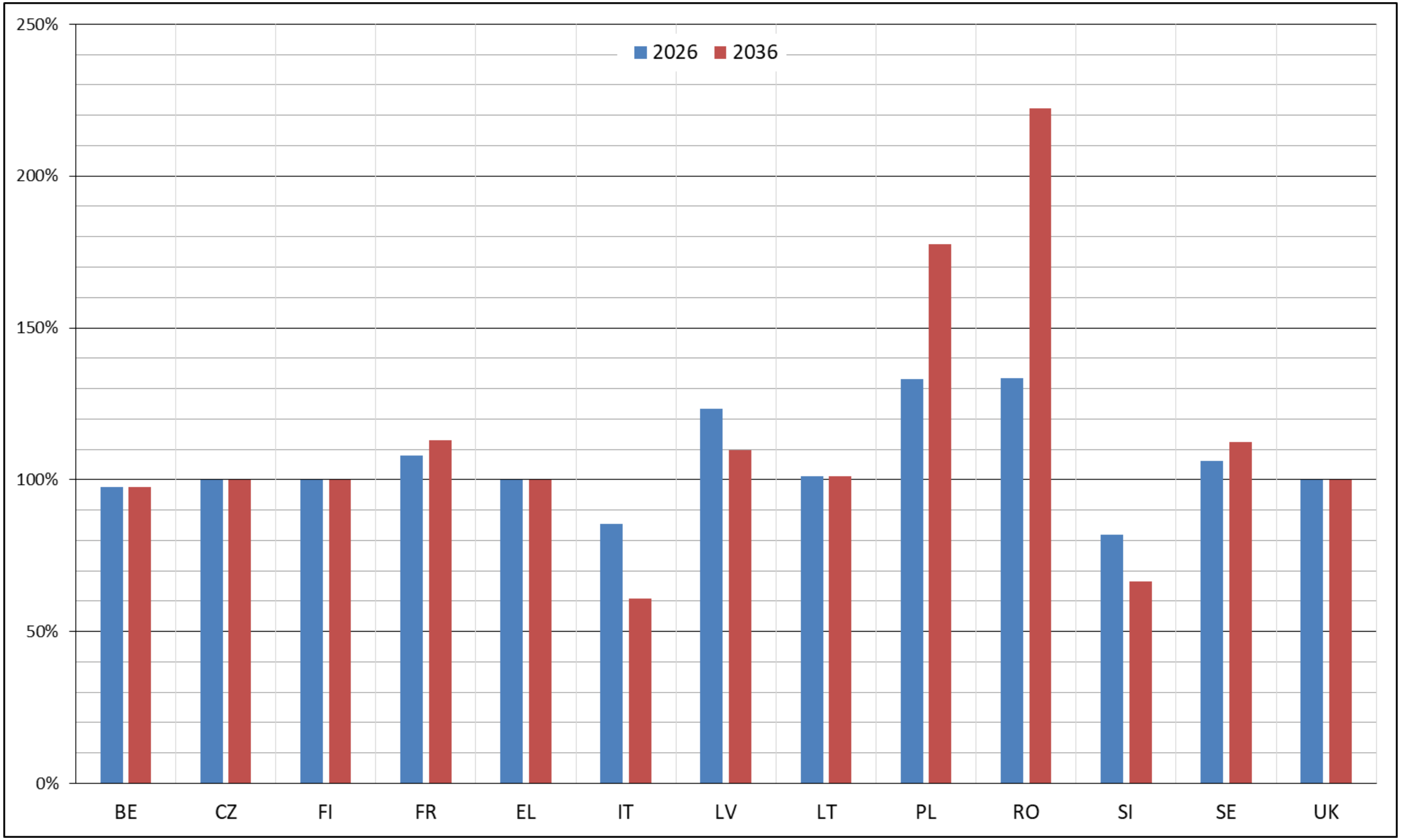


Figure 13: Expected changes for packages (% of 2016)

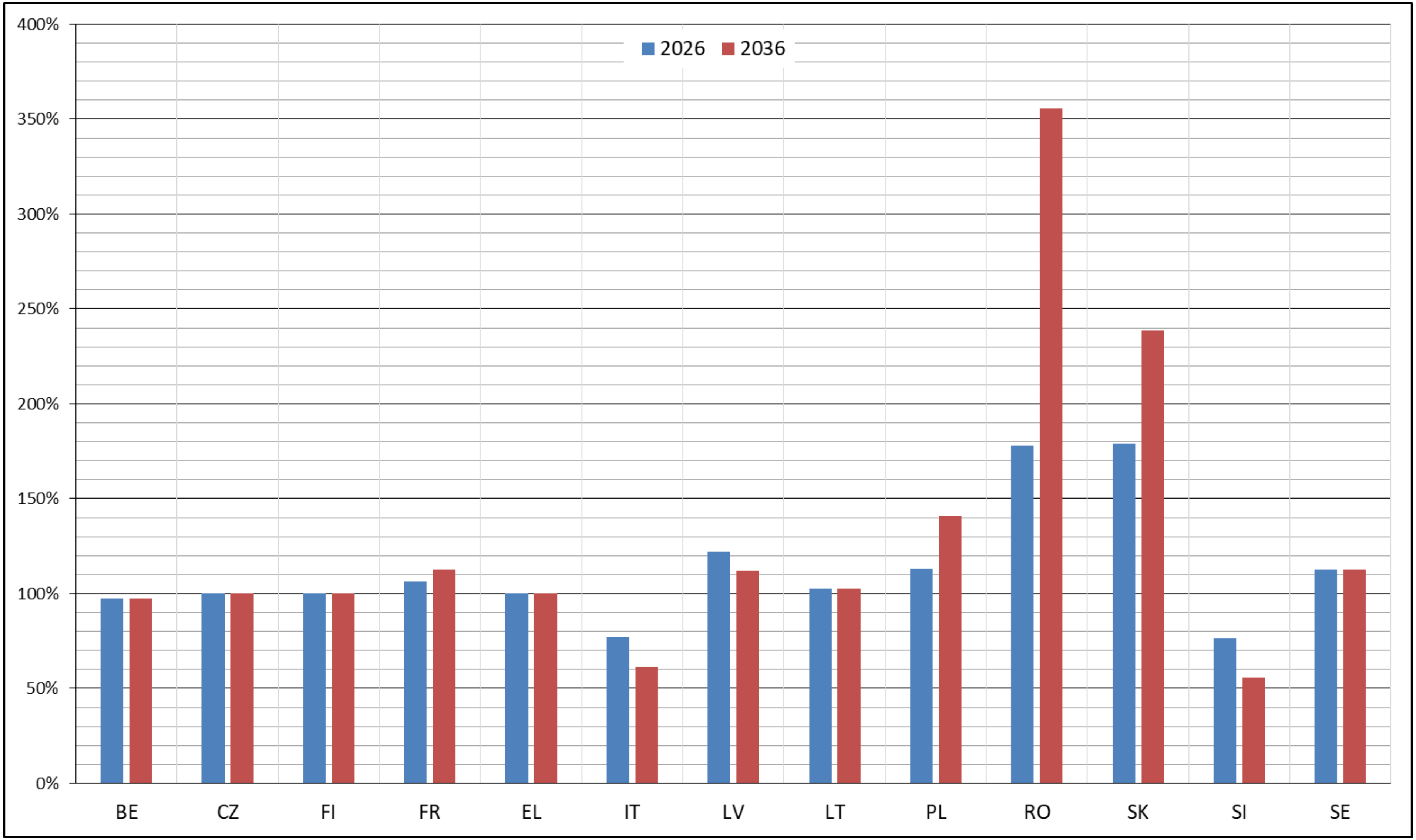


Figure 14: Expected changes for consignments (% of 2016)

Overall, based on the figures recorded in EU statistics, the number of MS that failed to report data, and the Consultant's knowledge of the industry, the conclusion reached is that the data collected in the EU could benefit from coordination. In particular, the purpose of data collection should be clearly identified to ensure that the value of data collection is understood by the MS.

Some data are currently collected in tonne-km units. However, the fact that packaging for radioactive materials can weigh tonnes while the radioactive contents weigh grams means that the data recorded for moving full and empty packages are almost identical in these units.

In addition, the transport of excepted packages is intended to be consistent with the transport of normal freight, requiring little or no operational controls other than those appropriate to normal freight transport. This makes the collection of shipment data difficult to achieve without undue regulatory burden.

Which areas do you see the major change occurring in?

This question was by eight MS. The replies of the other 17 MS are summarized in **Table 18**.

Table 18: Expected changes of importance over the next few years

Country	Areas with major change occurring
CZ	N/K, probably increase in nuclear cycle and medicine areas and decrease in research and industry areas
FI	Some ground carriers are refusing to transport radioactive material. The transport of high-activity sealed sources (carriers) will be a licensed practice as of 2/2018.
FR	The nuclear industry, with the increase of the transports due to the dismantling of the nuclear facilities. But it represents only a small percentage of the total number of consignments.
EL	No major changes are foreseen
IE	Some industry that use density gauges are now beginning to move towards non-radiometric gauges (ultrasonic).
IT	Medicine for diagnostic purposes Disposal/storage of waste taking into account the planning to construct a national repository for low and intermediate radioactive waste coming from the decommissioning of nuclear installations
LV	The major increase in the TRM is anticipated in the transport (to be accomplished by LEGMC) of waste from dismantling of Salaspils research reactor which will occur between 2020-2030.
LT	Currently there are no activities related to transport of nuclear fuel cycle material, nuclear and fissile materials in quantities established in Annex 1 of the Law on Nuclear Safety. Fresh nuclear fuel has been transported until the shutdown of Ignalina NPP, but there are no activities in transportation of nuclear fuel cycle material after the shutdown of Ignalina NPP. During the decommissioning (it is planned to start in 2020) of Maišiagala Radioactive Waste Storage Facility (RADON type storage facility, contained approximately 120 m^3 of radioactive waste from industry, medicine, research) all the radioactive content will be transported (mostly excepted, A type and IP-2 type of packages) to Ignalina NPP radioactive waste management and storage facilities. The transport of radioactive waste from Ignalina NPP is planning as well. After the start of operation of Low and Intermediate Radioactive Waste Disposal Facility (it is planned in the next decade) low and intermediate radioactive waste from Ignalina NPP will transported to this facility (capacity of 10000 m^3 of radioactive waste). IP-2 type packages for transportation of this radioactive waste will be used.
MT	A cyclotron facility is being constructed. This should increase the number of packages export consignments

Country	Areas with major change occurring
NL	The exact number of consigned packages and consignments is unknown, but it is a large number (thousands of consignments and tens of thousands of consigned packages each year), based on the activities like: production of medical isotopes and UF6 enrichment and industrial non-destructive testing. Projections are hard to make, but we expect no decrease in these numbers. All transports require either notification of a license, but unfortunately our current system cannot generate reports on exact numbers (it is not carrier based). What we do know is the exact number of shipments under special arrangements: in 2016 we had 38 of such shipments.
PL	In medicine
RO	Medical and industrial areas
SK	Increase in road and air transport related with nuclear medicine, waste and decommissioning
SI	Short-lived isotopes from cyclotrons (F-18 and similar) for PET diagnostics will increase also transport. On the other hand, it is envisaged in the future that moisture/density gauges (w. Cs-137/Am-241/Be) will be gradually replaced by non-radioactive alternatives.
ES	At medium time transports of Spent fuel is expected to start
SE	Increase of waste consignments due to decommissioning of NPS
UK	Continuing increase in the use of radioisotopes in medical procedures (PHE-CRCE-035, 2017), increase in transport of nuclear waste.

In summary, there are two areas where significant changes are foreseen: medical and waste from decommissioning. One area worth mentioning is the expected increase in the transport of short lived radionuclides. This is likely to increase the focus on efficient transport.

Q 1.1.2: TYPES OF PACKAGES TYPE A/B(U)/B(M)/C AND IN PARTICULAR EXCEPTED PACKAGES

As part of the analysis, the types of packages were broken down into three approximate groups (**Table 19**). These groups were broadly related to the graded approach.

Group I is where the quantity of material is such that the degree of regulatory oversight does not require package licencing by the Competent Authority. Group II includes radioactive materials that have an inherent level of safety based on specific activity or limited availability of contamination. Group III relates to those packages that require prior regulatory approval. Both Group I and Group II have compliance regimes based on sampling inspection, whereas Group III has a regime based on prior approval (and inspection).

- Group I is non-CA approved;
- Group II is generally waste and NORM (mainly non-CA approved);
- Group III is CA approved packages.

Table 19: Overview of package types

#	UN Number, name	Group #
1	UN 2908; UN 2909; UN 2910; UN 2911; UN 3507 Excepted Packages	I
2	UN 2912; UN 3321; UN 3322 LSA non-fissile	II
3	UN 3324; UN 3325 LSA fissile	II
4	UN 2913 SCO non-fissile	II
5	UN 3326 SCO fissile	II

#	UN Number, name	Group #
6	UN 2915; UN 3332 Type A non-fissile	I
7	UN 3327; UN 3333 Type A fissile	III
8	UN 2916; UN 2917 Type B non-fissile	III
9	UN 3328; UN 3329 Type B fissile	III
10	UN 3323; UN 3330 Type C	III
11	UN 2919; UN 3331 Special Arrangement	III
12	UN 2977; UN 2978 Uranium Hexafluoride	III

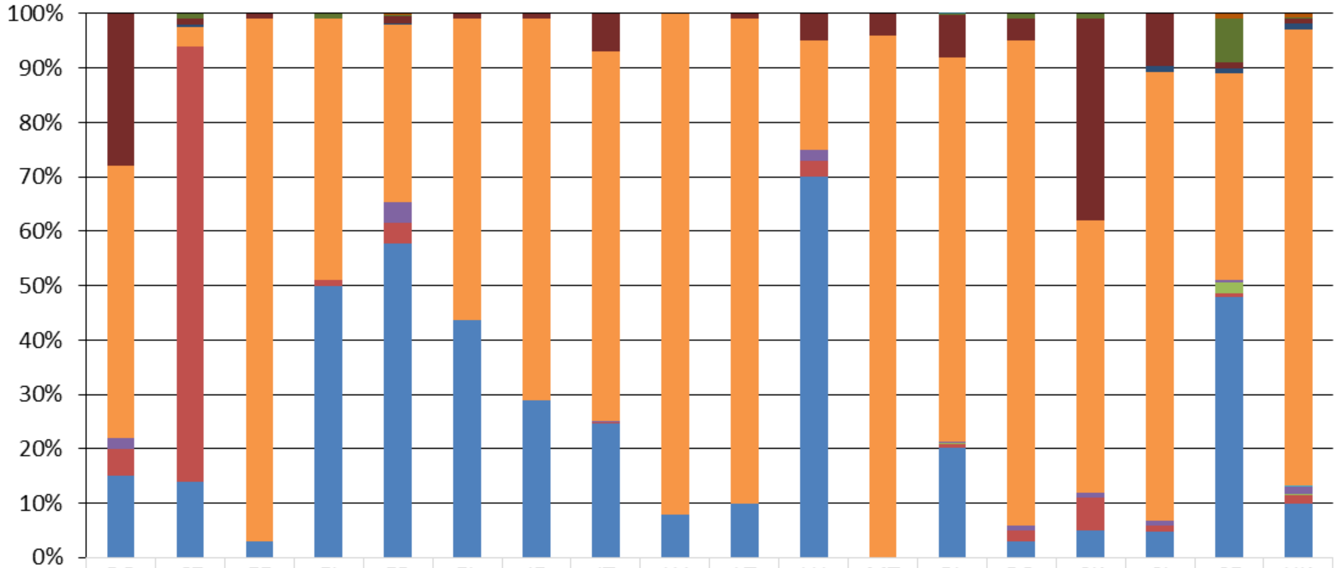
Please provide a breakdown of the package types consigned in 2016 by %

A total of 19 MS provided data for this question. DK provided only a few values which did not add up to 100% (this data set had to be excluded from the chart), while AT, BE, HR, DE, NL and ES did not answer this question (Table 20, Figure 15).

Over 95% of packages do not require Competent Authority approval. Out of these, 40% are excepted packages, 50% are Type A packages, and 5% are LSA and SCO — typical categories for waste and NORM. Previous studies (4.1020/D/01-003) had estimated a ratio of 1:2.3 for Excepted: Type A packages. This study estimates the ratio at 1:1.4.

Table 20: Breakdown of package types consigned in 2016

#1	**UN 2908; UN 2909; UN 2910; UN 2911; UN 3507 Excepted Packages**	**3 MS reported values 50% and above, 9 MS reported values between 10% and 50%, 6 MS reported values less than 10%**
#2	UN 2912; UN 3321; UN 3322 LSA non-fissile	1 MS (CZ) reported 80%, all other MS reported values less than 5%
#3	UN 3324; UN 3325 LSA fissile	All MS reported values of 2% or less
#4	UN 2913 SCO non-fissile	All MS reported values of 4% or less
#5	UN 3326 SCO fissile	All MS reported values of 0.1% or less
#6	UN 2915; UN 3332 Type A non-fissile	13 MS reported values of 50% or above, 4 MS reported values between 10% and 50%, and 1 MS reported a value less than 10%
#7	UN 3327; UN 3333 Type A fissile	All MS reported values of 1% or less
#8	UN 2916; UN 2917 Type B non-fissile	3 MS reported values between 10% and 50%, 5 MS reported values below 10%
#9	UN 3328; UN 3329 Type B fissile	All MS reported values of 8% or less
#10	UN 3323; UN 3330 Type C	No MS reported this package type
#11	UN 2919; UN 3331 Special Arrangement	3 MS reported values between 0,02% and 0,1%, 15 MS reported 0%
#12	UN 2977; UN 2978 Uranium Hexafluoride	3 MS reported values between 0,2% and 1%, 15 MS reported0%



	BG	CZ	EE	FI	FR	EL	IE	IT	LV	LT	LU	MT	PL	RO	SK	SI	SE	UK
12: UN 2977; UN 2978 Uranium Hexafluoride	0	0	0	0	0,2	0	0	0	0	0	0	0	0	0	0	0	1	0,6
11: UN 2919; UN 3331 Special Arrangement	0	0	0	0	0,02	0	0	0	0	0	0	0	0,1	0	0	0	0	0,1
10: UN 3323; UN 3330 Type C	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9:UN 3328; UN 3329 Type B fissile	0	1	0	1	0,2	0	0	0	0	0	0	0	0,1	1	1	0	8	0,2
8: UN 2916; UN 2917 Type B non-fissile	28	1	1	0	1,4	1	1	7	0	1	5	4	7,7	4	37	10	1	1
7: UN 3327; UN 3333 Type A fissile	0	0,5	0	0	0,3	0	0	0	0	0	0	0	0	0	0	1	1	1
6: UN 2915; UN 3332 Type A non-fissile	50	3,5	96	48	32,4	56	70	68	92	89	20	96	70	90	50	85	38	84
5: UN 3326 SCO fissile	0	0	0	0	0,05	0	0	0	0	0	0	0	0	0	0	0	0	0,1
4: UN 2913 SCO non-fissile	2	0	0	0	3,8	0	0	0,1	0	0	2	0	0,1	1	1	1	0,5	1,5
3: UN 3324; UN 3325 LSA fissile	0	0	0	0	0,05	0	0	0	0	0	0	0	0,2	0	0	0	2	0,1
2: UN 2912; UN 3321; UN 3322 LSA non-fissile	5	80	0	1	3,8	0	0	0,2	0	0	3	0	0,7	2	6	1	0,5	1,5
1: UN 2908; UN 2909; UN 2910; UN 2911; UN 3507 Excepted Packages	15	14	3	50	57,7	44	29	24,7	8	10	70	0	20	3	5	5	48	10

Figure 15: Breakdown of the package types consigned in 2016 by MS (%)

To the knowledge of the Consultant, it would appear that the numbers presented are rough estimates, but they are adequate to provide broad guidance. Using the numbers of packages reported as being shipped and the breakdown of types of packages, an estimate of the numbers of different packages can be made. Because some MS did not report either the numbers or the types of packages, they were excluded from the analysis (as a result the totals are not the same as the number of packages shipped in the EU).

Table 21 provides the breakdown of the number of packages by UN numbers, while **Table 22** provides the number of packages by three groups defined above. This is presented in graphical form in **Figure 16**, **Figure 17**, **Figure 18** and **Figure 19**.

Table 21: Number of packages split by UN numbers

	Packages Total reported	Total reported (%)
1: UN 2908; UN 2909; UN 2910; UN 2911; UN 3507 Excepted Packages	726,452	39
2: UN 2912; UN 3321; UN 3322 LSA non-fissile	55,132	3
3: UN 3324; UN 3325 LSA fissile	1,545	<1
4: UN 2913 SCO non-fissile	45,998	2
5: UN 3326 SCO fissile	1,000	<1
6: UN 2915; UN 3332 Type A non-fissile	981,691	52
7: UN 3327; UN 3333 Type A fissile	8,268	<1
8: UN 2916; UN 2917 Type B non-fissile	40,626	2
9:UN 3328; UN 3329 Type B fissile	4,768	<1
10: UN 3323; UN 3330 Type C	0	0
11: UN 2919; UN 3331 Special Arrangement	813	<1
12: UN 2977; UN 2978 Uranium Hexafluoride	5,160	<1
TOTAL	1,871,453	100

Table 22: Number of packages split by groups

	Packages Total reported	Total reported (%)
I: No approval (1+6)	1,708,143	91
II: Waste and NORM (2+3+4+5)	103,675	6
III: CA approved (7+8+9+10+11+12)	59,635	3
TOTAL	1,871,453	100

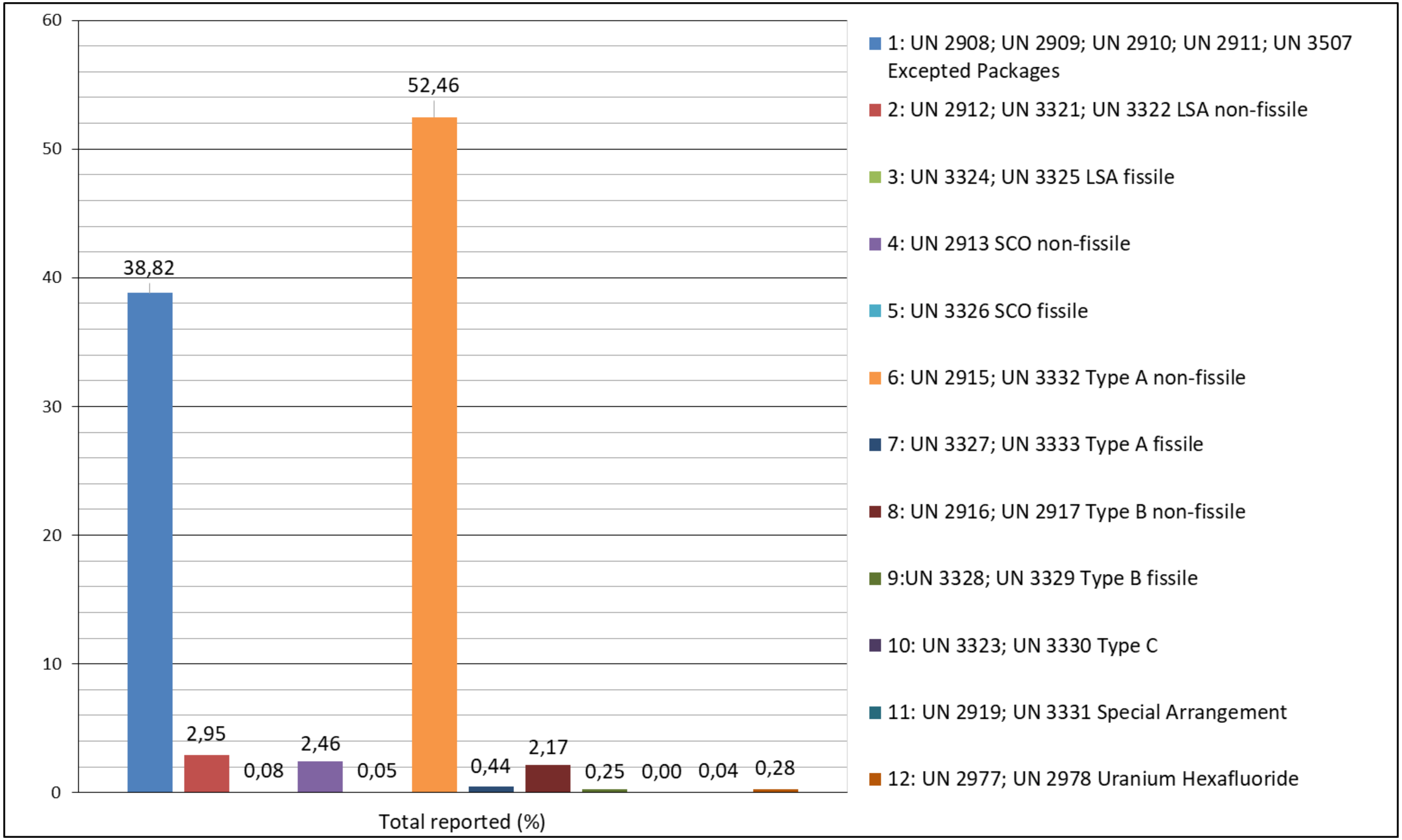


Figure 16: Weighted total for reported total by package type (% reported 2016)

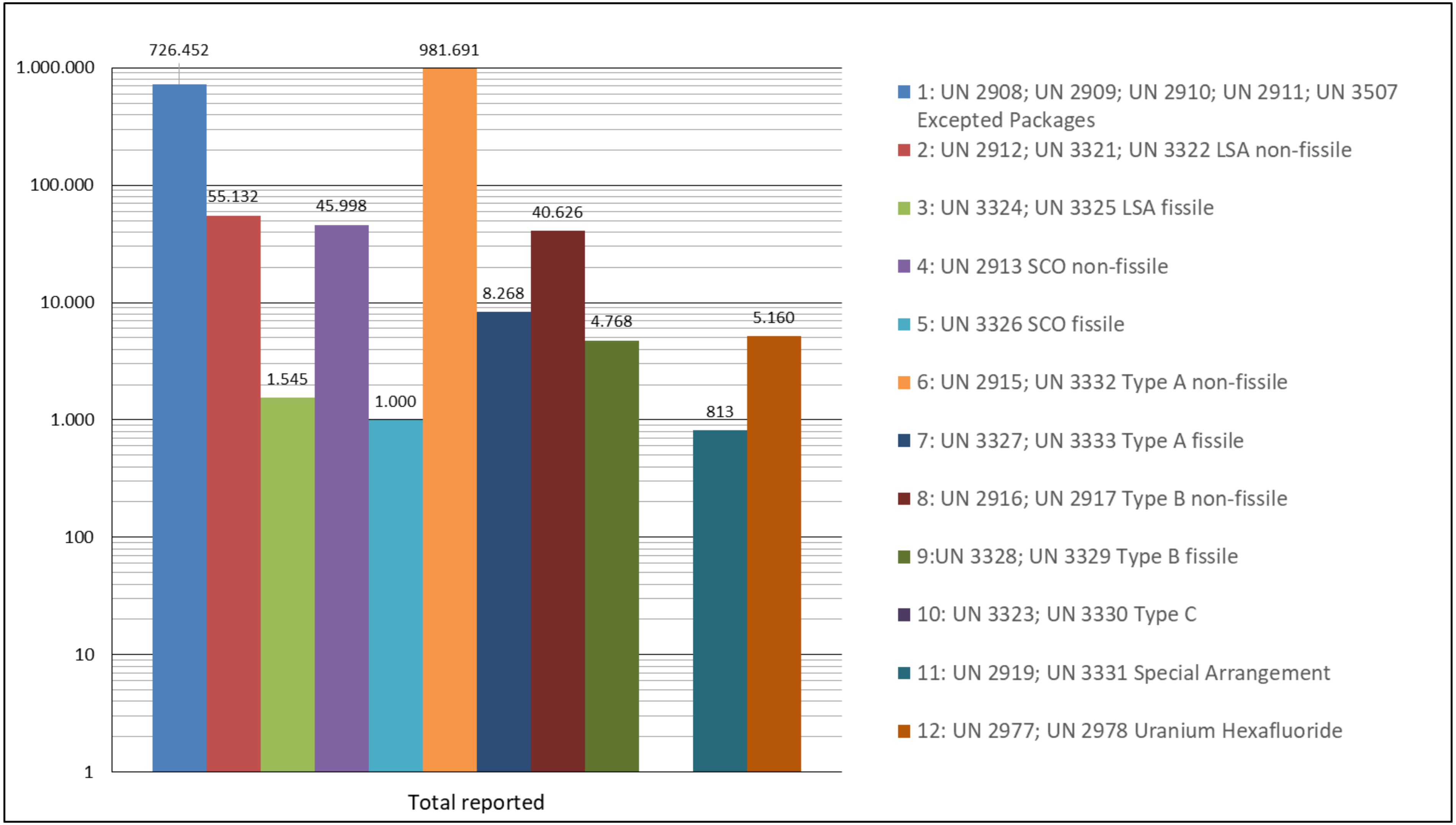


Figure 17: Weighted total for EU total by package type (Number of packages reported 2016)

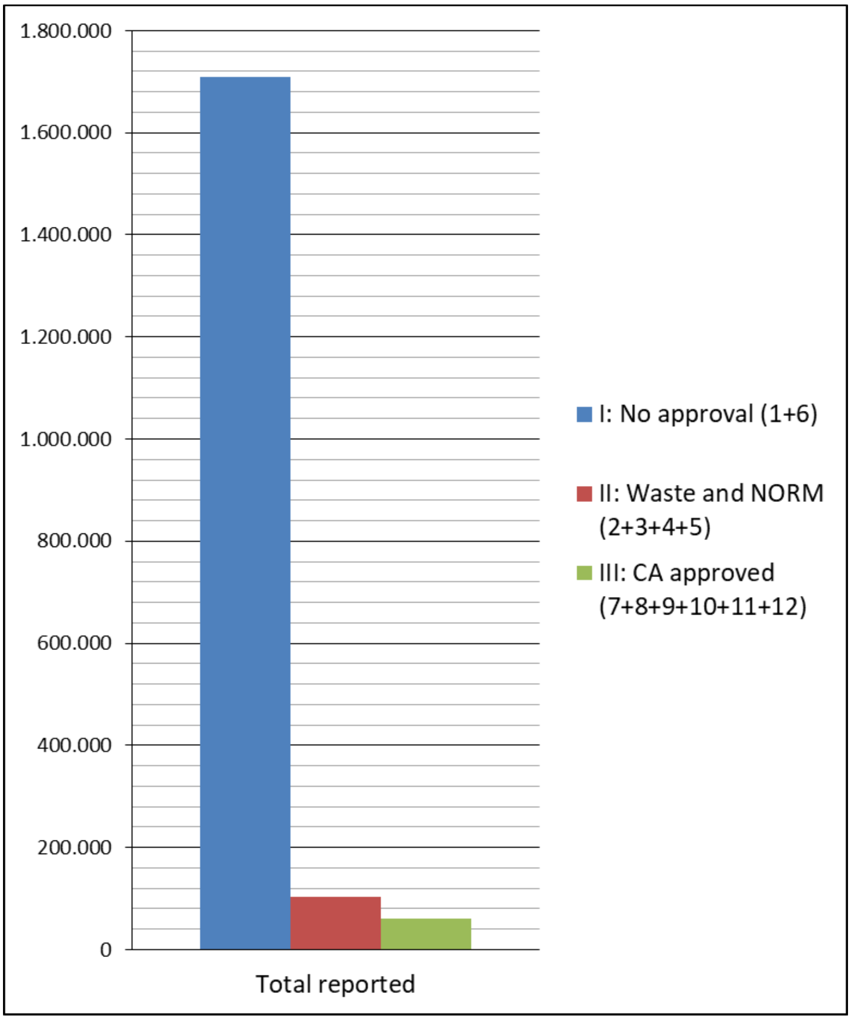


Figure 18: Breakdown of the package type groups consigned in 2016 (Number of packages reported 2016)

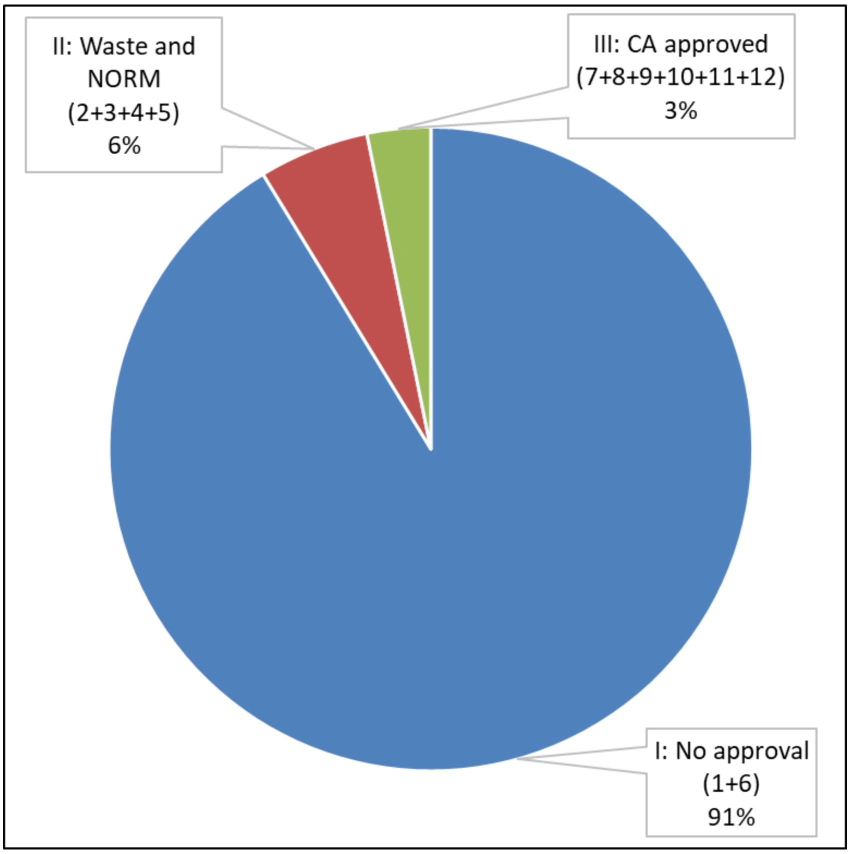


Figure 19: Breakdown of the package type groups consigned in 2016 (MS reported 2016 %)

An analysis of the number and type of packages carried in the community indicates some exceptional responses.

- The response from CZ indicates a significantly larger proportion of LSA packages than any other State (80% as compared to the next highest 5%).
- BG and SK report numbers of Type B non-fissile packages much larger than other states.
- A number of states provided fractions of excepted packages that are very small, while others report much higher values. The reasoning behind this is possibly limited availability of data. As noted above the number of excepted packages shipped is difficult to collect without creating excessive regulatory burden.

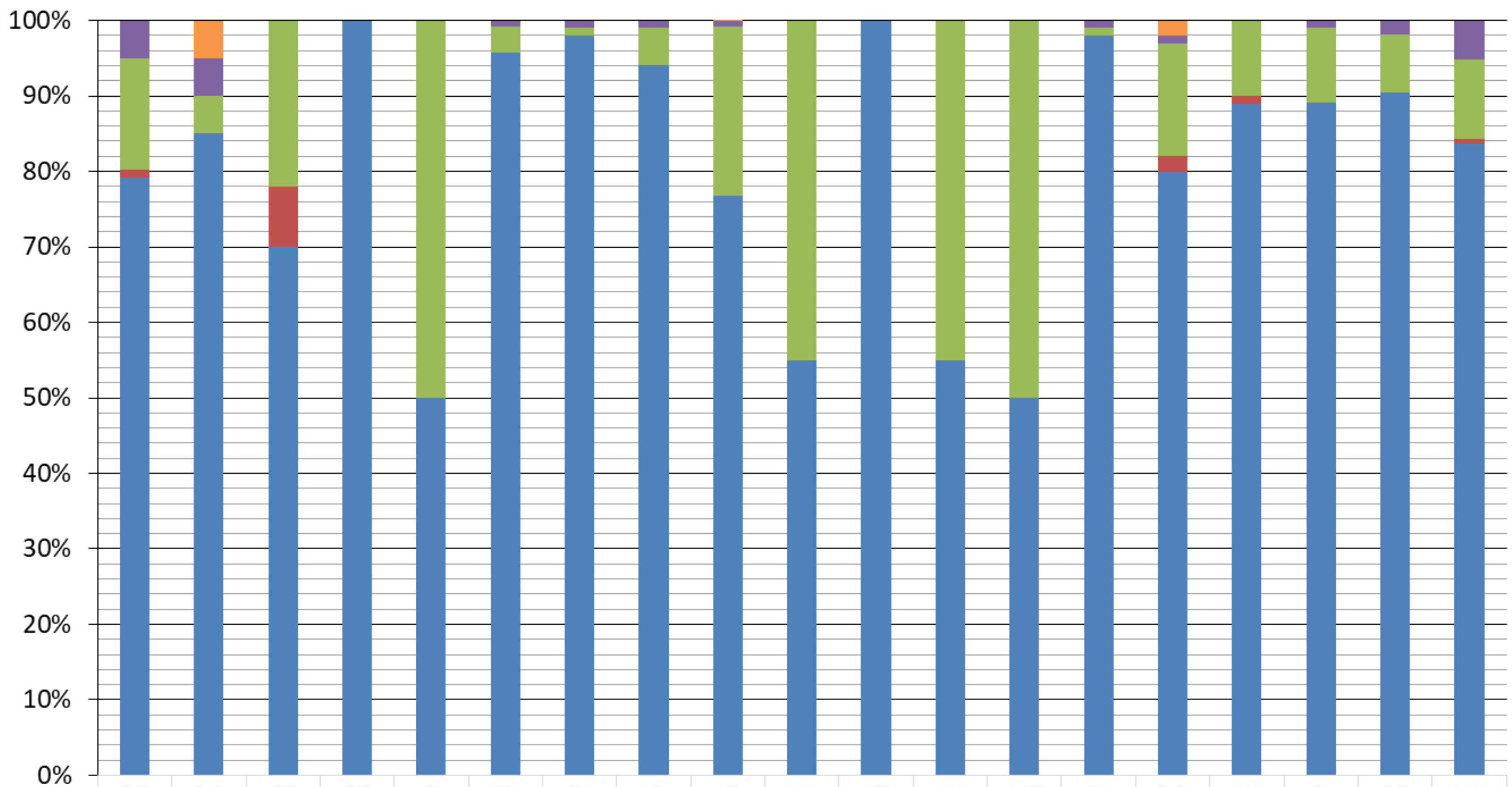
Overall, 97% of packages shipped are in the level which is not intended to have prior approval but rely on a graded approach of inspections. As a result it is essential that the Competent Authorities in MS can demonstrate that the compliance assurance programmes for the packaging not requiring CA approval are adequate based on the relative industry activities in their MS. Based on the data provided, this does not appear to be consistently carried out across the community. However, the consolidated data provided in this report is considered adequate to provide a first level review.

Q 1.1.3: MODES OF TRANSPORT

Please provide a breakdown of the modes of transport used for packages in 2016

Twenty MS provided data for this question, DK provided only a few values which are not adding up to 100% (this data set had to be excluded from the chart), while AT, HR, DE, NL and ES did not respond (**Figure 20**, **Figure 21**, **Figure 22**).

The sum of air and road transport ranges from 90% to 100% for each MS. Thirteen MS reported the total of road and air transport as 99% or above.



	BE	BG	CZ	EE	FI	FR	EL	IE	IT	LV	LT	LU	MT	PL	RO	SK	SI	SE	UK
Inland waterways	0,0	5,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0	2,0	0,0	0	0,0	0,0
Sea	5,0	5,0	0,0	0,0	0,0	0,8	1,0	1,0	0,8	0,0	0,0	0,0	0,0	1	1,0	0,0	1	2,0	5,0
Air	15,0	5,0	22,0	0,0	50,0	3,4	1,0	5,0	22,5	45,0	0,0	45,0	50,0	1	15,0	10,0	10	8,0	10,0
Rail	1,0	0,0	8,0	0,0	0,0	0,1	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0	2,0	1,0	0	0,0	0,5
Road	80,0	85,0	70,0	100,0	50,0	95,7	99,0	94,0	76,8	55,0	100,0	55,0	50,0	98,5	80,0	89,0	90	95,0	80,0

Figure 20: Breakdown of the modes of transport used for packages in 2016 (%)

DK*: Data set not complete, excluded from chart

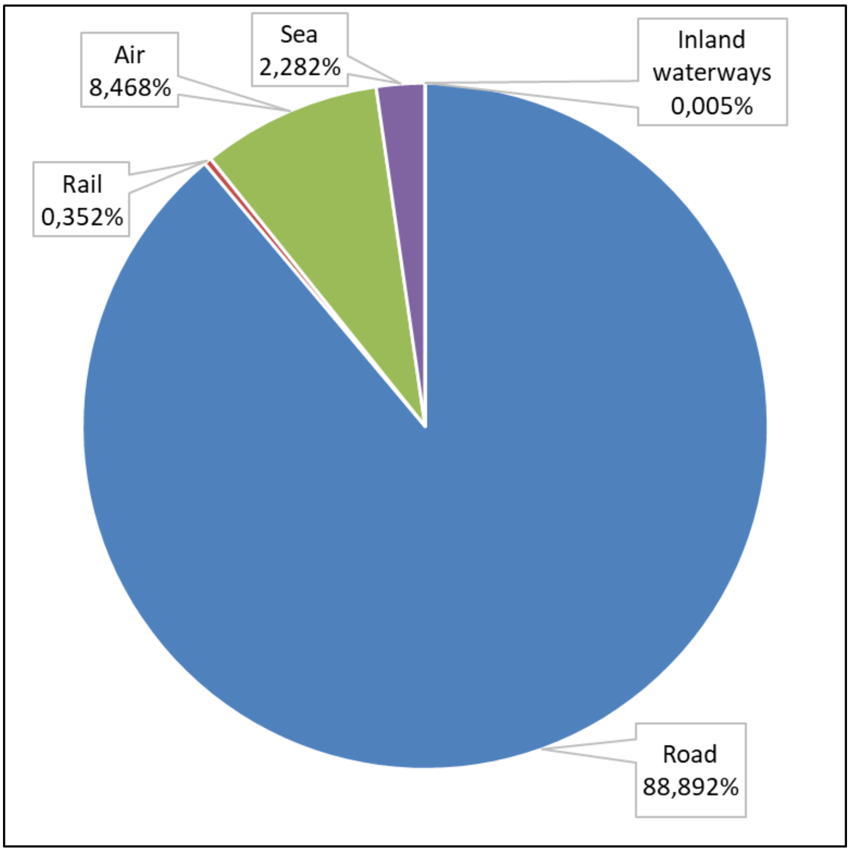


Figure 21: Breakdown of the modes of transport used for packages in 2016 (total number reported)

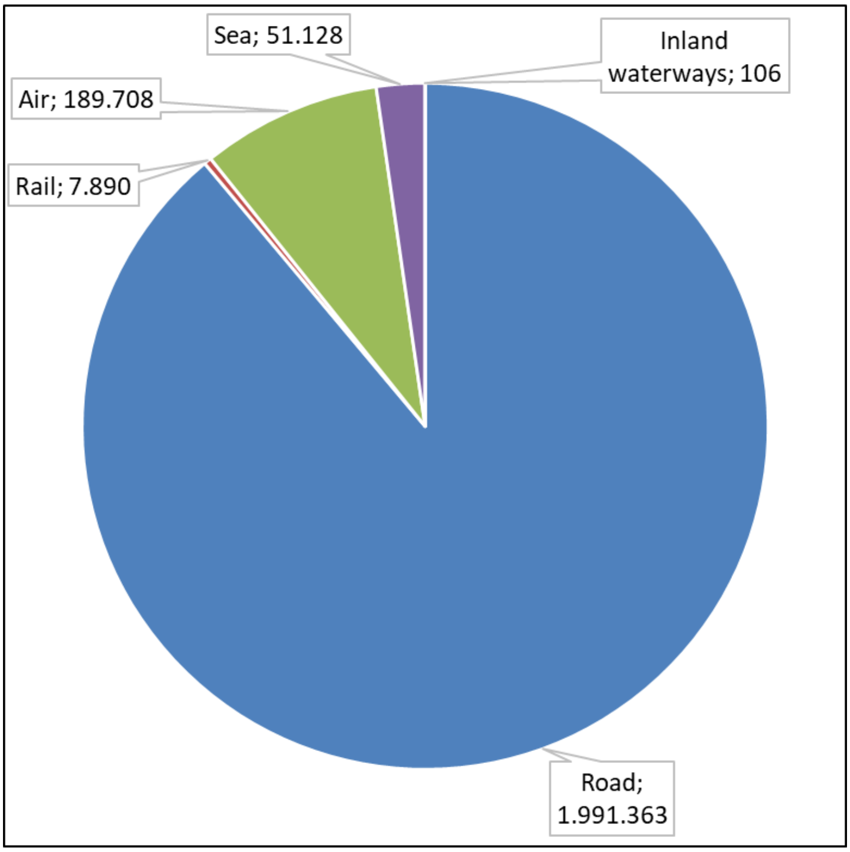


Figure 22: Breakdown of the modes of transport used for packages in 2016 (total number of packages reported)

Very little rail and sea transports were reported (8% and 5%, respectively). It was mainly road transport (50%), followed by air transport (average of 17 MS about 18%). Inland waterway transport was reported only by two MS.

By combining the number of packages shipped in the MS and the percentage of each mode it is possible to provide an estimate for the community (**Figure 21**). Road transport accounts for almost 90% of reported consignments and air transport almost 10%. Sea transport is around 2% of consignments, while rail is almost missing, with a notable exception of CZ, which reported 8%.

Previous studies ('Statistics on the Transport of Radioactive Materials and Statistical Analyses, Contract No: 4.1020/D/01-003') can be used to derive data for several key MS. Air transport appears to be more important than previously estimated (10% as opposed to 5%). Rail transport previously seems to have been estimated as being much more important. While sea transport was previously estimated as being less important, the data collected here suggest it is more important, but still relatively low compared to air and rail transport.

The importance of the relative split between modes is important in that it provides input to the regulatory system for the transport of radioactive materials.

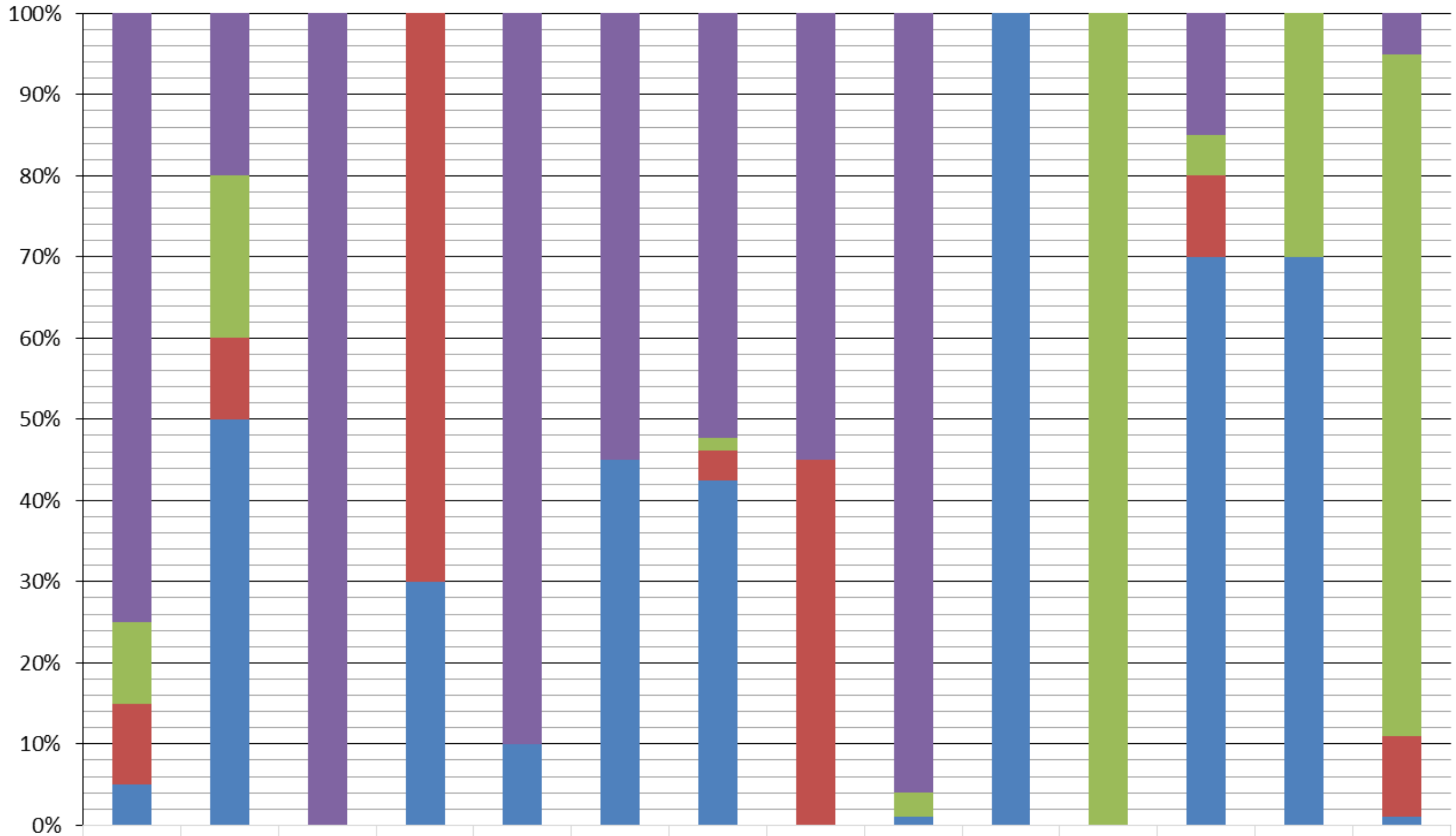
The current data suggest that the shipments of radioactive material by air in Europe are of the order of 200,000. Eurocontrol report around 10,000,000 flights over the same period, suggesting that only 1 in 50 flights carry radioactive material. The basis of the segregation calculations in 'Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2012 Edition)' (IAEA Safety Standards Series No. SSG-26) is a Radioactive Transport Factor (RTF) of 0.1 (i.e. it is estimated that 1 in 10 flights carry radioactive materials). As a result, the segregation calculations would seem to be overly restrictive (although more information related to the RTF for different flight lengths may provide different results). There is clearly a significant advantage in terms of both compliance assurance and regulatory standards in improving the collection of this data.

Q 1.1.4: CARRIER TYPES

Please provide a breakdown of the carrier types for packages in 2016

Fourteen MS provided data for this question, while AT, BG, HR, DK, FR, DE, NL, PL, SK, ES and UK did not answer (**Figure 23**). LU reported only 5% total. IT reported more than 100%.

The types of carriers vary significantly by MS. The data obtained here do not seem to be fully consistent with the data on modes of transport (for example, it is unlikely that the percentage of scheduled carriers will be less than the percentage of air mode). Few MS reported significant use of scheduled carriers. Significant use of specialist carriers was reported by some MS (including in an MS known to have a significant contract carrier fleet). Overall, the variation in the results suggests a lack of clarity over the meaning of the different categories of carriers.



	BE	CZ	EE	FI	EL	IE	IT	LV	LT	LU	MT	RO	SI	SE
Specialist RAM carrier	75	20	100	0	90	55	69	55	96	0	0	15	0	5
Contract freight carrier	10	20	0	0	0	0	2	0	3	0	100	5	30	84
Scheduled carrier	10	10	0	70	0	0	5	45	0	0	0	10	0	10
Carried by owner	5	50	0	30	10	45	56	0	1	5	0	70	70	1

Figure 23: Breakdown of the carrier types for packages in 2016 (%)

Q 1.1.5: END USE OF MATERIAL

Please provide a breakdown of the end use of material for packages in 2016

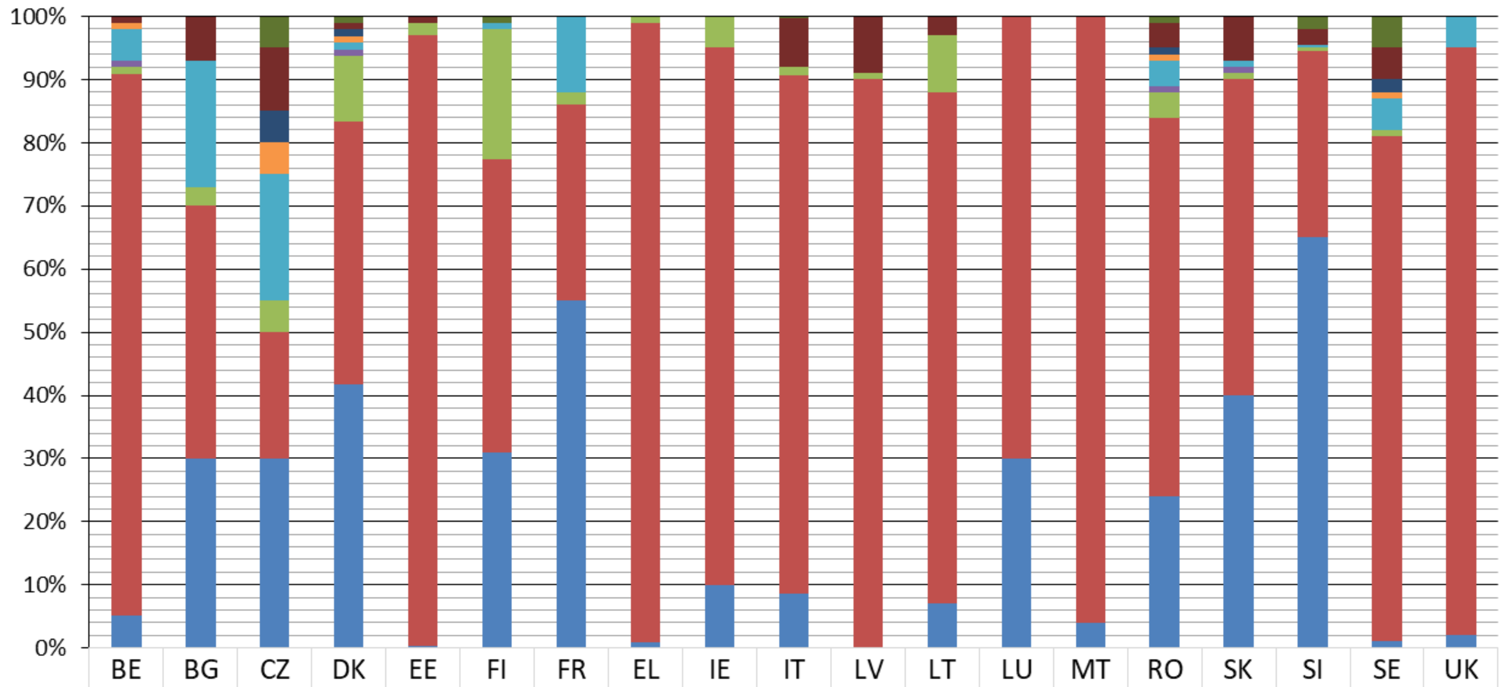
Nineteen MS provided data for this question, while AT, HR, DE, NL, PL and ES did not answer (**Figure 24**).

Medical and industrial use dominate the end use of transported radioactive materials, making up around 90% for most states. CZ appears, again, to be an outlier with nuclear making up 20% (medical and industrial making up only 50%). Only BG, CZ and FR reported the end use as nuclear exceeding 5%.

‘Research and education’ have been reported by 16 MS, with only DK and FI reporting more than 5%.

‘Disposal/storage of waste’ has been reported by 12 MS, values are all below 10%.

For the Community as a whole the data suggest that around 60% of Community shipments are for medical purposes, and around 25% are for industrial purposes, making up a total of 85% of Community shipments.



	BE	BG	CZ	DK	EE	FI	FR	EL	IE	IT	LV	LT	LU	MT	RO	SK	SI	SE	UK
Other	0	0	5	1	0	1	0	0	0	0,2	0	0	0	0	1	0	2	5	
Disposal/storage of waste	1	7	10	1	1	0		0	0	7,8	9	3	0	0	4	7	2,5	5	
Recycling	0	0	5	1	0	0		0	0	0	0	0	0	0	1	0	0	2	
Minerals	1	0	5	1	0	0		0	0	0	0	0	0	0	1	0	0	1	
Nuclear	5	20	20	1	0	1	12	0	0	0	0	0	0	0	4	1	0,5	5	5
Agriculture	1	0	0	1	0	0		0	0	0	0	0	0	0	1	1	0	0	
Research and education	1	3	5	10	2	20	2	1	5	1,4	1	9	0	0	4	1	0,5	1	
Medicine	85	40	20	40	96	45	31	99	85	82	90	81	70	96	60	50	29,5	80	93
Industry	5	30	30	40	0,3	30	55	1	10	8,6	0	7	30	4	24	40	65	1	2

Figure 24: Breakdown of the end use of material for packages in 2016 (%)

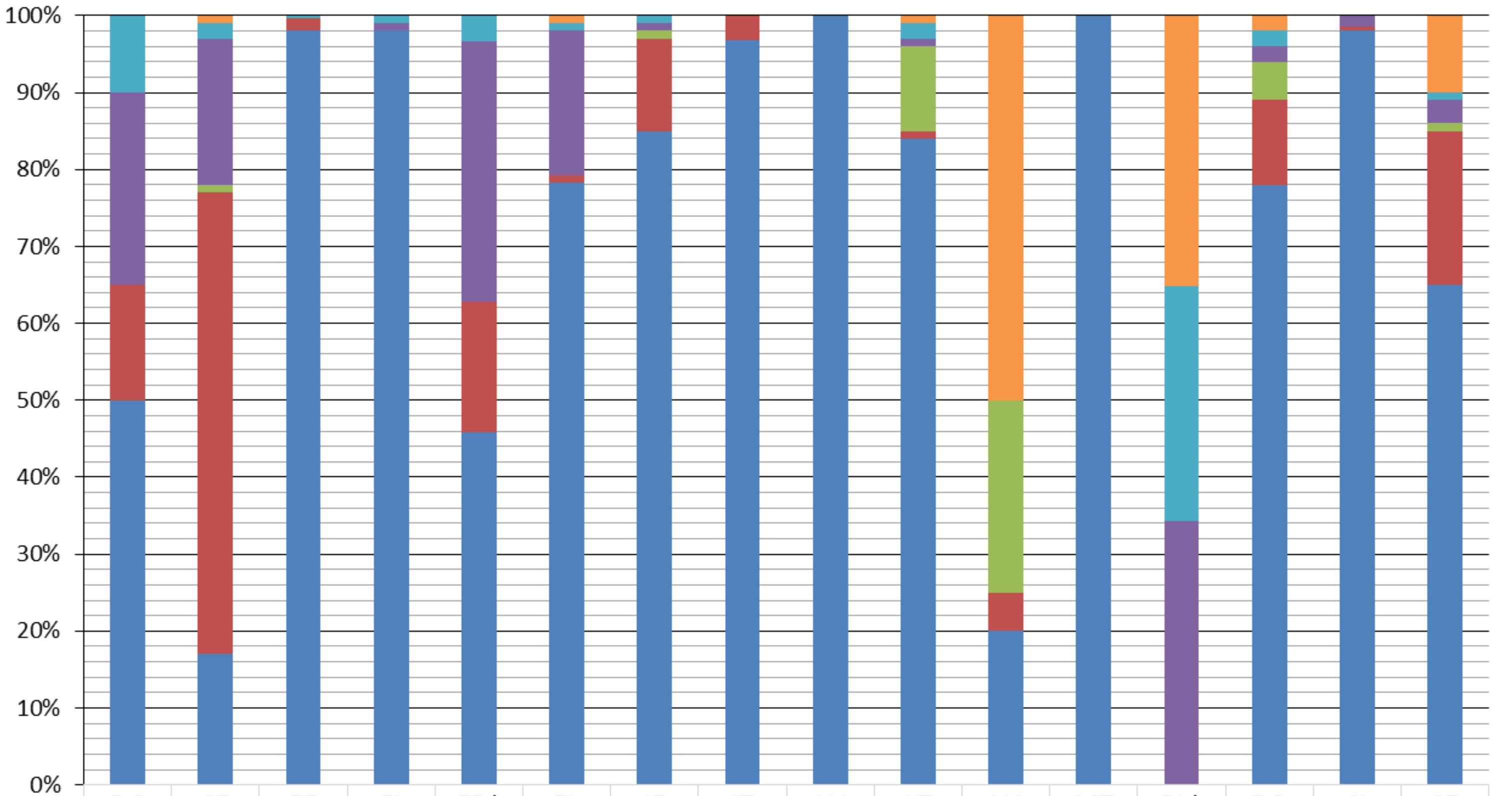
Q 1.1.6: TRANSBOUNDARY SHIPMENTS

The percentage of shipments of the types defined in the Shipment Directive (Transit (Extra-Community)-TT, Export from EU-ME, Import to EU-IM, Transit (Intra-Community)-MM, Outgoing only to EU-MM, Incoming only from EU-MM) was required in this question.

Sixteen MS provided data for this question (the per cent values for FR and PL have been calculated from the provided package numbers), while AT, BE, HR, DK, DE, NL, SK, ES and UK did not answer (**Figure 25**). IT values did not add up to 100%.

Only eight MS reported transit. LU and PL reported a significant number of transits.

Generally, intra-Community shipments were reported as being the majority of transboundary shipments. Only one MS has extra-Community shipments at the same level as intra-Community shipments.



	BG	CZ	EE	FI	FR*	EL	IE	IT	LV	LT	LU	MT	PL*	RO	SI	SE
Transit (extra-community)	0	1	0	0		1	0	0	0	1	50	0	35,1	2	0,0	10
Export from EU	10	2	0,3	1	3,4	1	1	0	0	2	0	0	30,5	2	0,0	1
Import to EU	25	19	0	1	33,8	19	1	0	0	1	0	0	34,4	2	1,5	3
Transit (intra-community)	0	1	0	0		0	1	0	0	11	25	0	0	5	0,0	1
Outgoing only to EU	15	60	1,7	0	16,9	1	12	1	0	1	5	0	0	11	0,5	20
Incoming only from EU	50	17	98	98	45,9	79	85	30	100	84	20	100	0	78	98,0	65

Figure 25: Transboundary shipments (%)

FR*, PL*: % values calculated from number of packages

REVIEW OF SHIPMENT DIRECTIVE REPORTS

Two reports were reviewed relating to transboundary shipments:

- REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE on Member States implementation of the Council Directive 2006/117/EURATOM on the supervision and control of shipments of radioactive waste and spent fuel, Second Report, {SWD(2018) 4 final}
- COMMISSION STAFF WORKING DOCUMENT Accompanying the document: Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee on the implementation by the Member States of Council Directive 2006/117/EURATOM on the supervision and control of shipments of radioactive waste and spent fuel, Second Report, {COM(2018) 6 final}

These are reports following the second three year period of implementation of Council Directive 2006/117/EURATOM of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel. The directive establishes requirements for the use of a standard document for the supervision and control of shipments of radioactive waste and spent fuel. The standard document was established by Commission Decision of 5 March 2008 establishing the standard document for the supervision and control of shipments of radioactive waste and spent fuel referred to in Council Directive 2006/117/EURATOM (notified under document number C(2008) 793) (2008/312/EURATOM).

The standard document includes six separate forms for:

- Application for authorisation for shipment(s) of spent fuel or radioactive waste;
- Acknowledgement of receipt of application – request for missing information for spent fuel and radioactive waste;
- Refusal or consent of radioactive waste or spent fuel shipment by the Competent Authorities concerned;
- Description of radioactive waste consignment and list of packages;
- Acknowledgement of receipt of radioactive waste and spent fuel;
- Authorisation of shipment of spent fuel and radioactive waste.

The standard document sets out different types of shipments which are related to the responses requested in the survey (**Table 23**):

Table 23: Different types of shipment

Survey Description	Shipment Directive Code	Description
Transit (Extra-Community)	TT	From a country external to EU to a country external EU (third countries of origin and destination)
Export from EU	ME	From an EU Member State to a country external to EU (third country)
Import to EU	IM	From a country external to EU (third country) to an EU Member State
Transit (Intra-Community)	MM	Transit from an EU Member State to another EU Member State
Outgoing only to EU	MM	Export from an EU Member State to another EU Member State, i.e. internal EU shipment
Incoming only from EU	MM	Import from an EU Member State to another EU Member State, i.e. internal EU shipment

In the period 2012–2014, there were 192 authorisations of MS of origin, of which 30 related to shipments to MS outside the community. This is consistent with the results collected for 2016 in this study. The number of shipments covered by the Shipment Directive (192) averages to around 65 a year.

This study estimates around 1,000,000 consignments each year in the Community, with the upper estimate of waste, NORM and CA-approved consignments as less than 100,000. From these figures it is clear that the Shipment Directive only applies to a very small proportion of consignments, and that the vast majority of waste shipments are internal to each MS.

Examination of the Competent Authorities responsible for approvals under the Shipment Directive identifies some MS with multiple regulators depending on region (e.g. DE and UK). Shipments between regions within a MS are not subject to the Shipment Directive. This is consistent with the definition of "transboundary movement" in the Basel Convention. However, this clearly does not demonstrate oversight or control of radioactive material or spent fuel at a community level, and leaves potential loopholes (for example a region within a MS could reject a shipment from another state, but the same shipment, if delivered to a neighbouring region within the same MS, would not subsequently be covered by the Shipment Directive).

The report identified differences in interpretation of the term 'radioactive waste' as a problematic area. This is dealt with in more detail in Chapter 8.4.1 of this report. Similar issues were identified in the case study related to NORM (Chapter 10.2), where material below the level of regulatory concern (i.e. not dangerous goods) was prevented from onward shipment in Europe without a declaration that it was dangerous goods.

An underlying issue was identified where an MS's regulatory system requires approvals by another state, but the second state has no process for issuing approvals. This was identified as an issue for the Shipment Directive, but it is also an issue that has been identified in terms of physical protection of HASS.

Overall, it would appear that the Shipment Directive, as it stands, adds little value to the safety of waste shipments within the community (first, it applies to only a very small fraction of the total waste shipments, and secondly, the essential transport safety requirements are in other legislation), however it does add value in other ways. It adds a regulatory interface to assure continuity of control for specified shipments.

The Shipment Directive identifies a clear area where it adds value. Given the issues related to clearance levels and the potential for cleared material in one MS being shipped to another MS where it is not considered cleared, but where no requirements exist in the transport safety legislation related to the shipment, this Directive now fills an important gap.

The recent update to the BSS Directive creates a new set of lower specific activities for waste, below transport safety concern, which will now rely on this Directive for continuity of regulatory oversight. Using the Shipment Directive to control the transfer of radioactive materials where there are no safety controls required, is an option that could be further examined for added benefits and potential pitfalls (such as waste definitions).

As part of this simplification, the aim of removing border controls, as intended by the Shipment Directive, should be integrated. As a result, transit would no longer be an activity requiring control, the only important issues remaining origin and destination. This could lead to the simplification of the Form A-1 as presented in **Figure 26**, **Figure 27** and **Figure 28**.

Application for authorisation of shipment(s) of radioactive waste

1.	Type of shipment (tick the appropriate box): ☐ type MM: shipment between Member States (via one or more Member States or third countries) ☐ type IM: import into the Community ☐ type ME: export out of the Community ~~☐ type TT: transit through the Community~~
2.	Application for authorisation for (tick the appropriate box): ☐ a single shipment ______ Planned period of execution: ______ ☐ several shipments: number (planned) ______ Planned period of execution: ______
3.	☐ Not applicable. ☐ Type MM shipment(s) via one or more third countries: Frontier post of exit from the Community (*): ______ Frontier post of entry to third country (*) (first country crossed): ______ Frontier post of exit from third country (*) (last country crossed): ______ Frontier post of return to the Community (*): ______ (*) These frontier posts must be identical for all shipments covered by the application unless otherwise agreed by the competent authorities.
4.	Applicant (trade name): ______ ~~☐ Holder (for types MM, ME)~~ ~~☐ Consignee (for type IM)~~ ~~☐ Other (for type TT), to be specified~~ ______ Address: ______ Postcode: ______ Town: ______ Country: ______ Tel. ______ Fax ______ E-mail: ______ Contact person: Mr/Ms ______
5.	Location of the radioactive waste before shipment (trade name): ______ Address: ______ Postcode: ______ Town: ______ Country: ______ Tel. ______ Fax ______ E-mail: ______ Contact person: Mr/Ms ______
6.	Consignee (trade name): ______ Address: ______ Postcode: ______ Town: ______ Country: ______ Tel. ______ Fax ______ E-mail: ______ Contact person: Mr/Ms ______
7.	Location of radioactive waste after shipment (trade name): ______ Address: ______ Postcode: ______ Town: ______ Country: ______ Tel. ______ Fax ______ E-mail: ______ Contact person: Mr/Ms ______

Figure 26: Potential simplification to Form A-1 Application for authorisation of shipment(s) of radioactive waste

8. Nature of radioactive waste: ____

Physicochemical characteristics (tick as appropriate):

☐ solid, ☐ liquid, ☐ gaseous, ☐ other (e.g. fissile, low dispersible, ...), to be specified ________________

Main radionuclides: ____

Maximum alpha activity: per shipment (GBq) ________________ ~~per package (GBq)~~ ________________

Maximum beta/gamma activity: per shipment (GBq) ______________ ~~per package (GBq)~~ ______________

Total alpha activity (GBq): ____

Total beta/gamma activity (GBq): ____

(These values are estimates if the application relates to several shipments)

9. Total number of packages: ____

Total net mass of shipment (kg): ____

Total gross mass of shipment (kg): ____

(These values are estimates if the application relates to several shipments)

Description of consignment:

☐ Plastic bags, ☐ metal drums (m^3): ________________ , ☐ ISO transport container (m^3): ________________ ,
☐ other, to be specified ________________

Type of package (1) (if known): ____

Means of identification of the packages (if labelling is used, annex examples): ____________________

(1) According to Regulations for the Safe Transport of Radioactive Material 2005 Edition, Safety Requirements No. TS-R-1 IAEA, Vienna, 2005.

10. Type of activity giving rise to the radioactive waste (tick as appropriate):

☐ medicine, ☐ research, ☐ (non-nuclear) industry, ☐ nuclear industry
☐ other activity (to be specified): ____

11. Purpose of the shipment:

☐ return of radioactive waste after (re)treatment or reprocessing of spent fuel

☐ return of radioactive waste after treatment of radioactive waste

☐ treatment, e.g. (re)packaging, conditioning, volume reduction

☐ interim storage

☐ return after interim storage

☐ final disposal

☐ other purpose (to be specified): ____

12.

Proposed mode of transport (road, rail, sea, air, inland waterway)	Point of departure	Point of arrival	Proposed carrier (if known)
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

Figure 27: Potential simplification to Form A-1 Application for authorisation of shipment(s) of radioactive waste (continued)

13.	Sequential list of countries concerned in the shipment (the first country is that where the radioactive waste is held and the last is the country of destination)			
	1.	3.	5.	7.
	2.	4.	6.	8.

14. In accordance with the provisions of Directive 2006/117/Euratom, I, the applicant, hereby:

1. apply for authorisation to make the shipment(s) of radioactive waste described above;

   and

2. certify that the information provided above is correct to the best of my knowledge and that the shipment(s) will be carried out in accordance with all the relevant statutory provisions;

   and

3. (*) (Where the shipment is of type MM or ME) undertake to take back the radioactive waste if the shipment(s) cannot take place or if the conditions for shipment cannot be fulfilled;

   or

   (*) (Where the shipment is of type IM [redacted]) attach hereto the evidence of the arrangement between the consignee and the holder of the radioactive waste established in the third country, which has been accepted by the competent authority of the third country, stating that the holder in the third country will take back the radioactive waste if the shipment(s) cannot take place or if the conditions for shipment cannot be fulfilled, unless an alternative safe arrangement can be made.

(Date and place) (Stamp) (Signature)

(*) Only one of the asterisked statements can apply: delete as applicable.

Figure 28: Potential simplification to Form A-1 Application for authorisation of shipment(s) of radioactive waste (continued)

IMPROVED DATA COLLECTION

A methodology for recording information has been in operation in IT for a number of years and has provided valuable information to State and Community studies. The methodology involves limited overhead for both the State and industry.

The Italian authorities provided this input to the study:

Data collection system on transport of radioactive material in Italy

The data on transport of radioactive material are collected, by licensed carriers, on the basis of the national Radiation Protection Law (Legislative Decree 17 March 1995, No. 230) that requires the provision, on quarterly basis, a summary of the shipments carried out. The information requested can be collected by a simple computer program, provided by ISPRA for small carriers, or by their own computer program for major carriers usually by the information contained in the transport document issued for the consignment. The structure of the record of the data is explained in the attached format (in Italian). The single format contains four records for four different shipments. For more than four shipments another format has to be used.

To transmit the summary of the data is available on the ISPRA website (https://tradaweb.isprambiente.it/acl_users/credentials_cookie_auth/require_login?came_from=https%3A//tradaweb.isprambiente.it/) a system called TRADAWEB by which a licensed carrier can send the data by web with a user name and password.

The data collection form is illustrated in **Figure 29**. A system such as this would benefit both MS and the EU/Community in deciding on the suitability of compliance assurance regimes. This demonstrates that a system of data collection can be implemented without introducing undue administrative burden.

There are legislative requirements for collecting of statistical information on transport of radioactive material are already in place (see Chapter 6.2.1). Enough legal basis exists to require collection of statistical data, however the data collected may need review to ensure the information collected is suitable for the purpose of reviewing the compliance assurance needs of the EU/Community. A suggestion for data recording is set out in Annex A8.

Matricola | **Nome o Ragione Sociale e Indirizzo del Vettore**

ALLEGATO II

N° Doc. Trasporto

Data Inizio Trasporto gg / mm / anno

Data Fine Trasporto gg / mm / anno

N° ONU

Nome o Ragione Sociale e Indirizzo del

Mittente (origine della spedizione)

Vettore Precedente (se esiste)

Località Partenza Tratta[9] (se esiste un vettore precedente)

Destinatario (finale della spedizione)

Vettore Seguente (se esiste)

Località Arrivo Tratta[9] (se esiste un vettore seguente)

Caratter. dei COLLI: Num. Dim.[1] Tipo[2] Marchio IAEA[10] Cat[3] IT[4,11]

Caratter. del Materiale Radioattivo: Radionuclide SF[5] M[6] CI[7] Attività[11] UM[8]

N° Doc. Trasporto

Data Inizio Trasporto gg / mm / anno

Data Fine Trasporto gg / mm / anno

N° ONU

Nome o Ragione Sociale e Indirizzo del

Mittente (origine della spedizione)

Vettore Precedente (se esiste)

Località Partenza Tratta[9] (se esiste un vettore precedente)

Destinatario (finale della spedizione)

Vettore Seguente (se esiste)

Località Arrivo Tratta[9] (se esiste un vettore seguente)

Caratter. dei COLLI: Num. Dim.[1] Tipo[2] Marchio IAEA[10] Cat[3] IT[4,11]

Caratter. del Materiale Radioattivo: Radionuclide SF[5] M[6] CI[7] Attività[11] UM[8]

N° Doc. Trasporto

Data Inizio Trasporto gg / mm / anno

Data Fine Trasporto gg / mm / anno

N° ONU

Nome o Ragione Sociale e Indirizzo del

Mittente (origine della spedizione)

Vettore Precedente (se esiste)

Località Partenza Tratta[9] (se esiste un vettore precedente)

Destinatario (finale della spedizione)

Vettore Seguente (se esiste)

Località Arrivo Tratta[9] (se esiste un vettore seguente)

Caratter. dei COLLI: Num. Dim.[1] Tipo[2] Marchio IAEA[10] Cat[3] IT[4,11]

Caratter. del Materiale Radioattivo: Radionuclide SF[5] M[6] CI[7] Attività[11] UM[8]

N° Doc. Trasporto

Data Inizio Trasporto gg / mm / anno

Data Fine Trasporto gg / mm / anno

N° ONU

Nome o Ragione Sociale e Indirizzo del

Mittente (origine della spedizione)

Vettore Precedente (se esiste)

Località Partenza Tratta[9] (se esiste un vettore precedente)

Destinatario (finale della spedizione)

Vettore Seguente (se esiste)

Località Arrivo Tratta[9] (se esiste un vettore seguente)

Caratter. dei COLLI: Num. Dim.[1] Tipo[2] Marchio IAEA[10] Cat[3] IT[4,11]

Caratter. del Materiale Radioattivo: Radionuclide SF[5] M[6] CI[7] Attività[11] UM[8]

Legenda

Forme collo: (cilindro) (box)

1) Dimensioni del collo (cm):
- **A** per colli (box) 20 x 20 x 20
- **B** per colli (box) 30 x 30 x 30
- **C** per colli (box) 40 x 40 x 40
- **D** per colli (cilindro) ϕ 40 x 50
- **E** per colli (box) maggiore di 40 x 40 x 40
- **F** per colli (cilindro) maggiore di ϕ 40 x 50

2) Tipo collo:
- **E** per collo ESENTE
- **1** per collo Industriale IP-1
- **2** per collo Industriale IP-2
- **3** per collo Industriale IP-3
- **A** per collo Tipo A
- **B** per collo Tipo B
- **C** per collo Tipo C

3) Categoria collo:
- **1** per categoria BIANCA-I
- **2** per categoria GIALLA-II
- **3** per categoria GIALLA-III

4) IT Indice di Trasporto

5) SF Stato Fisico della sorgente:
- **S** per materie radioattive Solide
- **L** per materie radioattive Liquide
- **G** per Gas radioattivo
- **F** per materie radioattive in forma speciale
- **X** per materie radioattive Solide + Liquide
- **K** Gas radioattivo in forma speciale

6) M per indicare miscele di più radionuclidi

7) CI Codice d'impiego del radionuclide:
- **RR** Rifiuto
- **IO** Impiego Ospedaliero
- **RA** Radiofarmaco
- **CN** Materiali del Ciclo del Combustibile
- **RI** Ricerca
- **I** Impiego Industriale
- **GA** Gammagrafia industriale
- **AG** Agricoltura/Indagine suolo

8) UM Unità di Misura dell'Attività:
- **Bq** Becquerel
- **KB** KiloBecquerel 10^3 Bq
- **MB** MegaBecquerel 10^6 Bq
- **GB** GigaBecquerel 10^9 Bq
- **TB** TeraBecquerel 10^{12} Bq
- **PB** PetaBecquerel 10^{15} Bq

9) La tratta è la parte del trasporto effettuata dal vettore dichiarante relativa ad una spedizione che prevede un vettore precedente e/o seguente.

10) Se il collo è certificato come tipo B, C o Fissile riportare il marchio di identificazione.

11) I valori relativi all'Indice di Trasporto e all'Attività sono riferiti al singolo collo anche quando sono trasportati più colli (voce Num maggiore di 1).

Firma del Vettore

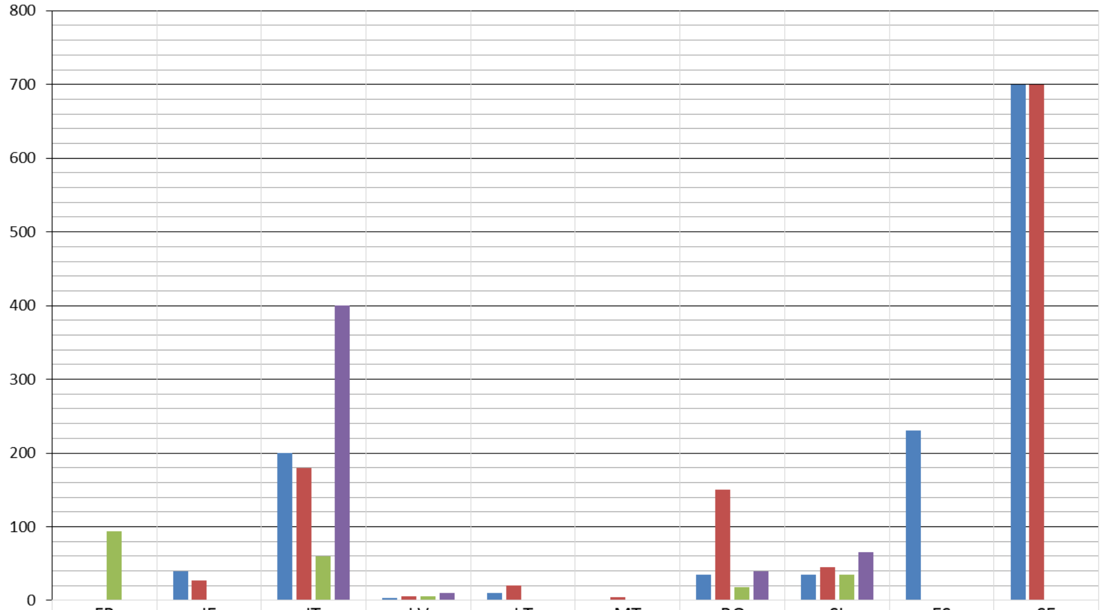
mod. TRADAT 2005

Figure 29: Italian Data Recording Form

Q 1.1.7: CONSIGNORS, CONSIGNEES, OWNERS, USERS (DUTYHOLDERS)

How many people were involved in radioactive material transport in the state in 2016?

Only ten MS provided data for this question, while AT, BE, BG, HR, CZ, DK, EE, FI, DE, EL, LU, NL, PL, SK and UK did not respond (**Figure 30**). In this area there was a very poor response — in essence regulators were not aware of how many bodies they regulated. This is a particularly important result. Without any idea of the extent of the industry being regulated it is effectively impossible for the regulator to determine if they are applying the graded approach appropriately.



	FR	IE	IT	LV	LT	MT	RO	SI	ES	SE
Consignors		40	200	3	10		35	35	230	700
Consignees		27	180	6	20	4	150	45		700
Package owners	94		60	6			18	35		
Package users			400	10			40	65		

Figure 30: Number of people involved in TRAM in MS in 2016

Q 1.1.7: CHANGES EXPECTED IN INDUSTRY

What is your best estimate of the change in industry experience (in terms of sum of the number of person years available)?

Twenty MS answered this question; of those, FI and SK did not answer the 'Designers' part of the question, BG and MT did not provide estimates for the 'Designers' and 'Package owners' parts, while AT, DK, EE, DE and LU did not answer.

The response to this question is summarized in the **Table 24** and **Figure 31**. Overall, the impression is that industry experience has remained the same.

Table 24: Expected changes to industry capacity

		Total YES	# of MS
Designers	Decreasing a little	1	16 of 25
	Staying the same	12	
	Increasing a little	3	
Consignors	Decreasing a little	2	20 of 25
	Staying the same	14	
	Increasing a little	4	
Package owners	Decreasing a little	1	18 of 25
	Staying the same	15	

		Total YES	# of MS
	Increasing a little	2	
Package users	Decreasing a little	1	20 of 25
	Staying the same	15	
	Increasing a little	4	

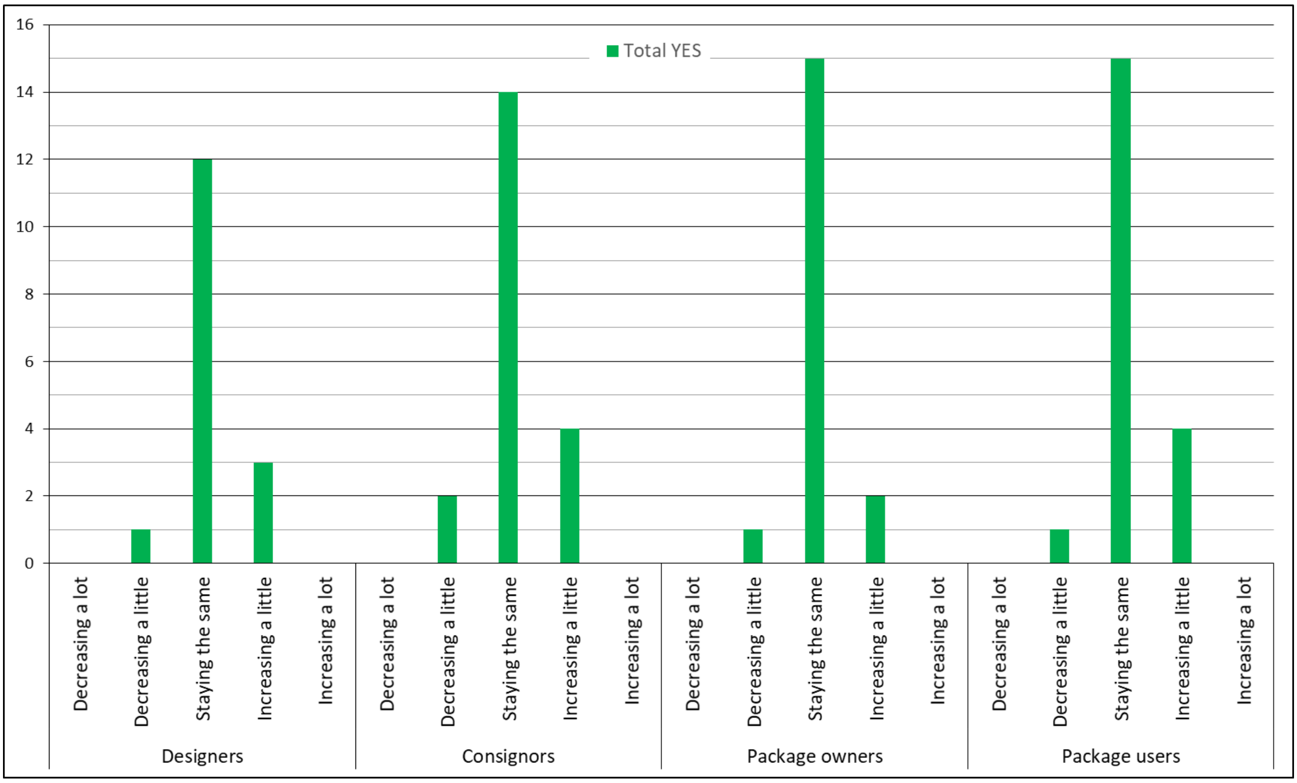


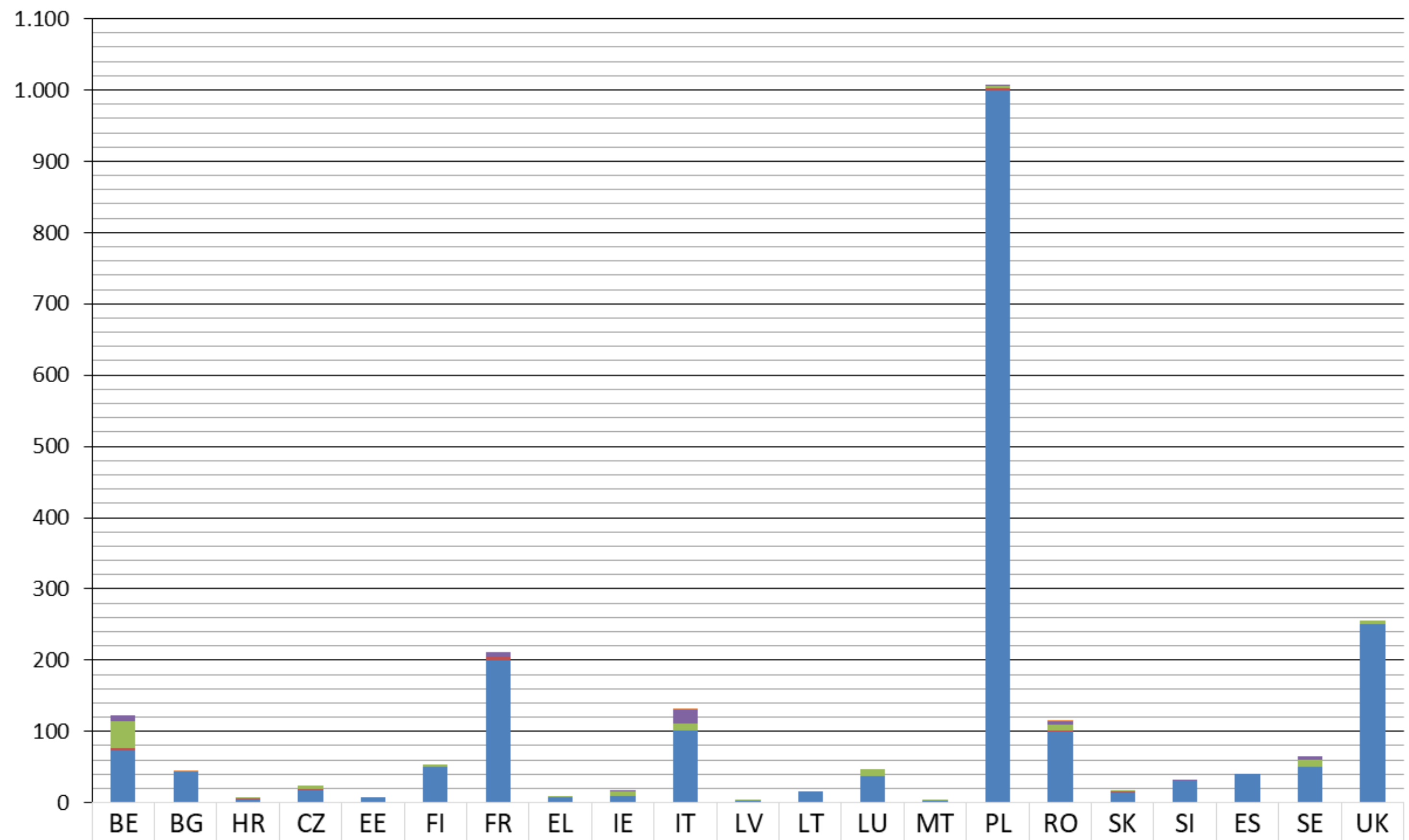
Figure 31: Best estimate of the change in industry experience

Given that most MS could did not provide any estimate of the number of dutyholders there must be a question as to the accuracy of the response to this question.

Q 1.2: TRANSPORT ENTERPRISES

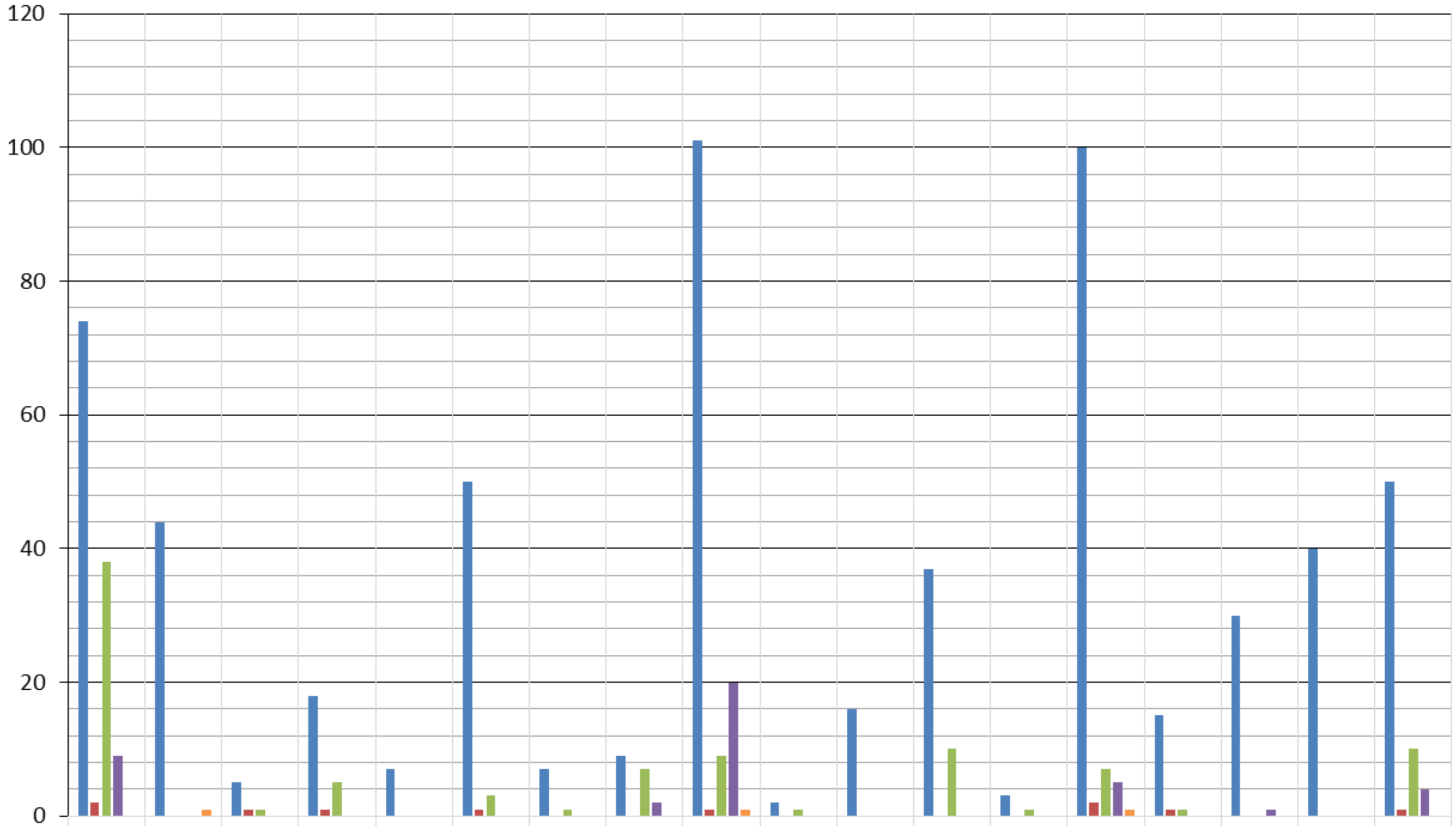
Regarding the question requesting the number of transport enterprises per mode of transport, 21 MS provided numbers while AT, DK, DE and NL did not answer this question (**Figure 32**).

The main part of transport enterprises are road carriers (92.3%), second ranked are aircraft operators (4.6%), third ranked are sea transport enterprises (2.2%), fourth ranked rail operators (0.8%) and fifth ranked inland waterways enterprises (0.1%). **Figure 33** excludes the numbers received from FR, PL and UK, which were significantly bigger than the ones from other MS, in order to present a clearer view of the figures in the majority of the MS.



	BE	BG	HR	CZ	EE	FI	FR	EL	IE	IT	LV	LT	LU	MT	PL	RO	SK	SI	ES	SE	UK
Inland waterways enterprises		1								1						1					
Sea transport enterprises	9						7		2	20					1	5		1		4	
Aircraft operators	38		1	5		3		1	7	9	1		10	1	3	7	1			10	5
Rail operators	2		1	1		1	4			1					3	2	1			1	1
Road carriers	74	44	5	18	7	50	200	7	9	101	2	16	37	3	1000	100	15	30	40	50	250

Figure 32: Number of transport enterprises that carry radioactive material



	BE	BG	HR	CZ	EE	FI	EL	IE	IT	LV	LT	LU	MT	RO	SK	SI	ES	SE
Road carriers	74	44	5	18	7	50	7	9	101	2	16	37	3	100	15	30	40	50
Rail operators	2		1	1		1			1					2	1			1
Aircraft operators	38		1	5		3	1	7	9	1		10	1	7	1			10
Sea transport enterprises	9							2	20					5		1		4
Inland waterways enterprises		1							1					1				

Figure 33: Number of transport enterprises that carry radioactive material (Minus FR, PL and UK)

The calculated values for the number of carriers one regulatory body inspector would be responsible for is presented in **Figure 34**.

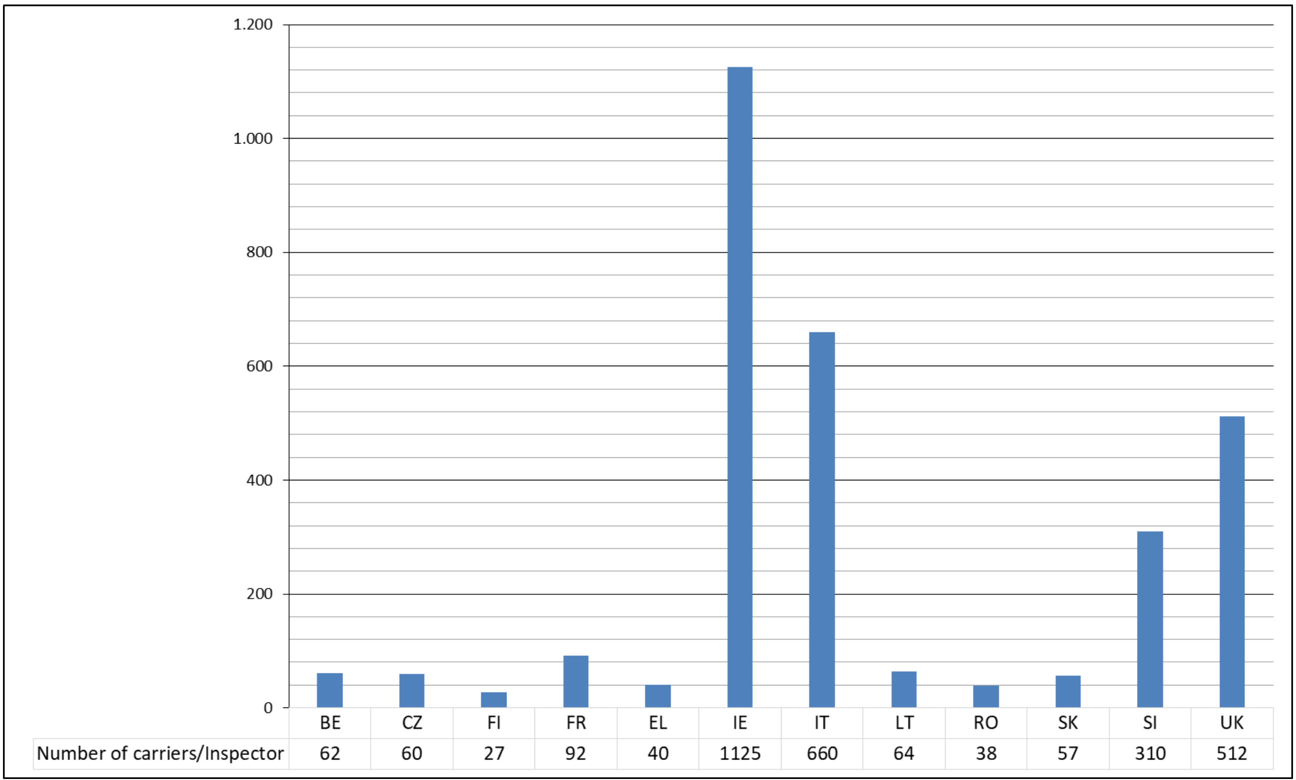


Figure 34: Number of carriers per regulatory body inspector

The results for IE have poor accuracy as a result of the very small amount of inspection resource. The variation in the number of transport enterprises divided by the inspection resource available is notable. The average for the Community is around 135 transport enterprises for each inspection year of resource, with the majority of MS reporting data having values close to 50. Obviously, the amount of inspection resource necessary for compliance checking will vary depending on the complexity of the transport enterprises, and this does seem to be reflected in the results. Clearly there is no ‘right’ answer to the amount of resource required, however it would seem that a value of around 50 transport enterprises per year of inspection resource is considered appropriate even for MS with complex transport industry.

Q 1.3: ROUTE RESTRICTION

MS were asked to provide numbers for major airports/sea ports and inland waterway ports that permit TRAM.

Twenty MS provided data, although, depending on their geographical position and/or lack of inland waterways, they often could not provide numbers for all three possibilities (**Figure 35**).

For sea transport the list was compared to the ‘European Commission List of Sea Ports in the Core and Comprehensive Networks’. For air transport the list was compared to the ‘DG Move Statistical Pocketbook 2017, EU transport in figures’ (major airports >100,000 passengers). For inland waterway the figures were compared to data from the CIA factbook.

This suggests that around two-thirds of airports and three quarters of sea ports in the community do not accept radioactive material (**Figure 36**). While the issue with airports is significant, the level of refusal by sea ports would seem closer to a critical level. The reason behind this is that air transport is normally point to point, while sea transport relies on multiple stops on journeys.

Taking a simplistic view this can be demonstrated. For any particular air journey a simplistic approach suggests that there is a probability of around 90% that it cannot be made. However, for a sea journey the probability that a particular journey cannot be made depends on the number of ports. A journey with direct service has a probability that the journey cannot be made of around 94%, a three-ports journey raises this probability to 99% and for a four-ports journey the same probability is around 99.5%.

While this is an overly simplistic approach the situation could in fact be much worse if a major port refuses radioactive material. The effect could be that a single port refusing the transit of radioactive material could create a total barrier to sea shipments to other MS.

Moreover, some ports that accept radioactive materials have specific administrative barriers that impede free shipment. One port has recently started to accept radioactive material transit, but subject to additional requirements. Similarly, key ports in France have implemented new requirements related to security. The percentage of major ports reported as willing to carry radioactive material is presented in **Figure 37**.

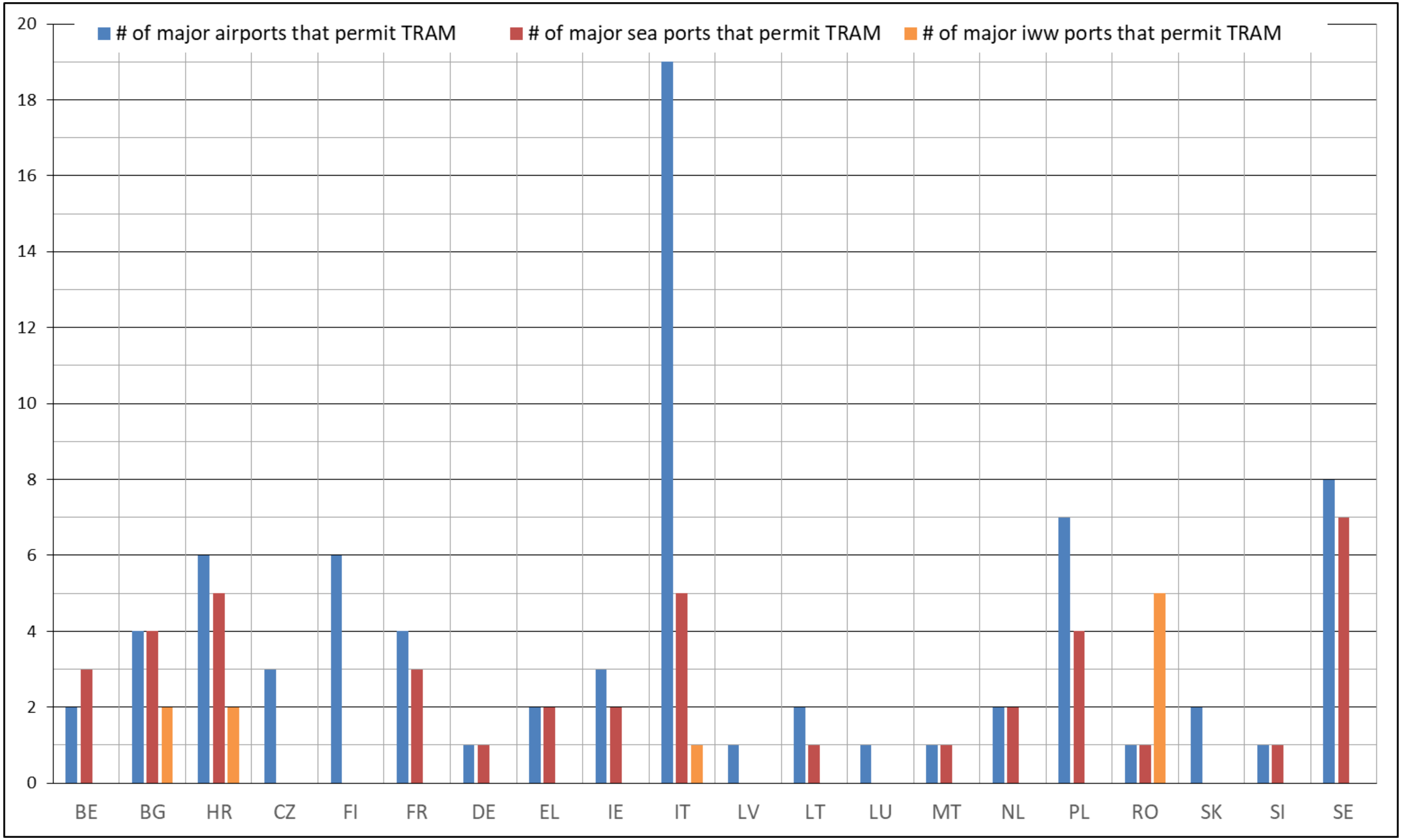
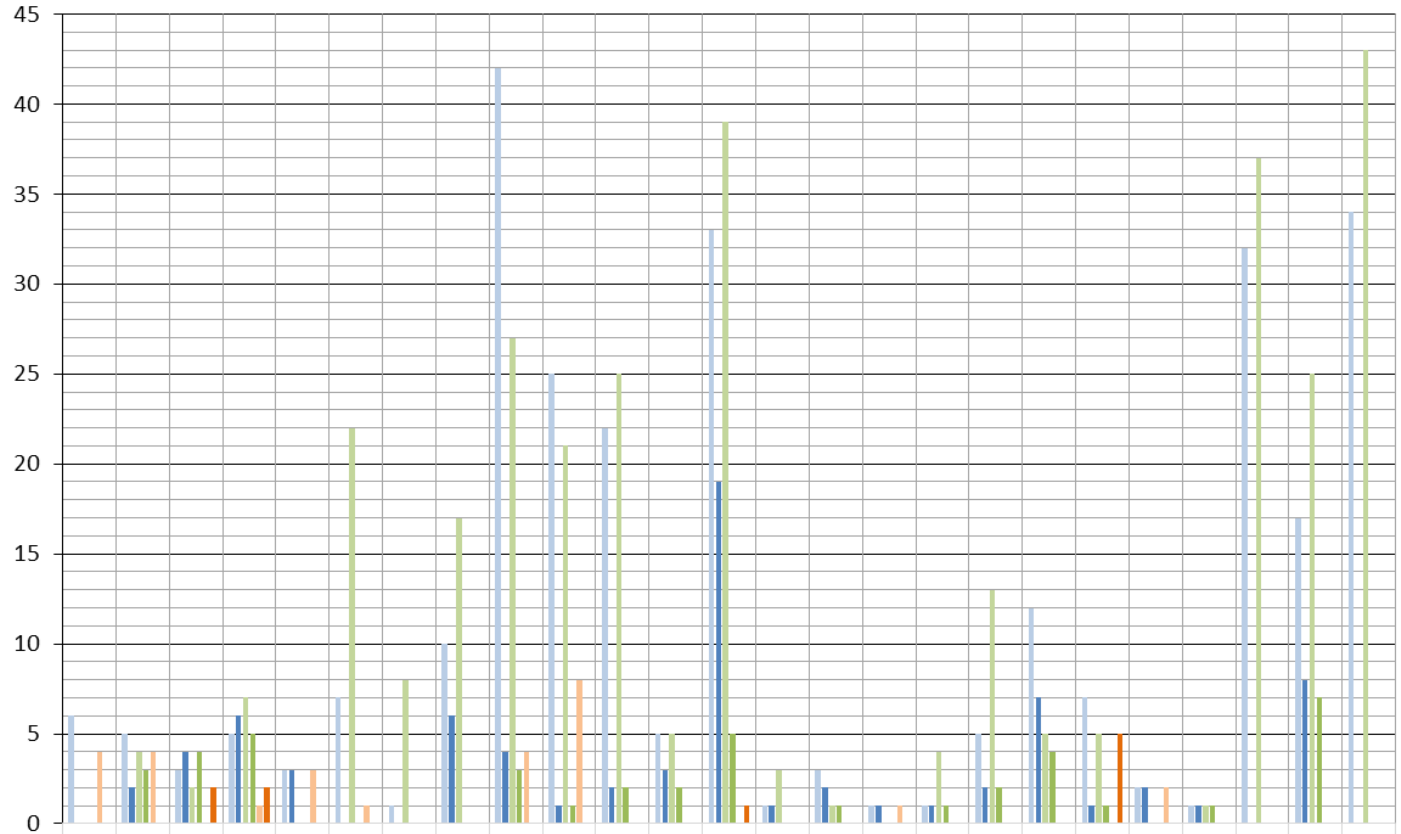


Figure 35: Number of major air/sea/inland waterways ports that permit TRAM



	AT	BE	BG	HR	CZ	DK	EE	FI	FR	DE	EL	IE	IT	LV	LT	LU	MT	NL	PL	RO	SK	SI	ES	SE	UK
# of major airports (>100.000 passengers)*	6	5	3	5	3	7	1	10	42	25	22	5	33	1	3	1	1	5	12	7	2	1	32	17	34
# of major airports that permit TRAM	0	2	4	6	3	0	0	6	4	1	2	3	19	1	2	1	1	2	7	1	2	1	0	8	0
# of major sea ports**	0	4	2	7	0	22	8	17	27	21	25	5	39	3	1	0	4	13	5	5	0	1	37	25	43
# of major sea ports that permit TRAM	0	3	4	5	0	0	0	0	3	1	2	2	5	0	1	0	1	2	4	1	0	1	0	7	0
# of major iww ports***	4	4	0	1	3	1	0	0	4	8	0	0	0	0	0	1	0	0	0	0	2	0	0	0	0
# of major iww ports that permit TRAM	0	0	2	2	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	5	0	0	0	0	0

Figure 36: Route restrictions (all participating MS)

Data sources: * Statistical Pocketbook 2017, EU transport in figures, DG Move, ** List of Sea Ports in the Core and Comprehensive Networks (EC 2014) *** CIA Factbook

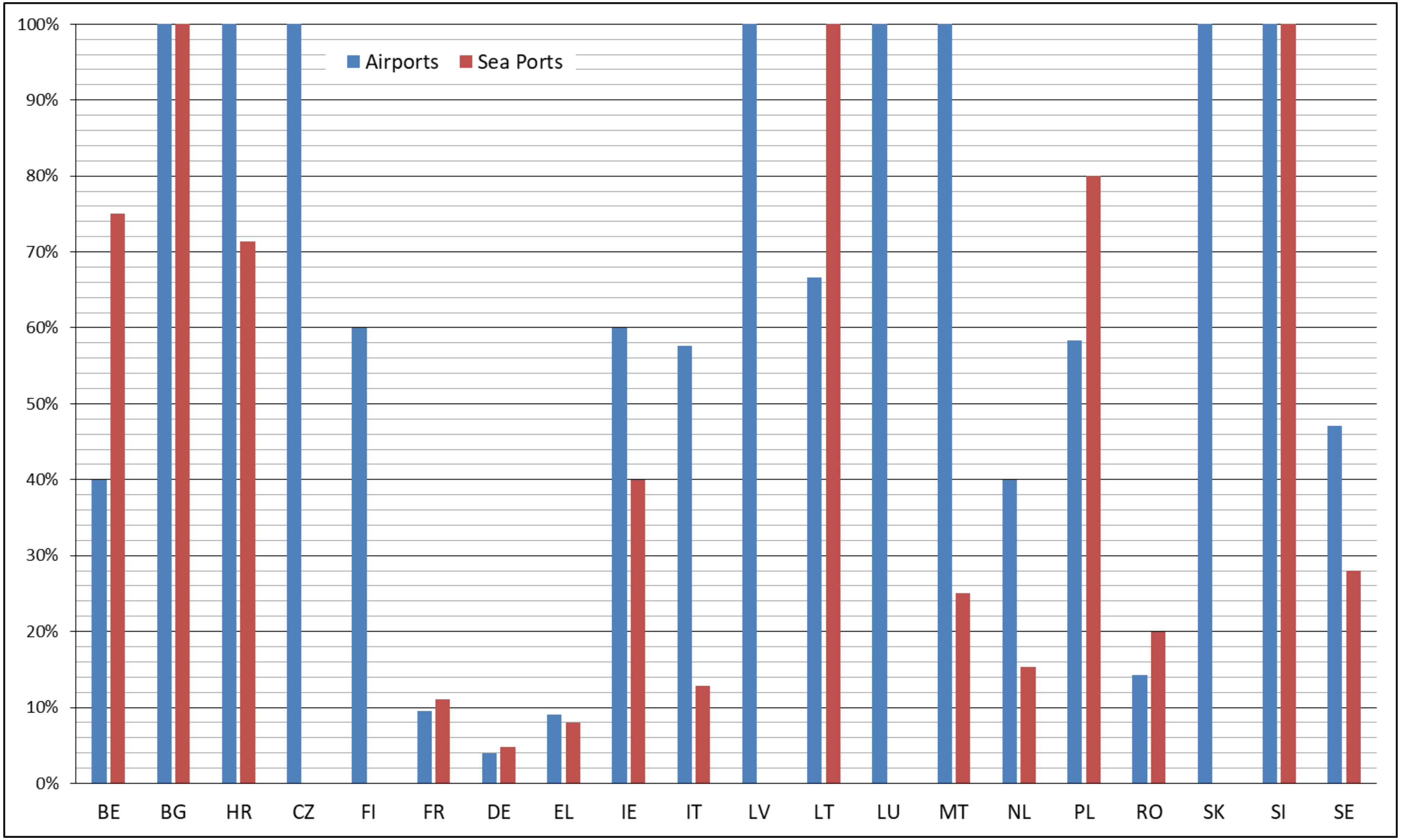


Figure 37: Percentage of major ports reported as willing to carry radioactive material

MS were asked if there were any restrictions on road/rail routes for transport of radioactive materials. It was expected that this would identify a number of restrictions, particularly related to tunnels, where there are standardised methodologies applied across the EU. This question was answered by all 25 participating MS (**Figure 38**, **Figure 39**). Over 50% reported having road route restrictions for TRAM in place, only 25% reported having rail restrictions in place.

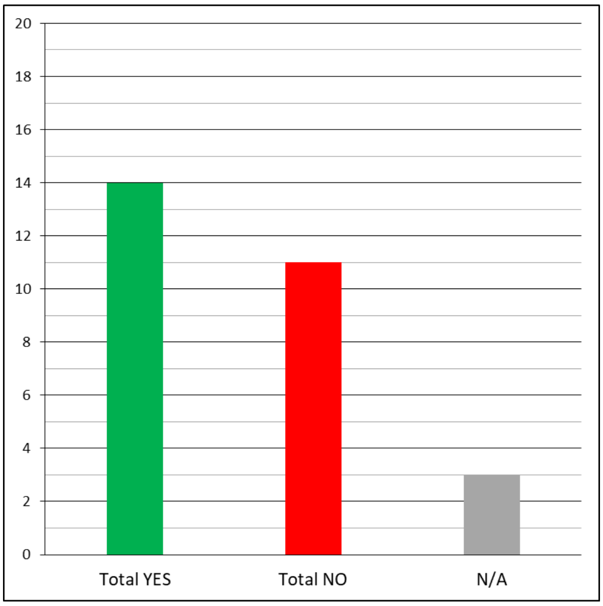


Figure 38: Any restrictions on road routes for TRAM

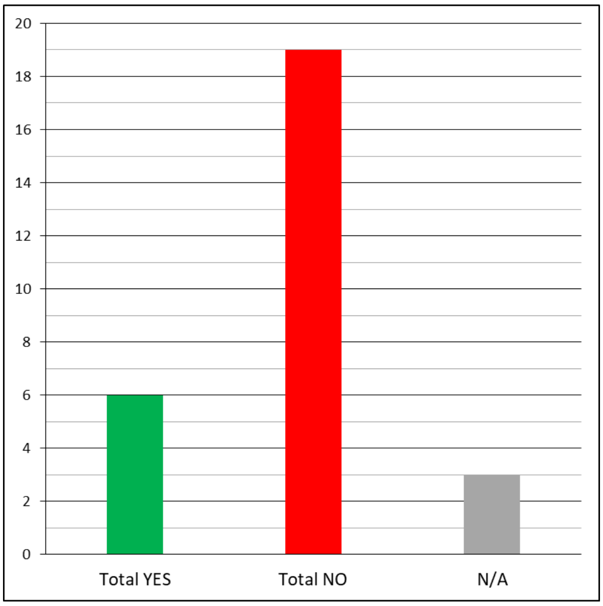


Figure 39: Any restrictions on rail routes for TRAM

If YES, please describe (for road and rail)

The explanatory details, which should be provided in case of existing route restrictions are summarized in **Table 25**.

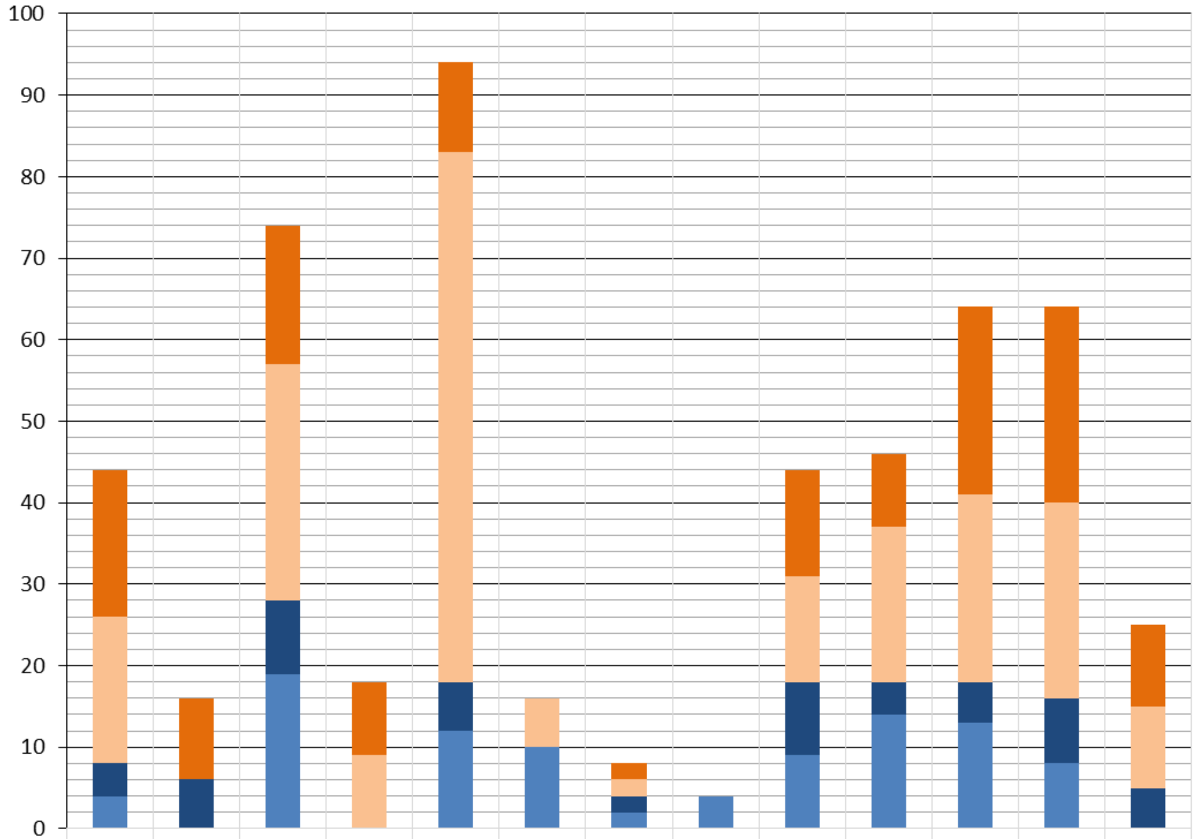
Table 25: Reported route restrictions

Country	Route restrictions
AT Road	Specific operating measures designed to reduce the risks and related to vehicles using tunnels (1.9.5.3.8) as described in 'Operating measures_Austria_04-2010e.pdf, available at www.unece.org/trans/danger/publi/adr/country-info_e.html#Austria' II: Restrictions on roads other than highways These restrictions are based on the ordinances (Verordnungen) issued by the governments of the federal provinces or by the regional administration authorities. Transport units with high risk are transport units subject to marking with orange-coloured plates whose hazard identification number - has "2" as first figure (f.i. 20 or 23) or - has doubling of figures "2" to "8" (f.i. 33 or 44) or - is prefixed by the letter "X". Types of conditions 3 The transport unit must be fitted with at least one amber warning lamp. That lamp must be switched on before entry and remain in operation throughout the route concerned. 4 The drivers of the transport units have to notify the tunnel control of the ADR classification of the goods being carried, as contained in the transport documents, together with the quantity. 5 The transport units must be accompanied by at least one escort vehicle. During the escort the escort vehicle must operate an amber warning light as well. 6 The drivers must obtain permission to pass by the tunnel control. 7 The drivers have to observe a minimum distance to the vehicle in front.
BE Rail	Transport of dangerous goods is not allowed in the railway network in and around Brussels
DK Road	When transporting fissile material, planned route must be accepted by DEMA
DK Rail	Class 7 material is very rarely transported by rail in Denmark
EE Road	[Translated from Estonian] Dangerous Goods Road Transport Regulation; §12_3 (5) In the case of the carriage of a high-risk cargo of high-risk category 1 in Appendix 12 of the Regulation, for the purposes of the Explosive Material Act, the owner of the handling permit for an explosive and the carriage of high-risk cargo falling within class 7 shall notify the owner of the radiation practice permit, the route of the choice of the police, who decides on the need for police involvement or other appropriate measures. The notifier may also be the carrier. Annex 12 to the Regulation: Radioactive materials: 3000 A1 (in special form) or 3000 A2, B (U), B (M) or C type, respectively
FR Road	According to ADR, road tunnels of category E are forbidden This restriction can be more severe for transport under special arrangement (UN 2919 and 3331) Some part of the ring road around Paris are forbidden
IE Rail	While RID and CDG by Rail Regs are in place, there is no Company that carries Class 7 by Rail (no business need)
IT Road	The restrictions on road routes are foreseen for those roads along which there are tunnels of category E according to ADR
LU Road	The tunnel of the Holy Spirit with the Cote d'Eich in Luxembourg-Ville is prohibited to vehicles transporting hazardous materials.
MT Road	Transport direct from airport to consignee using shortest route

Country	Route restrictions
SK Road	Only prescribed public roads for transport of dangerous goods according ADR are permitted.
SI Road	no restrictions particular to Class 7.
SE Road	Tunnel restrictions according to ADR 1.9.5: City Tunnel TCat Gothenburg Tingstadstunneln E Götatunneln E Lundbytunneln E Stockholm Blekholmstunneln E Hundra Knutars Backe E Klaratunneln E Muskötunneln E Söderledstunneln E Kvarnholmförbindelsen E
SE Rail	Öresund bridge tunnel
UK Road	Tunnel category codes below indicate the restrictions which apply to 9 tunnels in Great Britain in terms of the dangerous goods which you can transport through them (from https://www.gov.uk/government/publications/adr) Dartford - Cat C Mersey - Cat D Clyde - Cat D Limehouse - Cat E Rotherhithe - Cat E Blackwall - Cat E East India Dock Road - Cat E Tyne - Cat D Heathrow Airport between 0400 and 2300: Cat E. At other times: Cat C.
UK Rail	Depends on the rail gauge size of wagons Channel Tunnel - see Eurotunnel’s dangerous goods guide 2017 (https://www.eurotunnelfreight.com/uploadedFiles/xnt/ADR_2017_UK.pdf)

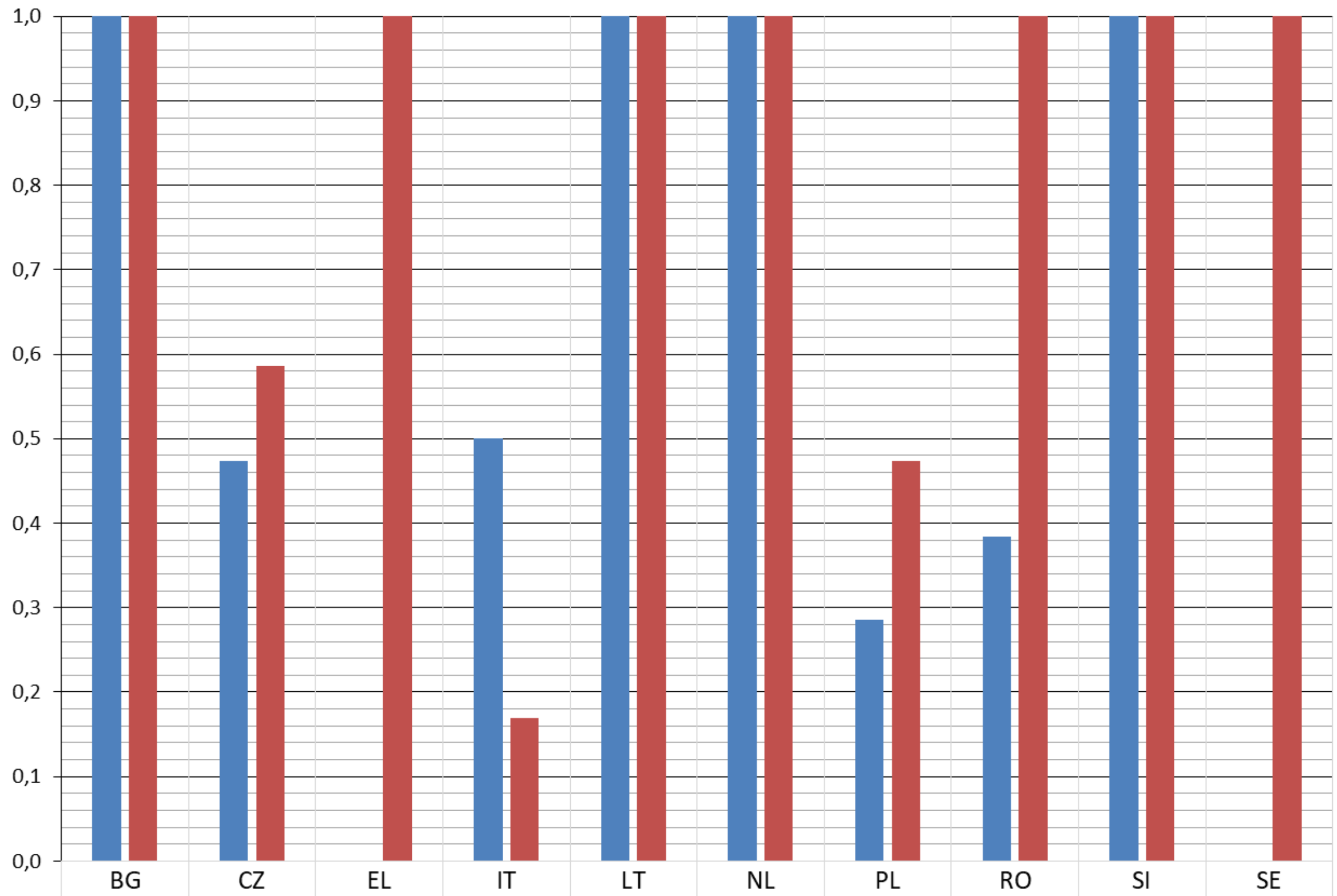
Q 1.4: ALLOWABLE BORDER CROSSING POINTS (BOTH EU AND NON-EU)

13 MS answered this question, MT has no border crossings, while AT, BE, DK, EE, FI, FR, DE, IE, SK, ES and UK did not answer (**Figure 40**, **Figure 41**).



	BG	HR	CZ	EL	IT	LV	LT	LU	NL	PL	RO	SI	SE
Border crossings road where RAM can cross	18	10	17	9	11		2		13	9	23	24	10
Border crossings road	18		29	9	65	6	2		13	19	23	24	10
Border crossings rail where RAM can cross	4	6	9		6		2		9	4	5	8	5
Border crossings rail	4		19		12	10	2	4	9	14	13	8	

Figure 40: Allowable border crossing points



	BG	CZ	EL	IT	LT	NL	PL	RO	SI	SE
Ratio Border crossings rail	1,0	0,5		0,5	1,0	1,0	0,3	0,4	1,0	
Ratio Border crossings road	1,0	0,6	1,0	0,2	1,0	1,0	0,5	1,0	1,0	1,0

Figure 41: Ratio RAM crossing points by total crossing points

Particularly low numbers of acceptable crossing points are identified for IT, where many border crossings involve tunnels, which may have restrictions. Overall the allowable crossing point rate is reasonably high for most MS.

Regulators

The current resources of Competent Authorities in terms of person-years and levels are presented in **Figure 42** and **Figure 43**.

Competent Authorities found it difficult to identify the resource requirements for different areas of compliance assurance, and some data was clearly incompatible. As a result, some manipulation was carried out to attempt to understand the areas that Competent Authorities felt were under or over resourced. The only area where there is considered to be a community shortage of resource appears to be liaison and cooperation.

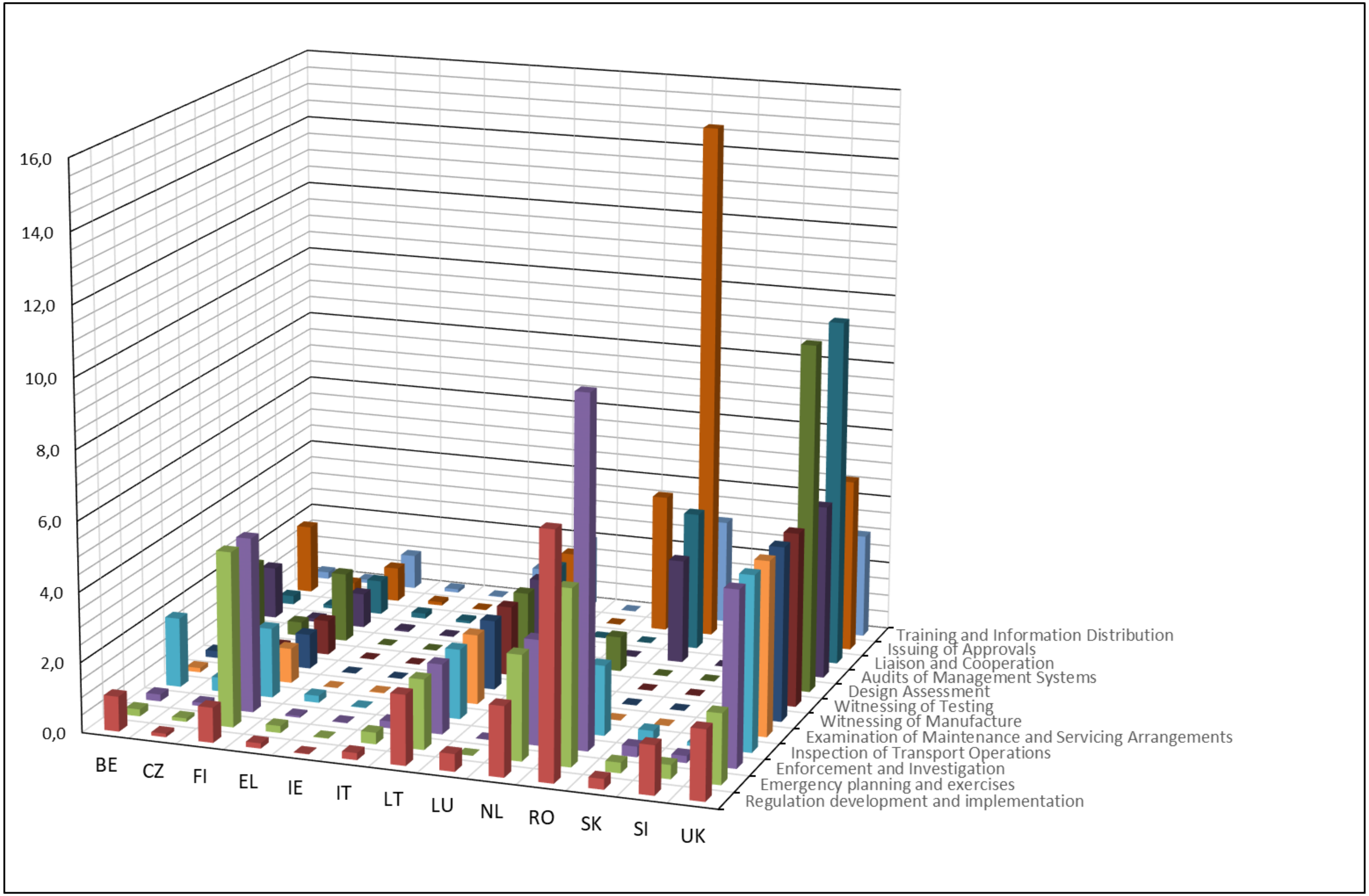


Figure 42: Current resources (person years)

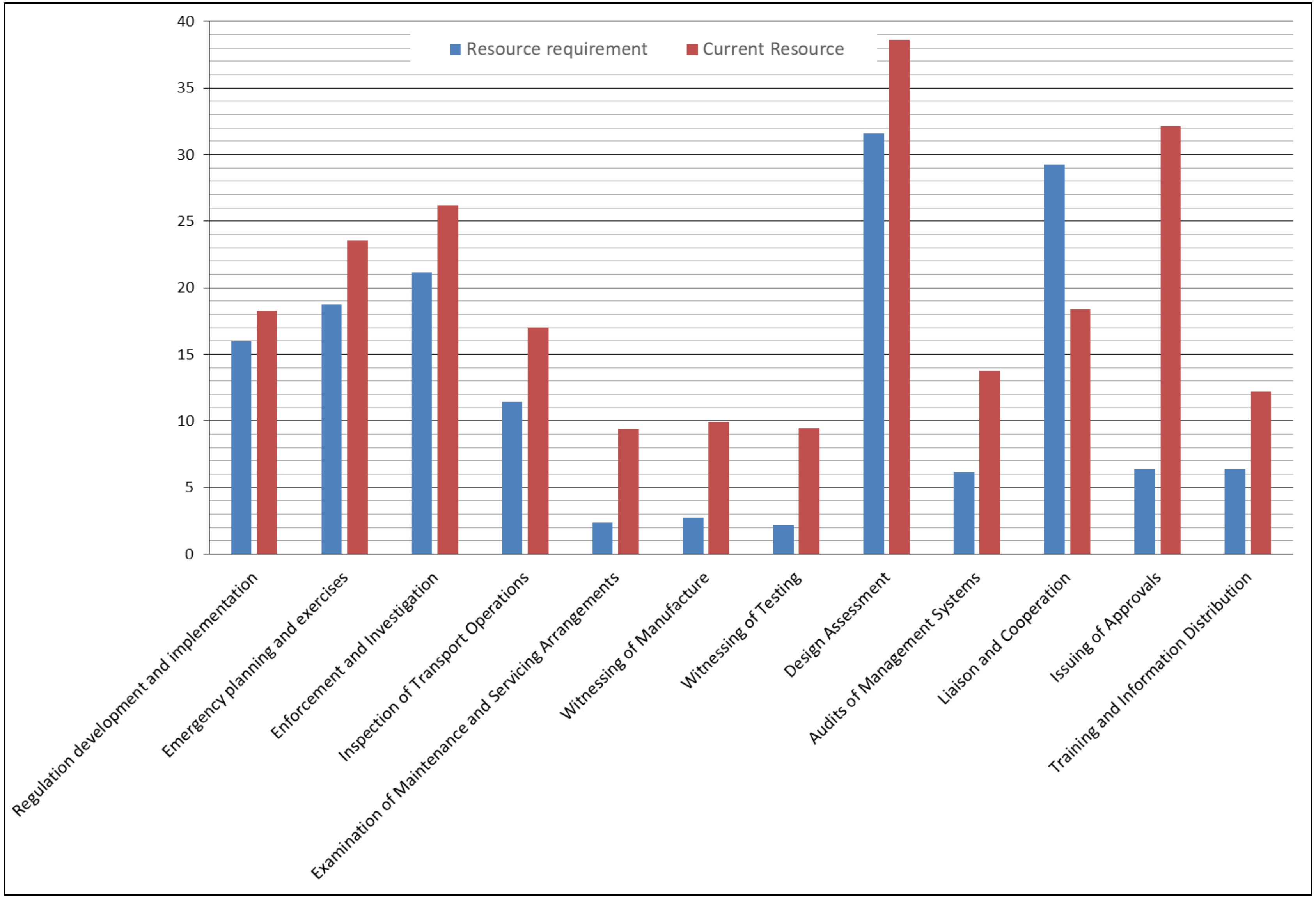


Figure 43: Current resource levels

In order to eliminate the expected different ways the data has been presented by each MS, a simple analysis was carried out. This is presented as a dimensionless chart indicating the expected trends in resources relative to needs (**Figure 44**). It can be seen that in most areas the Competent Authorities are either reporting a reduction in resource or are expecting a reduction in resource.

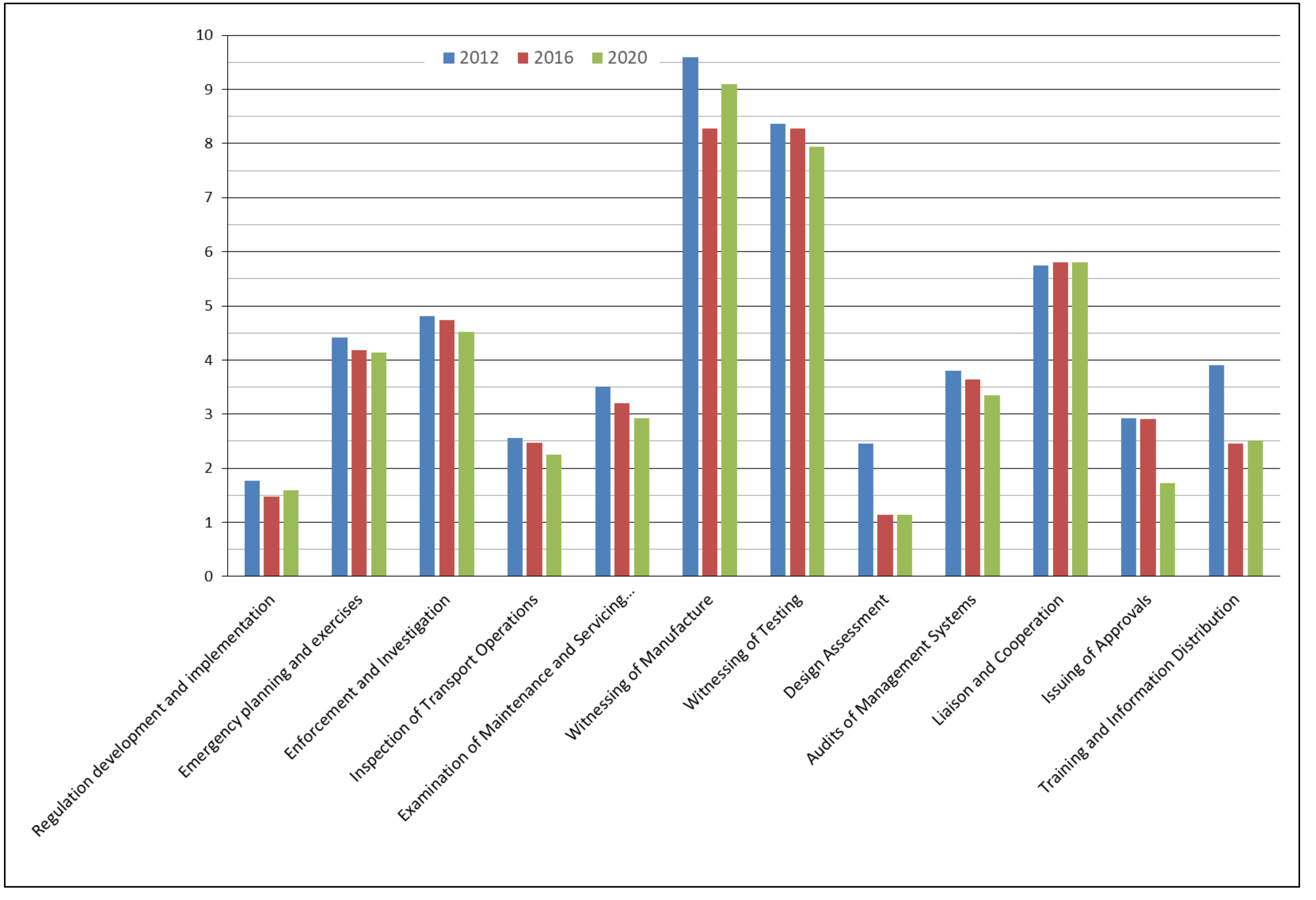


Figure 44: Indication of resource availability in regulatory bodies

The comparison of the resource requirements and availability for each area of compliance assurance with the numbers of inspections in each area suggests a mismatch. For example, one of the highest resource uses is reported to be witnessing of testing, yet only five tests were recorded as being witnessed. A number of MS reported in later questions no activity in fields where they considered resource needs to be significant.

Overall there would seem to be room for MS to improve on the estimated regulatory resource requirements.

A5 QUESTIONNAIRE RESPONSE — REGULATORY INFRASTRUCTURE

MAINTAINING AN EFFECTIVE REGULATORY FRAMEWORK

LEGISLATION

Most MS supplied references to regulations governing the transport of radioactive material for each of the modes of transport.

One MS failed to reference regulations for road, rail, air and inland waterway. One MS failed to reference regulations for air, sea and inland waterway. In addition, several MS did not reference regulations for inland waterway (which is permissible).

Due to European Directives in this area the actual legislation was not reviewed directly. However the references were reviewed against the transposition records on the EUR-Lex web page. Some references supplied in the response appeared to be to out of date legislation, at least one reference was different to the transposition record. It was noted that one MS that failed to reply has no record regarding transposition.

I-1. A comprehensive set of interested parties should be developed by MS, and more extensive sharing of information between regulators should be ensured.

The majority of MS have consolidated the legislation for the transport of radioactive materials by different modes into single sets of documents (sometimes with different levels, i.e. primary and secondary).

REGULATORS

Around 75% of MS have a single regulator covering all modes, while the remaining 25% have multiple regulators, differentiated by mode or by nuclear/radioactive.

INTERNATIONAL MODAL REQUIREMENTS

MS mostly implement international modal regulations, except for inland waterway where several states do not apply ADN, which is permitted in Directive 2008/68/EC.

A small number of MS implement SMGS in addition to RID. At this point there is no known relevant difference between RID and SMGS. While only a small number of MS work with the Union on the issue of SMGS text, the potential for shipments under SMGS to move on to other MS under RID would appear to suggest all MS may have a valid interest in SMGS.

I-2. The EU may wish to consider to extend its involvement in SMGS.

VARIATIONS AND PROHIBITIONS

At least one MS has not ratified the IMO IMDG code. Two MS acknowledged that at the start of the study they did not comply fully with the requirements of Directive 2008/68/EC. Based on the responses, there is one further MS that is showing indications of not fully complying. At least five MS have chosen to vary from the Directive

2008/68/EC. One MS indicated in an off the record comment that they considered the use of administrative delays as a valid means of prohibiting transport. A key aspect of Directive 2008/68/EC is that shipments complying with the annexes are deemed to be authorised, and any variations that deem these shipments not to be authorised need to be justified against a very limited set of requirements. It appears that two or three of the variations may not be consistent with this Directive. There also appears to be an increased use of “security” as a reason to prevent transport of radioactive material rather than a method of ensuring safe and secure shipments.

The risk for administrative burdens to become so significant that companies will refuse radioactive material shipments is a reality in certain areas. The addition of the BSS Directive, which applies a facility-based regulatory system to transport, is a potential further barrier.

I-3. Identify all the legislation applying to the transport of radioactive material.

ENFORCEMENT AND PENALTIES

The regulatory system in most MS offers a wide range of enforcement powers and penalties, however some MS were unable to identify either powers or penalties for certain modes.

The questionnaire asked MS to identify the body who had enforcement powers. A comparison of the “regulator” and the enforcement body provided in the responses identified some differences.

Several MS identified the powers of police for road. The need for integration of the regulator for transport of radioactive material to interface with uniformed officers to carry out roadside checks is normal. The lack of police in some responses may be an indication that routine roadside checks are not common in some MS.

There would seem to be several small gaps in legal powers and some question as to who has regulatory powers in some MS.

PARTICIPATION IN INTERNATIONAL REGULATORY REVIEW AND REVISION

The majority of MS take part in the IAEA review and revision process, and some MS have a process whereby reviews and revision of their national regulations are required. However, there was no indication from MS of a policy for the transport of radioactive material that would guide the review and revision of transport regulations, or the application of a procedure associated with such a policy.

NATIONAL REVIEW

Most MS reported a process of some kind for reviewing the suitability of their regulations, however, at least six MS did not, including two MS indicating there is no such process in place. Several MS appeared to rely heavily on the review of international regulations for their suitability, rather than reviewing the suitability of the national regulations.

Based on the concerns raised on this topic a follow-up questionnaire was formulated at the first workshop to address this issue and improve clarity. It became clear that most MS have a well organised review policy and there is considerable harmonisation in the Union/Community even when there is no explicit legislative driver.

MONITORING AND INSPECTION OF TRANSPORT OPERATIONS

AUTHORISATION

Registration requirements are not consistent within the community (**Figure 45**). For example, for road transport, 17 MS require registration of carriers, 10 require registration of consignors, 8 MS require registration of both, and 4 MS require neither (Austria failed to answer). Eleven MS indicate variability of registration requirements depending on mode.

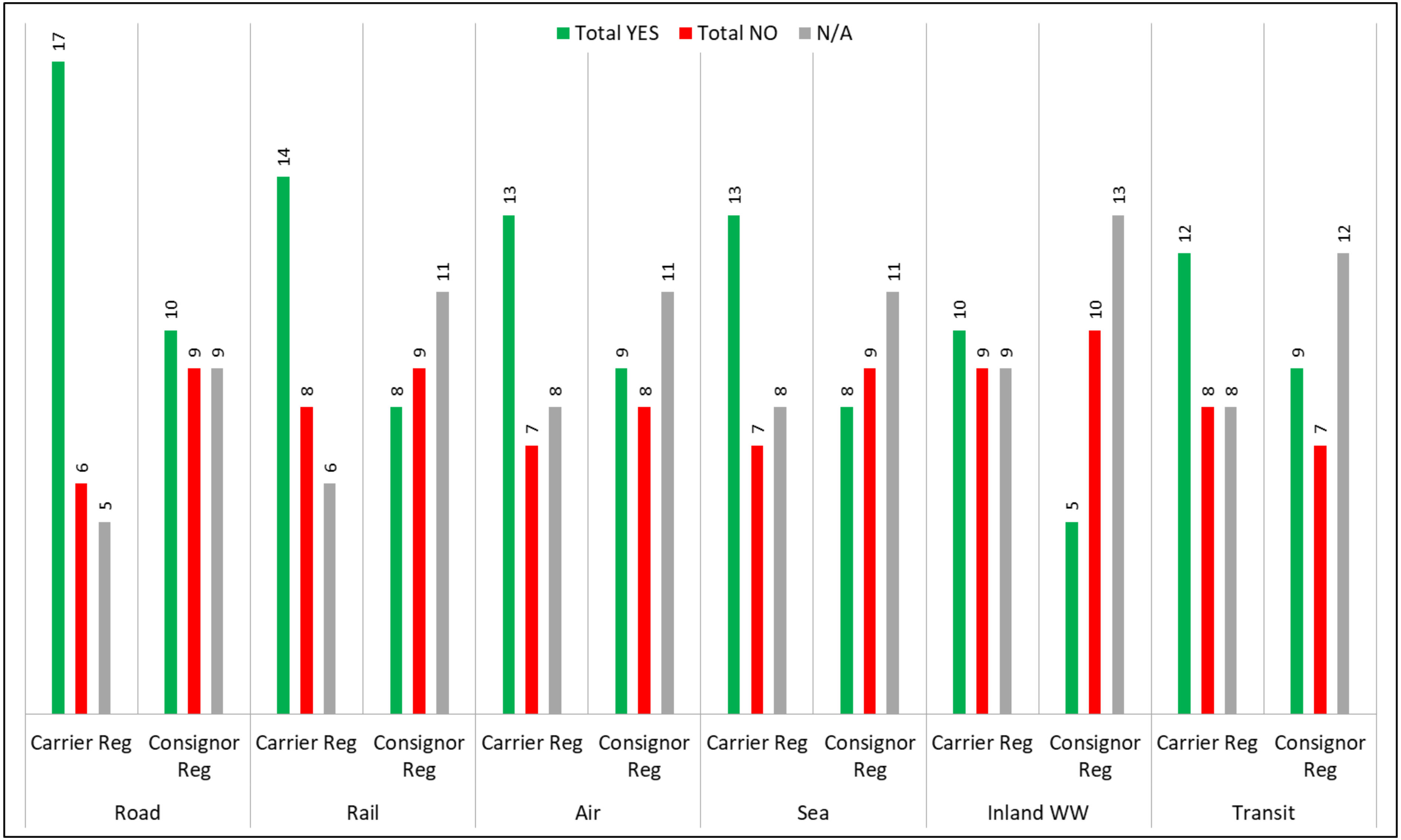


Figure 45: Do you have a registration scheme for TRAM in regulation?

The European Parliament, in setting up the SWG in 1982, identified the importance of achieving consistency of responsibilities of carriers and consignors in the community. 35 years later this still appears to be an outstanding issue.

In terms of radiation protection, registration is a form of authorisation. The authorised person is then the person with primary responsibility for safety. The fact that this can vary from state to state could cause problems in understanding where the primary responsibility for safety lies. An example is set out in the **Table 26** below:

Table 26: Example for primary responsibility for safety

State A	State B	Primary Responsibility for safety of shipment A to B (Registration)	Primary Responsibility for safety of shipment B to A (Registration)
Consignor Registration	Carrier Registration	Consignor in State A and Carrier in State B	Carrier in State B, undefined in State A

Some years ago, the Commission proposed a carrier registration scheme, which was subject to opposition to such a degree that it was not implemented. The variation in party required to be authorised from State to State is likely to have played an important part. Following a systematic approach, similar to the approach used for facilities, and paying particular attention to activities that can be influenced by specific parties, it seems that a consistent approach requiring licencing of consignors, who are made responsible for subcontractors (e.g. carriers), may be a suitable approach. This would be consistent with the current regulatory requirement that the consignor makes a declaration prior to transport.

Paragraph 1.4.2 of ADR sets out the obligations of the main participants. This clearly points to the consignor as being responsible for ensuring the material shipped is classified, authorised and packaged in line with the regulatory requirements. Additional responsibilities include documenting the shipment, marking and labelling the package, and ensuring bulk containers are placarded appropriately.

The current approach results in an unacceptable difference between MS and could lead to significant compliance gaps.

I-4 Guidance on carrier and consignor responsibilities should be developed for radioactive material.

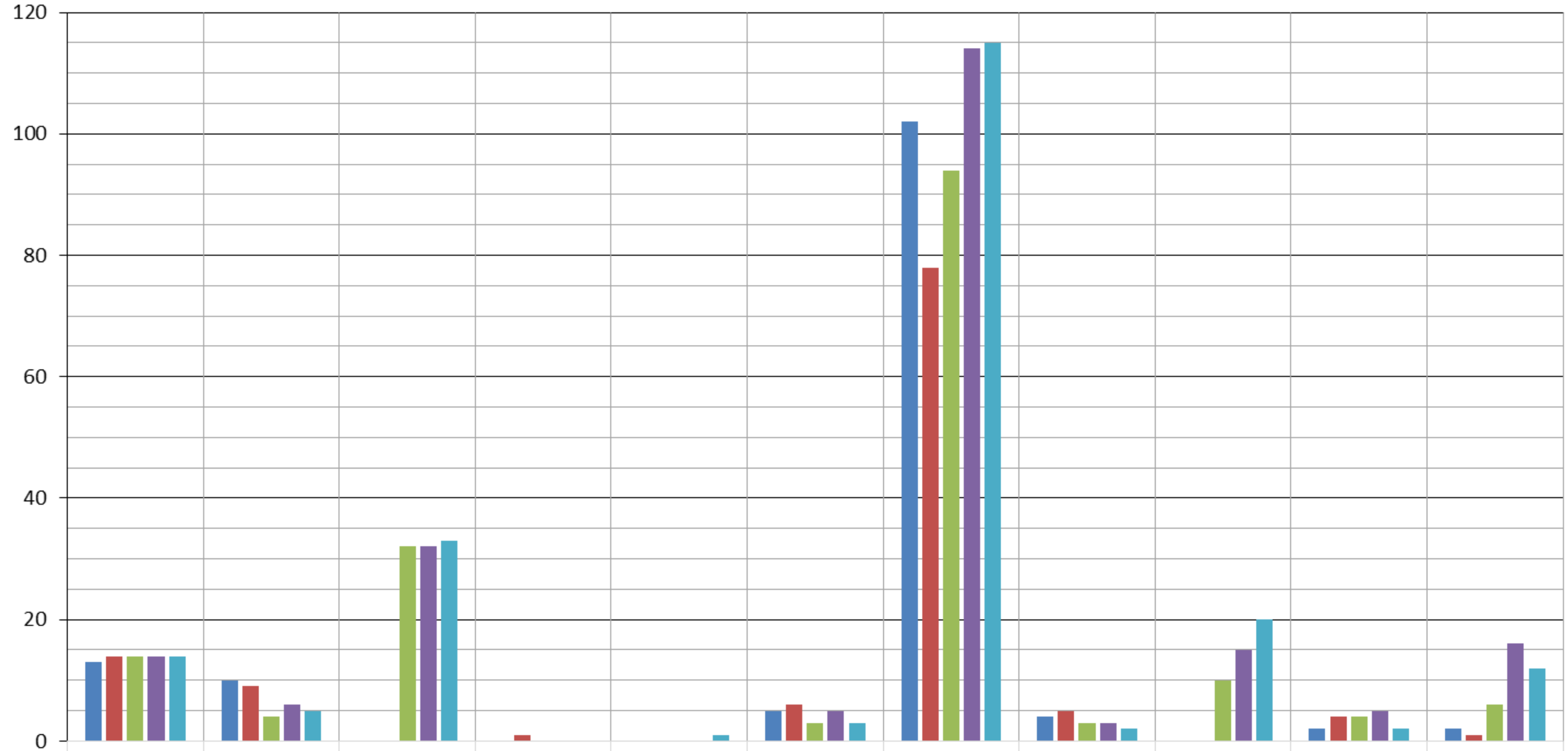
POWERS OF INSPECTION

There are broad powers of inspection in all MS, and most but not all MS reported compliance with the Directive 95/50/EC. Some MS failed to report complying with this Directive, although records show all MS have supplied responses as required. This is an indicator of fragmented regulator for road transport in those MS, lacking appropriate interface.

FREQUENCY OF CONSIGNMENT INSPECTIONS

Eleven MS reported carrying out checks on consignors. Where data is available the inspection rates are around 1 in 100 consignors inspected per year (**Figure 46**, **Figure 47**, **Figure 48**). This would seem a very low rate.

I-5 Facilitate compliance assurance that involves the inter-dependency between state regulators, particularly in the areas of design, testing, manufacture and servicing.



	BE	CZ	FR	EL	IE	IT	NL	RO	SK	SE	UK
2012	13	10	0	0	0	5	102	4	0	2	2
2013	14	9	0	1	0	6	78	5	0	4	1
2014	14	4	32	0	0	3	94	3	10	4	6
2015	14	6	32	0	0	5	114	3	15	5	16
2016	14	5	33	0	1	3	115	2	20	2	12

Figure 46: Consignment operations witnessed in MS 2012-2016

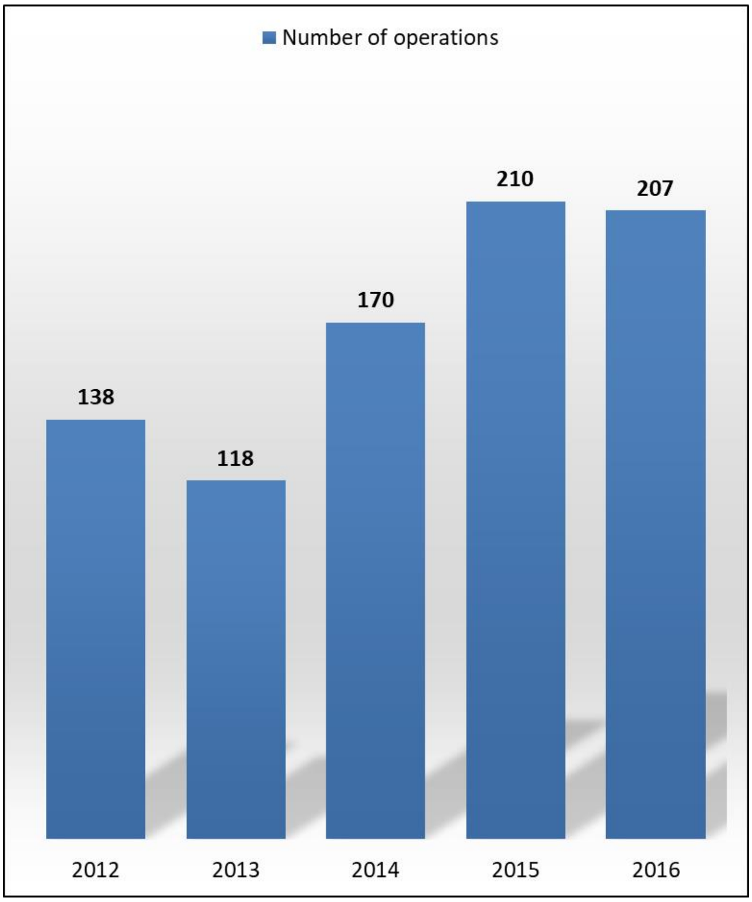


Figure 47: Consignment operations witnessed 2012-2016 (EU)

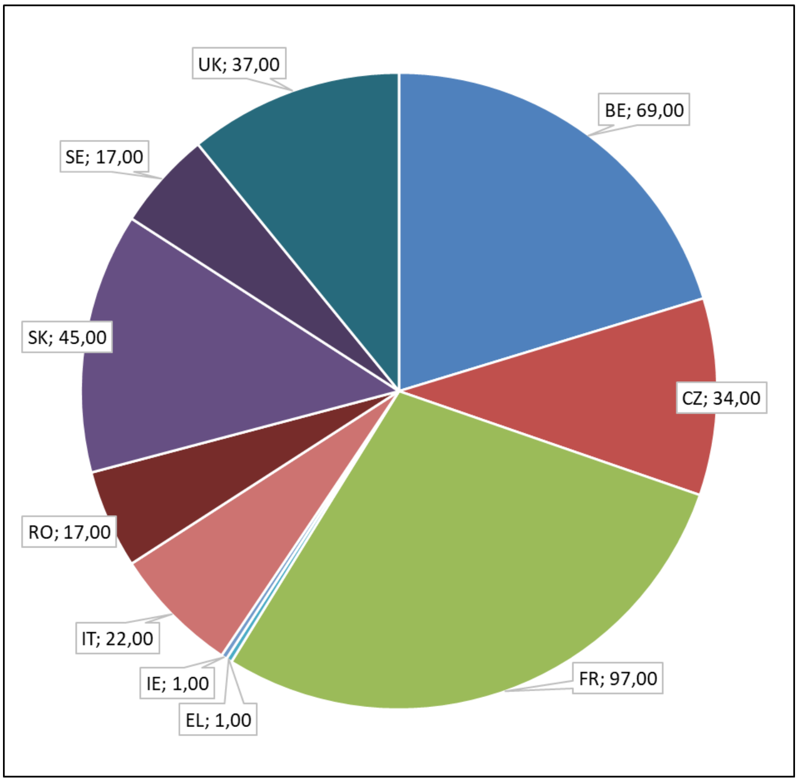


Figure 48: Consignment operations witnessed in MS 2012-2016

FREQUENCY OF CARRIER INSPECTIONS

Comparing the number of inspections of carriers (**Figure 50**, **Figure 51**, **Figure 52**) with the number of roadside checks reported under the Directive 95/50/EC, there is a large number of MS that reported that around 1% of roadside checks are related to radioactive material. One MS reported 18 infringements resulting from 58 carrier inspections, consistent with the infringement rate for other classes of dangerous goods. Ten MS were unable to confirm any consignor or carrier checks.

Considering the requirements of Council Directive 95/50/EC, a specified list of checks need to be performed (**Figure 49**):

CHECKLIST

1. Place of check	2. Date	3. Time	
4. Vehicle nationality mark and registration number	....		
5. Trailer/semi-trailer nationality mark and registration number	....		
6. Undertaking carrying out transport/address	....		
7. Driver/driver's assistant	....		
8. Consignor, address, place of loading (1) (2)	....		
9. Consignee, address, place of unloading (1) (2)	....		
10. Total quantity of dangerous goods per transport unit	....		
11. ADR 1.1.3.6 quantity limit exceeded	☐ yes	☐ no	
12. Mode of transport	☐ in bulk	☐ package	☐ tank
Documents on board			
13. Transport document	☐ inspected	☐ infringement established	☐ not applicable
14. Instructions in writing	☐ inspected	☐ infringement established	☐ not applicable
15. Bilateral/multilateral agreement/national authorisation	☐ inspected	☐ infringement established	☐ not applicable
16. Certificate of approval for vehicles	☐ inspected	☐ infringement established	☐ not applicable
17. Driver's training certificate	☐ inspected	☐ infringement established	☐ not applicable
Transport operation			
18. Goods authorised for transport	☐ inspected	☐ infringement established	☐ not applicable
19. Vehicles authorised for goods carried	☐ inspected	☐ infringement established	☐ not applicable
20. Provisions related to the mode of transport (bulk, package, tank)	☐ inspected	☐ infringement established	☐ not applicable
21. Mixed loading prohibition	☐ inspected	☐ infringement established	☐ not applicable
22. Loading, securing of the load and handling (3)	☐ inspected	☐ infringement established	☐ not applicable
23. Leakage of goods or damage to package (3)	☐ inspected	☐ infringement established	☐ not applicable
24. UN packaging marking/tank marking (2) (3) (ADR 6)	☐ inspected	☐ infringement established	☐ not applicable
25. Package marking (e.g. UN no) and labelling (2) (ADR 5.2)	☐ inspected	☐ infringement established	☐ not applicable
26. Tank/vehicle placarding (ADR 5.3.1)	☐ inspected	☐ infringement established	☐ not applicable

(1) To be filled only if relevant for an infringement.
(2) To be stated under 'remarks' for groupage transport operations.
(3) Check of visible violations.

Figure 49: COUNCIL DIRECTIVE 95/50/EC roadside check requirements

The severity of failures is judged against three risk categories:

1. Risk Category I

Where failure to comply with relevant ADR provisions creates a high-level risk of death, serious personal injury or significant damage to the environment such failures would normally lead to taking immediate and appropriate corrective measures such as immobilisation of the vehicle.

Failures are:

1. The dangerous goods being carried are prohibited for transport

2. Leakage of dangerous substances

3. Carriage by a prohibited mode or an inappropriate means of transport

4. Carriage in bulk in a container which is not structurally serviceable

5. Carriage in a vehicle without an appropriate certificate of approval

6. Vehicle no longer complies with the approval standards and presents an immediate danger (otherwise it goes in risk category ii)

7. Non-approved packaging is used

8. Packaging does not conform to the applicable packing instruction

9. The special provisions for mixed packing have not been complied with

10. The rules governing the securing and stowage of the load have not been complied with

11. The rules governing mixed loading of packages have not been complied with

12. The permissible degrees of filling of tanks or packages have not been complied with

13. The provisions limiting the quantities carried in one transport unit have not been complied with

14. Carriage of dangerous goods without any indication of their presence (e.g. Documents, marking and labelling on the packages, placarding and marking on the vehicle)

15. Carriage without any placarding and marking on the vehicle

16. Information relevant to the substance being carried enabling determination of a risk category I offence is missing (e.g. Un number, proper shipping name, packing group)

17. Driver does not hold a valid vocational training certificate

18. Fire or an unprotected light is being used

19. The ban on smoking is not being observed.

2. Risk Category II

Where failure to comply with relevant ADR provisions creates a risk of personal injury or damage to the environment such failures would normally lead to taking appropriate corrective measures such as requiring rectification at the site of control if possible and appropriate, but at the completion of the current transport movement at the latest.

Failures are:

1. The transport unit comprises more than one trailer/semi-trailer

2. Vehicle no longer complies with the approval standards but does not present an immediate danger

3. The vehicle is not carrying operational fire extinguishers as required; a fire extinguisher can still be deemed operational if only the prescribed seal and/or the expiry date are missing; however, this does not apply if the fire extinguisher is visibly no longer operational, e.g. pressure gauge at 0

4. The vehicle does not carry the equipment required in the ADR or in the instructions in writing

5. Test and inspection dates and use periods of packaging, IBCs or large packaging have not been complied with

6. Packages with damaged packaging, IBCs or large packaging or damaged uncleaned empty packaging are being carried

7. Carriage of packaged goods in a container which is not structurally serviceable

8. Tanks/tank containers (including ones that are empty and uncleaned) have not been closed properly

9. Carriage of a combination packaging with an outer packaging which is not closed properly

10. Incorrect labelling, marking or placarding

11. There are no instructions in writing conforming to the ADR, or the instructions in writing are not relevant to the goods carried

12. The vehicle is not properly supervised or parked.

3. Risk Category III

Where failure to comply with relevant provisions result in a low level of risk of personal injury or damage to the environment and where appropriate corrective measures do not need to be taken at the roadside but can be addressed at a later date at the undertaking.

Failures are:

1. The size of placards or labels or the size of letters, figures or symbols on placards or labels does not comply with the regulations

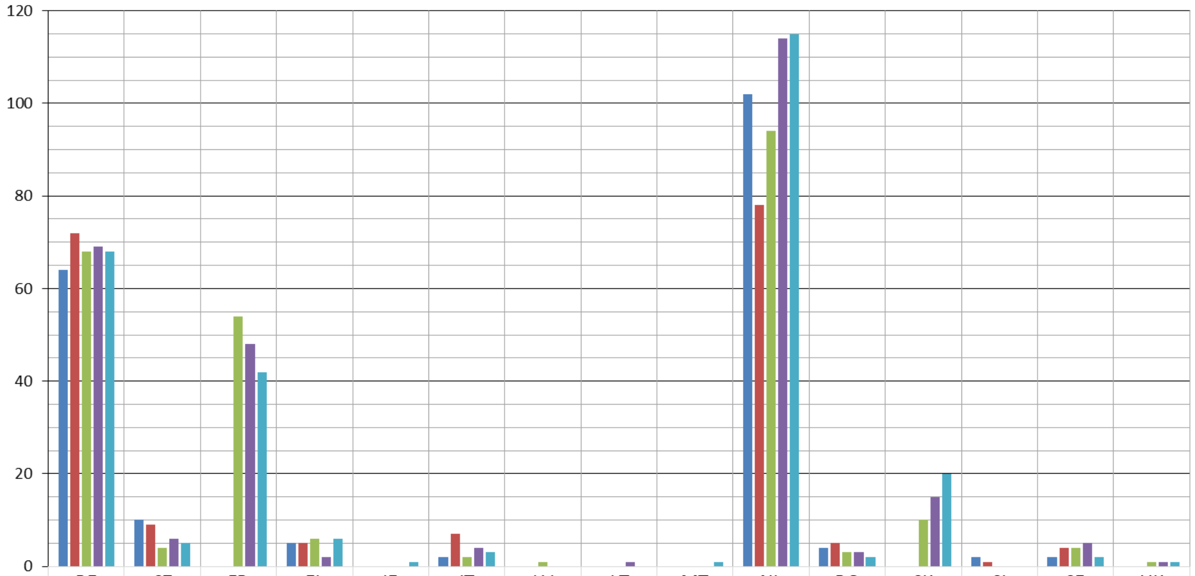
2. Information in the transport documentation other than that in risk category I/(16) is not available

3. The training certificate is not on board the vehicle but there is evidence that the driver holds it.

These checks seem appropriate to a carrier; however, they are certainly not enough to ensure the safety of aspects controlled by the consignor. Given that the safety of radioactive material transport is primarily in the correct consigning of packages meeting the regulatory standards, there is some question as to whether focussing on roadside checks is the correct approach for Class 7, and certainly the units (e.g. mass) for transport reported to the Union seem to be inappropriate.

One issue identified at the first workshop was that some MS have a demarcation issue for regulatory bodies related to inspection of consignors and carriers.

I-6 Review the need for additional information requirements for roadside checks for radioactive material and guidance for consignor checks.



	BE	CZ	FR	EL	IE	IT	LV	LT	MT	NL	RO	SK	SI	SE	UK
2012	64	10	0	5	0	2	0	0	0	102	4	0	2	2	0
2013	72	9	0	5	0	7	0	0	0	78	5	0	1	4	0
2014	68	4	54	6	0	2	1	0	0	94	3	10	0	4	1
2015	69	6	48	2	0	4	0	1	0	114	3	15	0	5	1
2016	68	5	42	6	1	3	0	0	1	115	2	20	0	2	1

Figure 50: Carriage operations witnessed in 15 MS 2012-2016

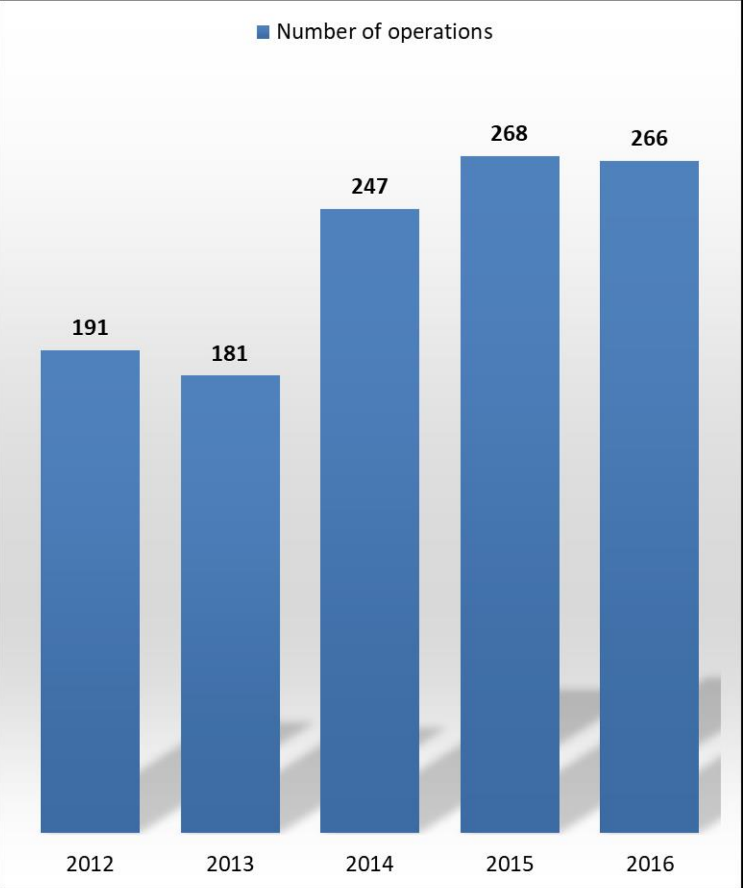


Figure 51: Carriage operations witnessed 2012-2016 (15 MS)

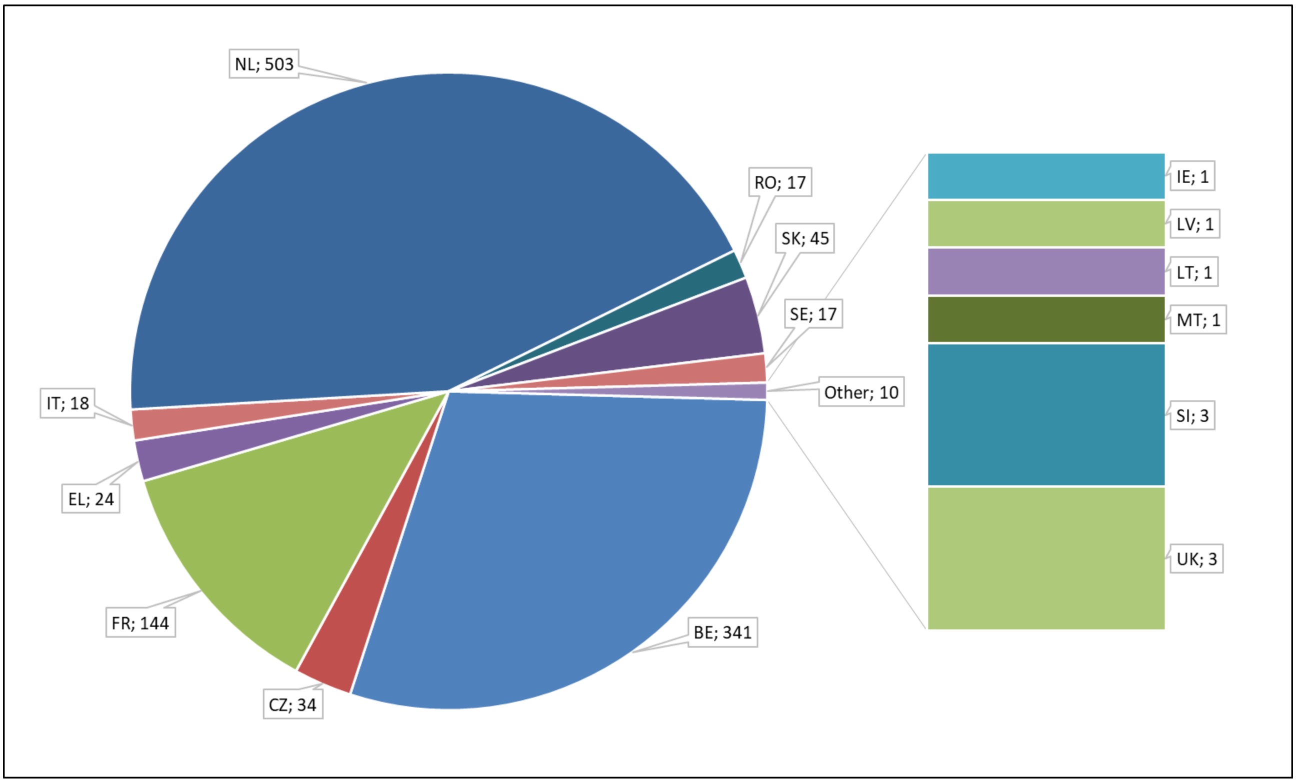
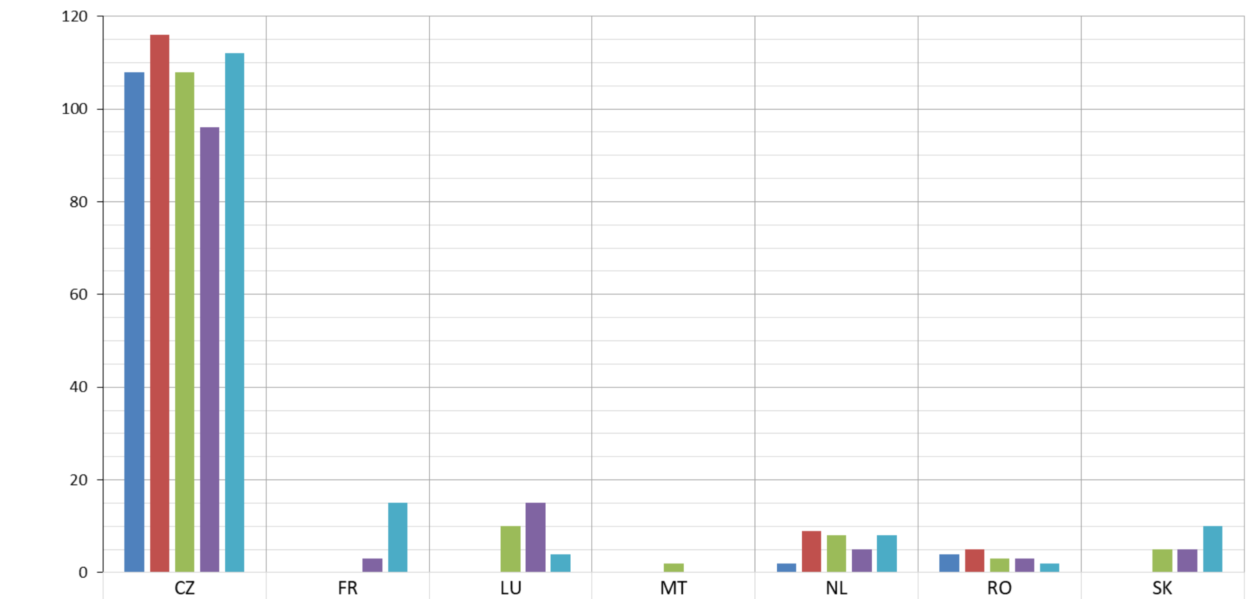


Figure 52: Carriage operations witnessed in 15 MS 2012-2016

FREQUENCY OF CHECKS FOR CONTAMINATION

Seven MS reported on independent checks for contamination being carried out on behalf of the regulator (**Figure 53**, **Figure 54**, **Figure 55**). Given the issues that have occurred in the past involving surface contamination of packages, this number of checks appears to be too low.



	CZ	FR	LU	MT	NL	RO	SK
2012	108	0	0	0	2	4	0
2013	116	0	0	0	9	5	0
2014	108	0	10	2	8	3	5
2015	96	3	15	0	5	3	5
2016	112	15	4	0	8	2	10

Figure 53: Packages independently monitored for contamination by or on behalf of the regulatory body 2012-2016 (7 MS)

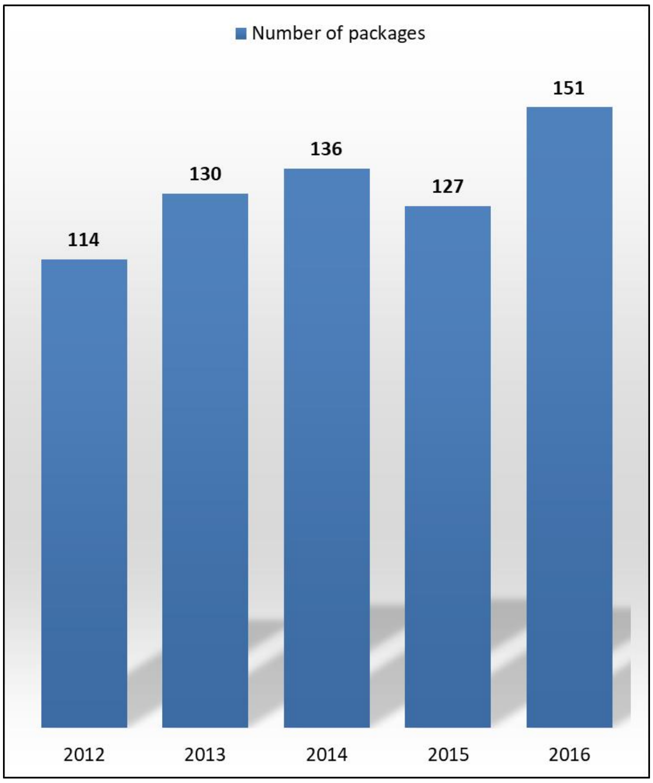
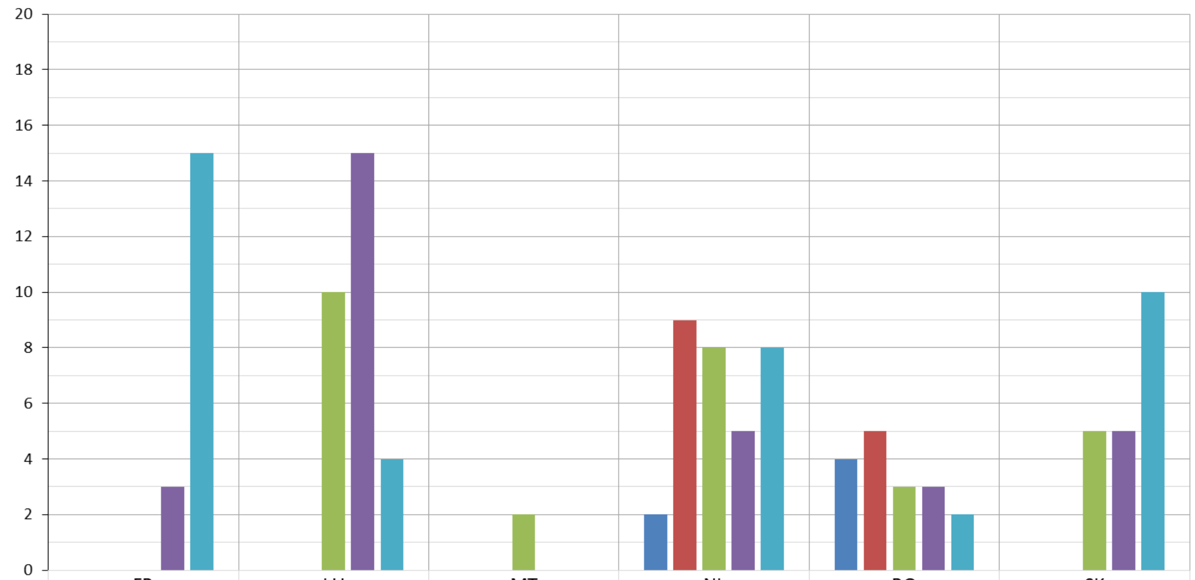


Figure 54: Packages independently monitored for contamination 2012-2016 (7 MS)



	FR	LU	MT	NL	RO	SK
2012	0	0	0	2	4	0
2013	0	0	0	9	5	0
2014	0	10	2	8	3	5
2015	3	15	0	5	3	5
2016	15	4	0	8	2	10

Figure 55: Packages independently monitored for contamination by or on behalf of the regulatory body 2012-2016 (Excluding CZ)

AUDITS OF MANAGEMENT SYSTEMS

Management systems are an extension of regulatory inspections, in that they provide a means for the regulator to ensure compliance with regulation. As a result, the auditing of management systems is one of the most effective means of assisting industry that wishes to comply with regulation to do so.

REGULATORY POWERS

Around a quarter of the respondent MS identified that management systems have to be registered with the regulatory body (**Figure 56**). However, all MS identified powers to review management systems.

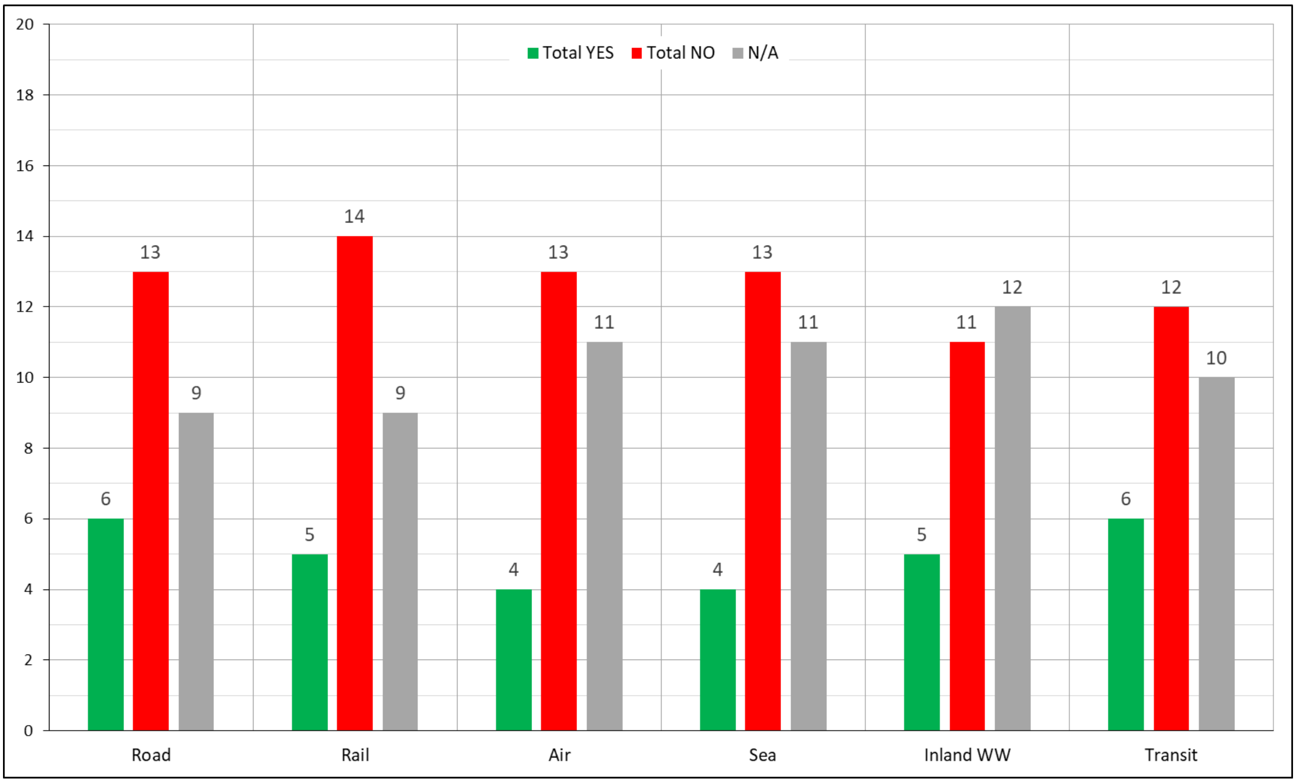


Figure 56: Do you have a registration scheme for management systems of users for RM in regulation?

AUDIT FREQUENCY

Only four MS identified a national audit programme (**Figure 57**) and only 13 MS confirmed audits of management systems. Approximately 170 audits were reported in 2016, 70% of which were in one MS. A total of 55% of audits took place in one MS. However, the number of audits has been increasing over the past five years, showing year on year improvement (**Figure 58**, **Table 27**).

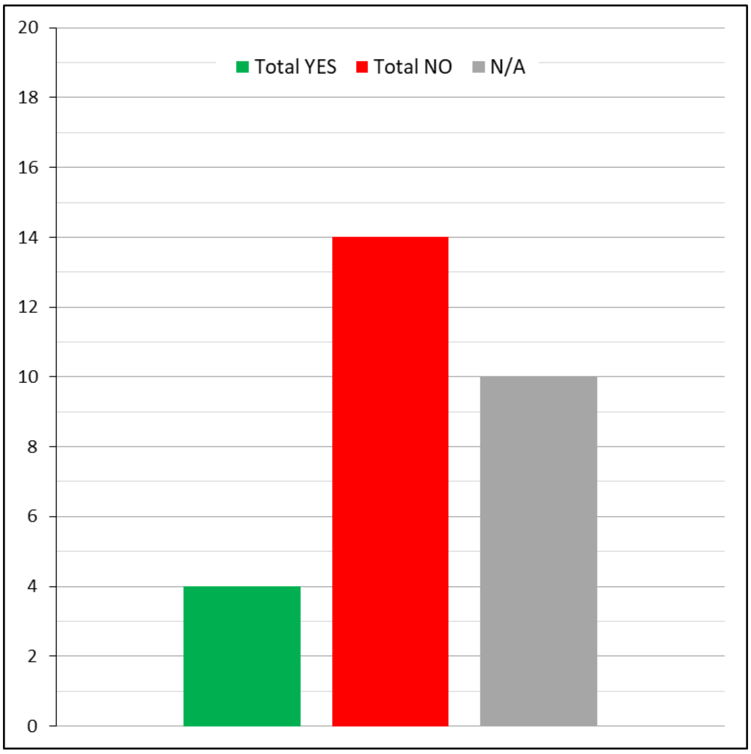


Figure 57: Is there a national audit programme?

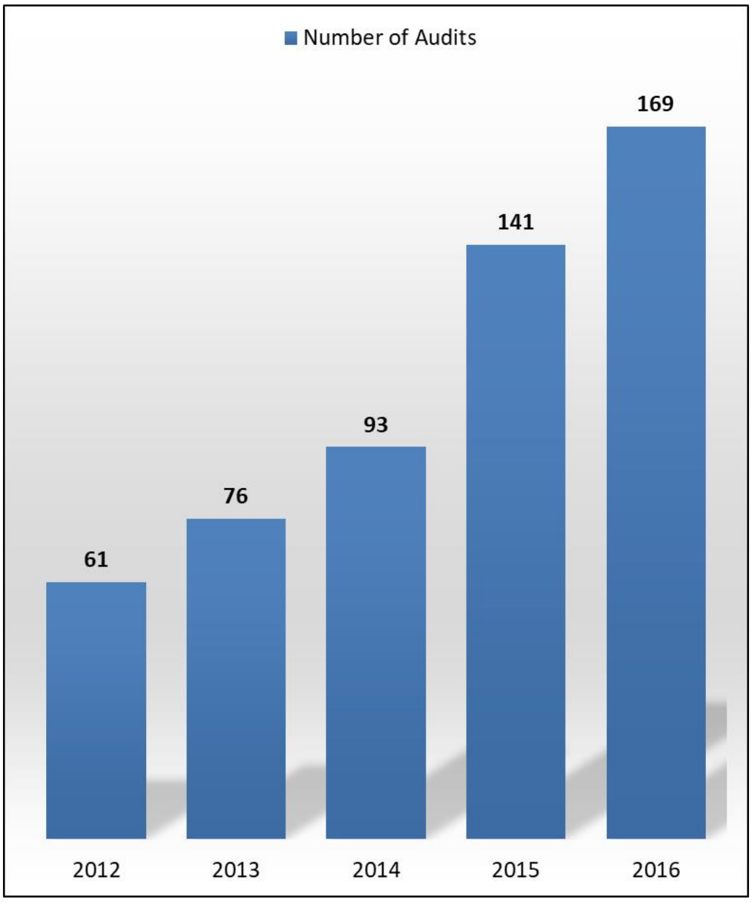


Figure 58: How many management systems were audited by the regulator?

Table 27: Number of audits compared to number of audits minus top MS

Number of audits

2012	61
2013	76
2014	93
2015	141
2016	169

Number of audits minus top MS

2012	44
2013	44
2014	46
2015	50
2016	54

This points to improvement over time, and there is a suggestion that this is as a result of the positive influence of EACA.

I-7 Consideration should be given as to how the existing grouping of MS for Europe and the Mediterranean region can link to community initiatives. SG and CTF input from the second workshop indicated that steps are already made towards addressing this issue.

AUDITS OF RPPs

The audits of Radiation Protection Programmes (RPPs) (**Figure 59**, **Figure 60**) follow a similar profile to audits of management systems. This would suggest that the audits of management systems might have incorporated audits of RPPs; in fact, in a number of cases, the audit profiles were identical over five years. This suggests that the auditors ought to be qualified both in management systems and radiation protection. However, this would not be usual since the two specialities do not often converge.

The data raise a question over the technical competence of regulators, which was discussed at the first workshop. This issue is taken up in the section on training. There does not seem to be a well-established profile of technical competence for the different areas of compliance assurance against which a training regime can be established.

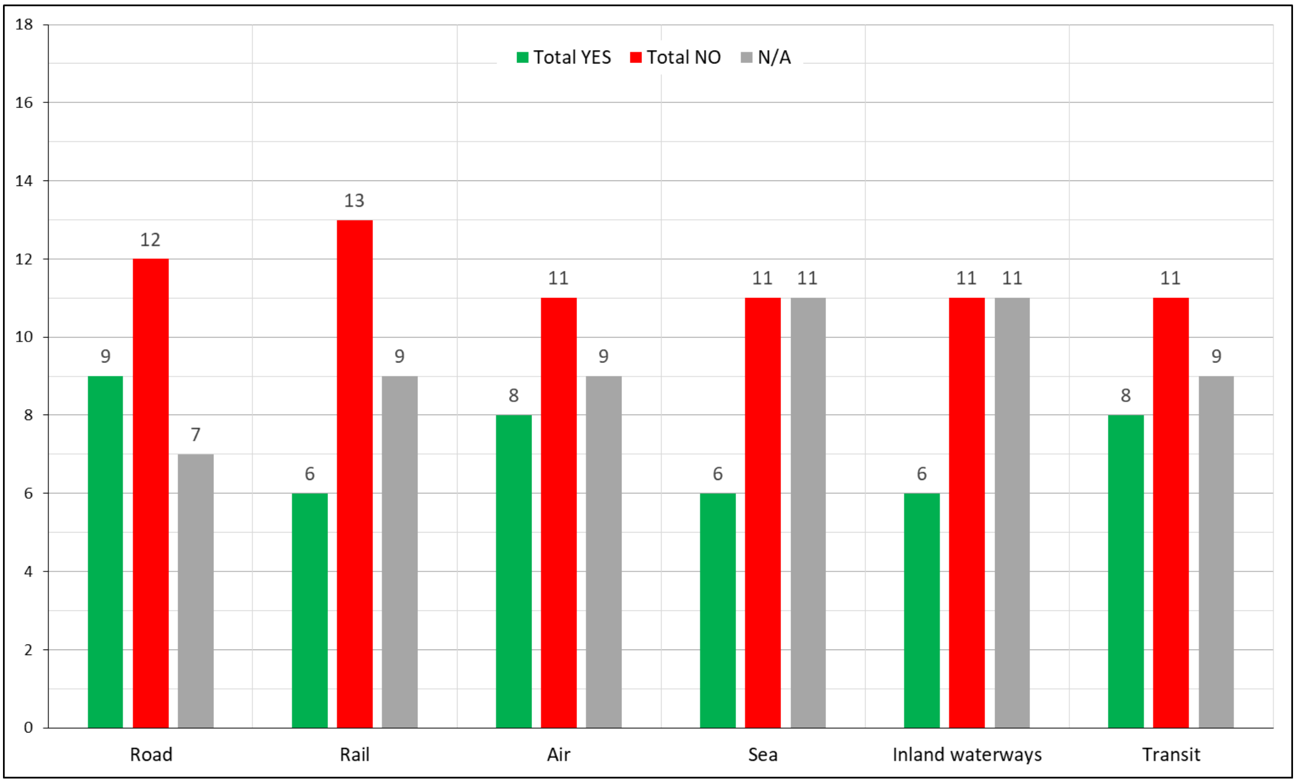


Figure 59: Do you have a registration scheme for radiation protection programmes of users for RM in regulation?

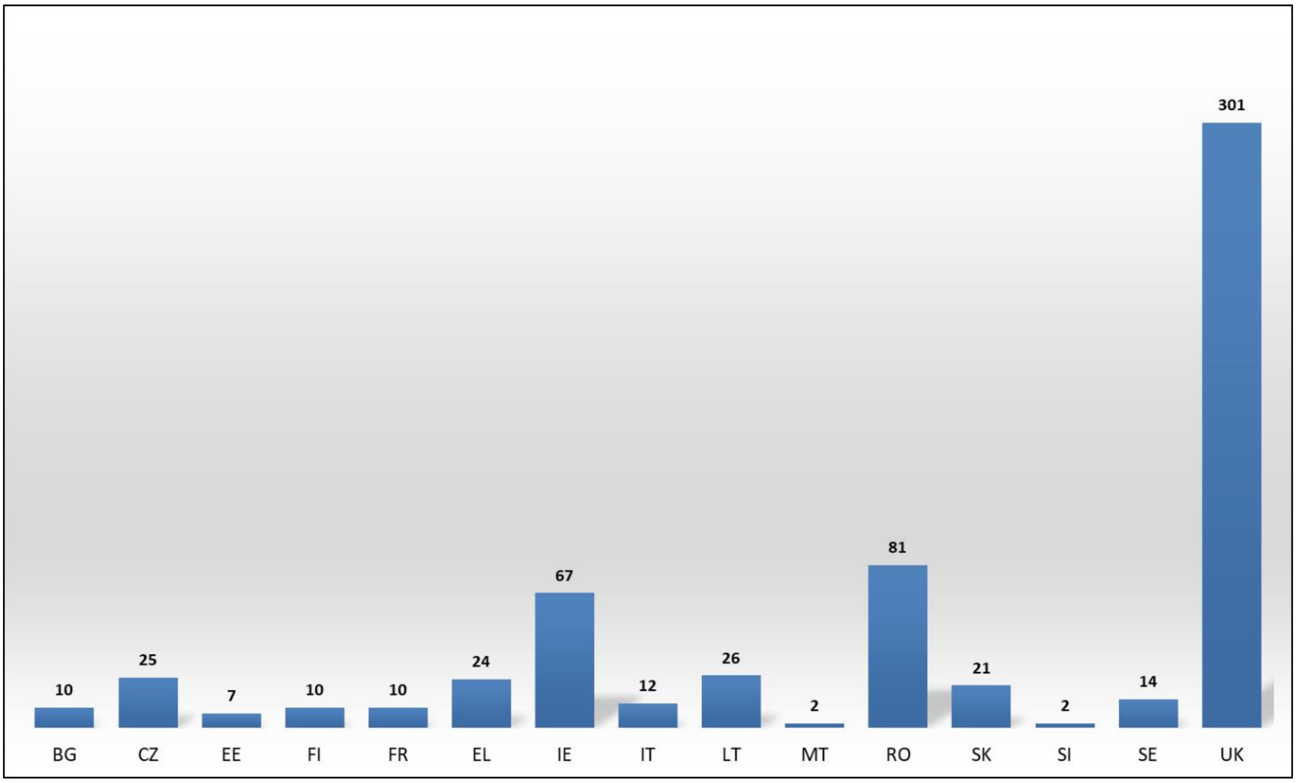


Figure 60: Radiation protection programmes audited 2012-2016

DESIGN ASSESSMENT

TIMESCALES FOR ASSESSMENT

There is a wide variety of time scales for assessment provided for the examples in the questionnaires. Twelve MS indicated specific time scales to carry out assessments. Several MS indicated that certain approvals take one year or longer if the application is complete and accurate, and a majority of states identified that typical timescales for some approvals take one year or longer. Against a background of regulations being updated every two years this seems problematic, particularly in one case where approvals were noted as taking up to 10 years to issue in practice.

ASSESSMENT OF NON-CA APPROVED PACKAGES

Less than 25% of MS acknowledged the review of the approval of Non-CA approved packages, and only one MS confirmed the re-assessment of some of these package designs (**Table 28**, **Table 29**). Only 33 Non-CA package designs were reviewed in the EU over 5 years, and only 9 were re-assessed by the regulator. For Class 7 material the mantra is that 'safety is in the packaging'. Given that the shipment of Non-CA approved packages accounts for over 95% of the packages transported in the EU, the proportion of checks of the primary safety feature seems to be very small even taking into account the application of a graded approach.

The graded approach is a concept used throughout the regulations governing the safe transport of radioactive material, and it applies to the activities of the regulator as much as the consignor or carrier.

As an example, the larger packages require approval by the competent authority before use, while others do not. It would not be appropriate for a regulator to apply the same level of compliance effort to all areas of their work. This study has shown that the graded approach is applied by regulators in Europe, but that many have different emphasis. This may be appropriate, since the industry and legal structure varies from MS to MS. However, many MS were unable to provide the type of data that would be expected to inform their judgement over the level of resource to be applied in each area.

Essentially, the graded approach relates to sampling rates and is informed by issues such as the extent of activities carried out in a MS, the historical evidence of failures and the degree of risk posed by failure.

The beneficiaries of an effective compliance system are the public in the MS, and for this reason it is important that regulators are able provide public information that provides guidance on how they are being protected through the appropriate application of the graded approach.

So, I-5 also applies in the area of review of non-CA approved packages.

Table 28: How many non-CA approved packages have been reviewed to confirm a design assessment has been carried out in years 2012 - 2016

How many non-CA approved packages have been reviewed to confirm a design assessment has been carried out in year:	Packages
2012	3
2013	4
2014	5
2015	8
2016	13
TOTAL	**33**

Table 29: How many non-CA approved packages were re-assessed by the regulator in years 2012 - 2016

How many non-CA approved packages were re-assessed by the regulator in year:	Packages
2012	3
2013	2
2014	1
2015	0
2016	3
TOTAL	**9**

ASSESSMENT OF SHIPMENTS

Around a third of MS assessed shipments during a five year period, out of which the majority (75%) were limited to transport within the EU (**Table 30**, **Table 31**). This is consistent with the idea of working together in the Union on assessment.

Table 30: How many shipments were assessed in years 2012 - 2016

How many shipments were assessed in year:	Shipments	Shipments -NL
2012	148	46
2013	117	39
2014	134	40
2015	155	41
2016	365	250
TOTAL	**919**	**416**

Table 31: How many of these shipments (Doesn't include NL) were limited to the EU in years 2012 - 2016

How many of these shipments (Does not include NL) were limited to the EU in year:	Shipments	Shipments %
2012	36	78%
2013	27	69%
2014	25	63%
2015	27	66%
2016	241	96%

ISSUING OF APPROVALS

COUNTRY OF ORIGIN APPROVALS

Less than 50% of MS reported issuing country of origin approvals. Of these approvals, approximately 65% were issued in two MS and 35% in four other MS (**Figure 61**). Typically, there are around 100 country of origin approvals issued each year. This clearly demonstrates that there is a limited number of centres of excellence in the EU.

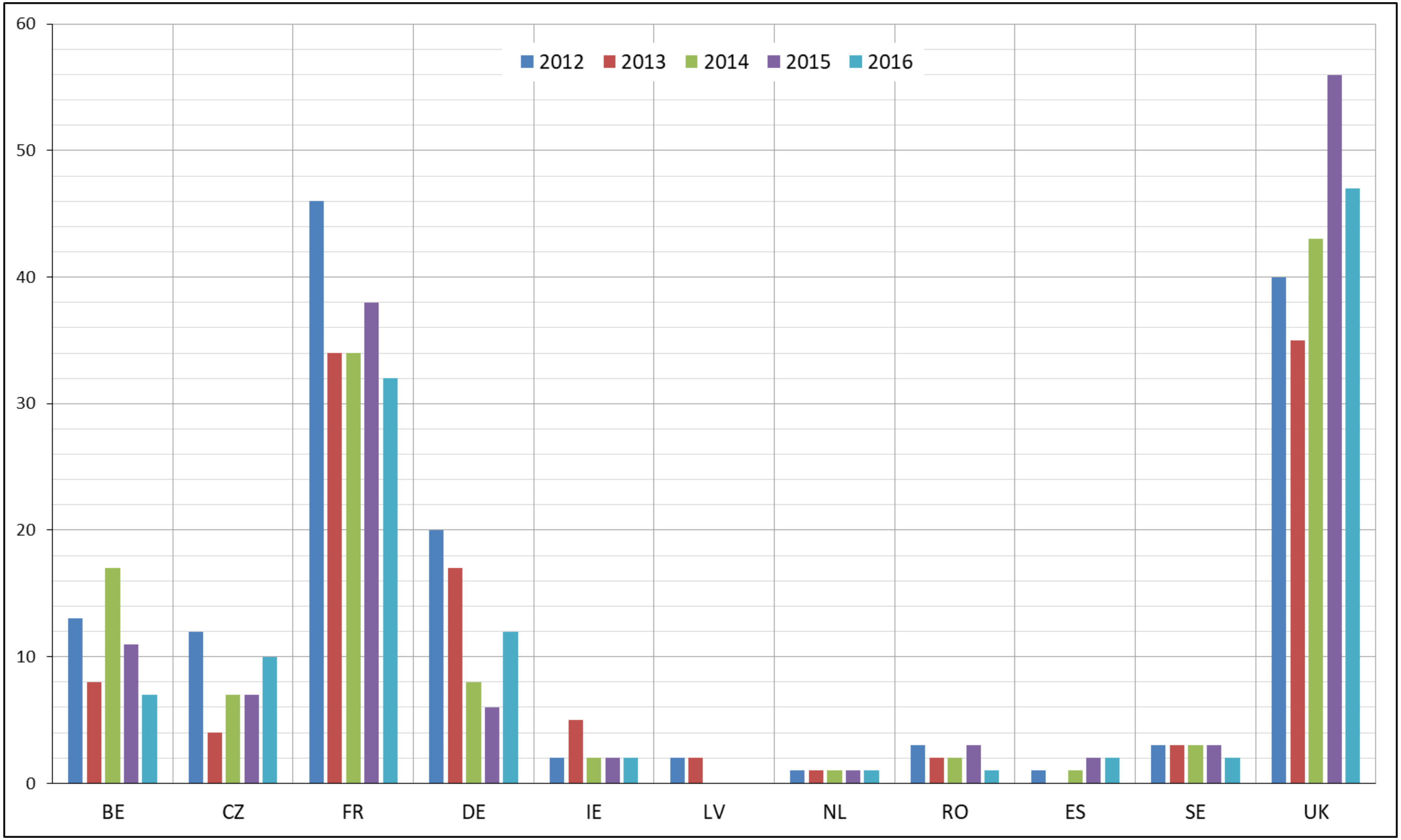


Figure 61: How many country of origin approvals was issued in 2014 – 2016

MULTILATERAL APPROVAL

Multilateral approval is where a State requires its own authorisation of a design authorised in another State. Typically, there are around 90 multilateral approvals a year in the community with around 75 % of reported cases involving reassessment of designs approved in other EU MS (**Figure 62**, **Figure 63**, **Figure 64**, **Table 32**).

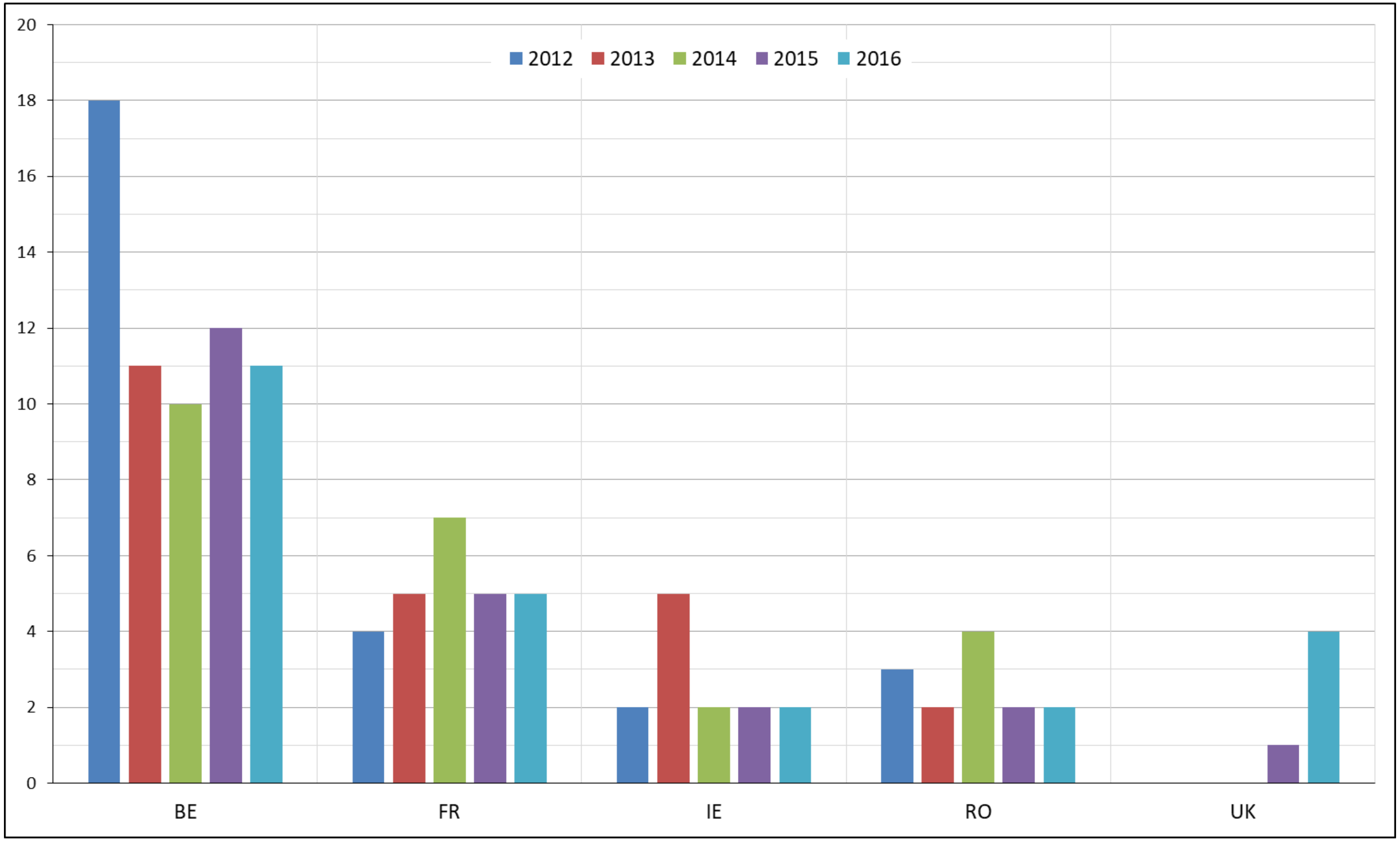


Figure 62: How many multilateral approvals by re-certification were issued in 2012 – 2016

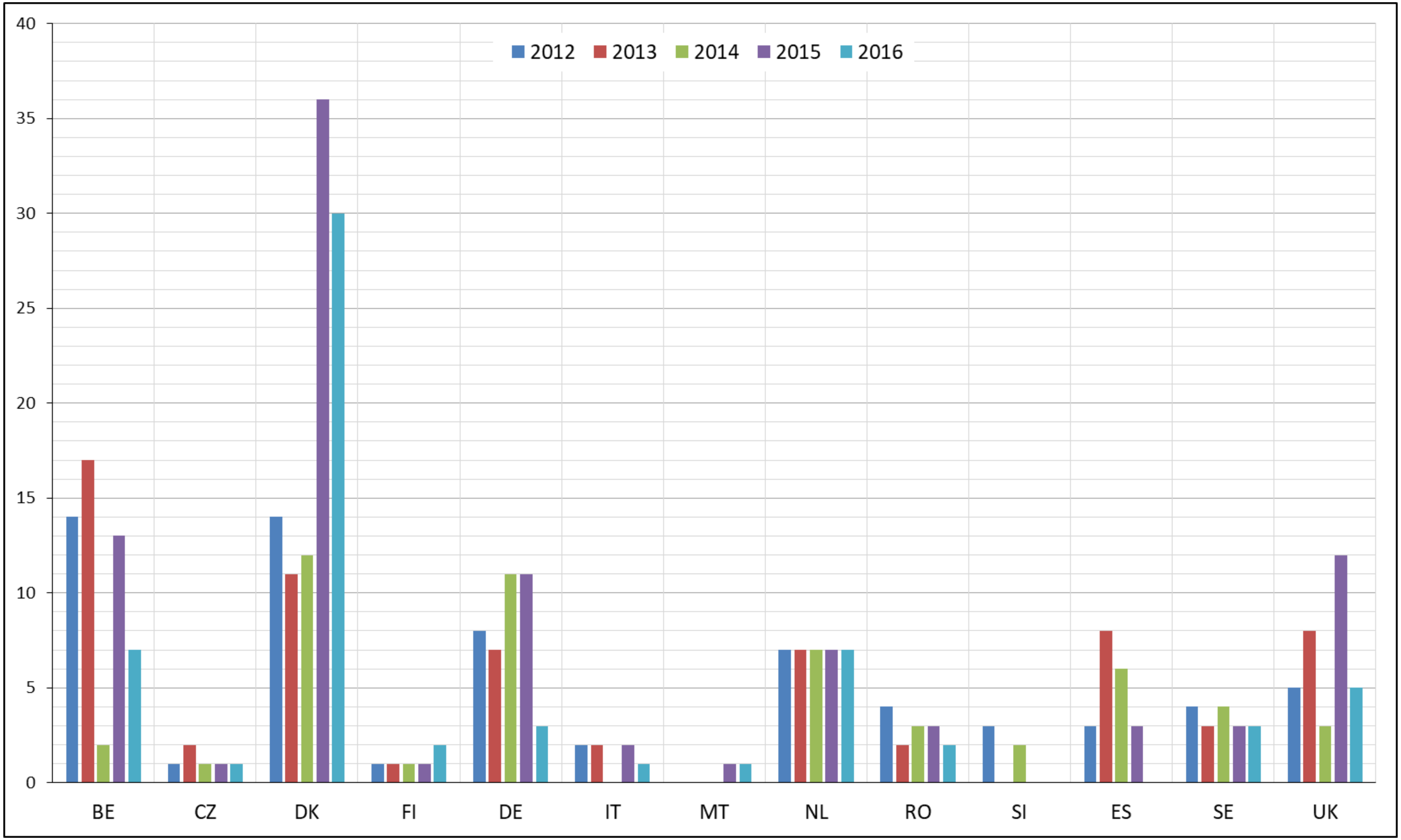


Figure 63: How many multilateral approvals by validation were issued in 2012 - 2016

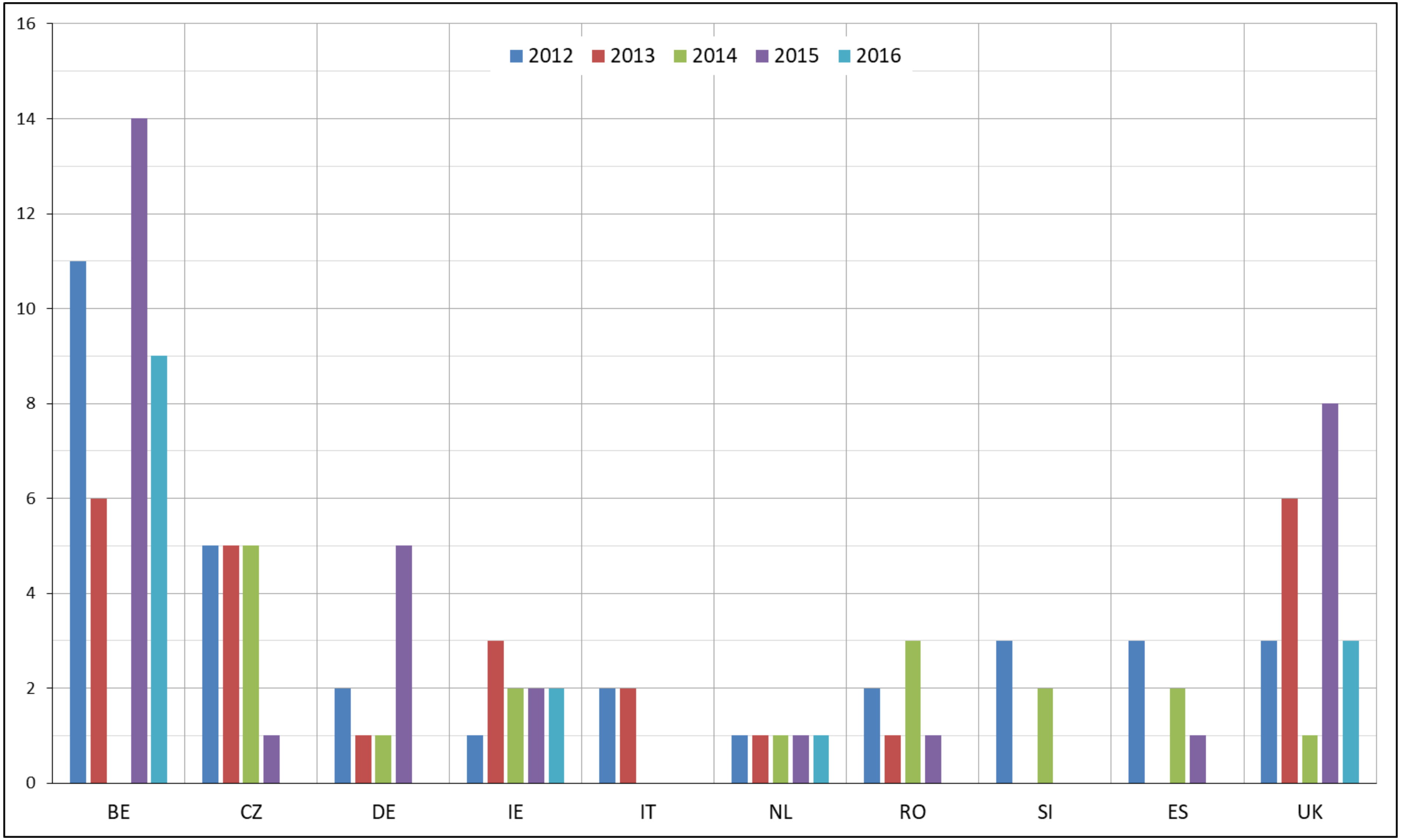


Figure 64: How many re-certifications or validations of non-EU package or shipment certificates were issued in 2012 – 2016

Table 32: Percent of multilateral approvals from outside of the EU

Percent of multilateral approvals from outside of the EU	%
2012	35%
2013	27%
2014	23%
2015	29%
2016	17%
AVERAGE OVER 5 YEARS	**27%**

A common certification system would reduce the burden in the EU. Around 75% of approvals involve re-checking work carried out to the same regulations elsewhere in the EU. Assessment in multiple MS against identical regulatory frameworks can give the impression that regulators are not working to the same standard in practice. Given the small number of MS performing most assessments this may be the case. However, based on the available data, a European centre of excellence for approval, sourced from the existing expertise, may be more appropriate.

I-8 Encourage cooperation between Competent Authorities in the assessment of packages.

WITNESSING OF TESTING

REGULATION AND REGISTRATION

Around a quarter of MS have a registration scheme for testing of packages (**Figure 65**). Around two thirds of the MS identified powers to witness tests. There is an issue related to knowledge of when tests are likely to occur. MS believe they have powers to inspect tests but may not have a system for being informed about the tests. For non-CA approved packages, these may be developed without the intention for use in transporting radioactive material, so it is difficult to identify these tests in advance. Some MS also identified differences in requirements depending on mode.

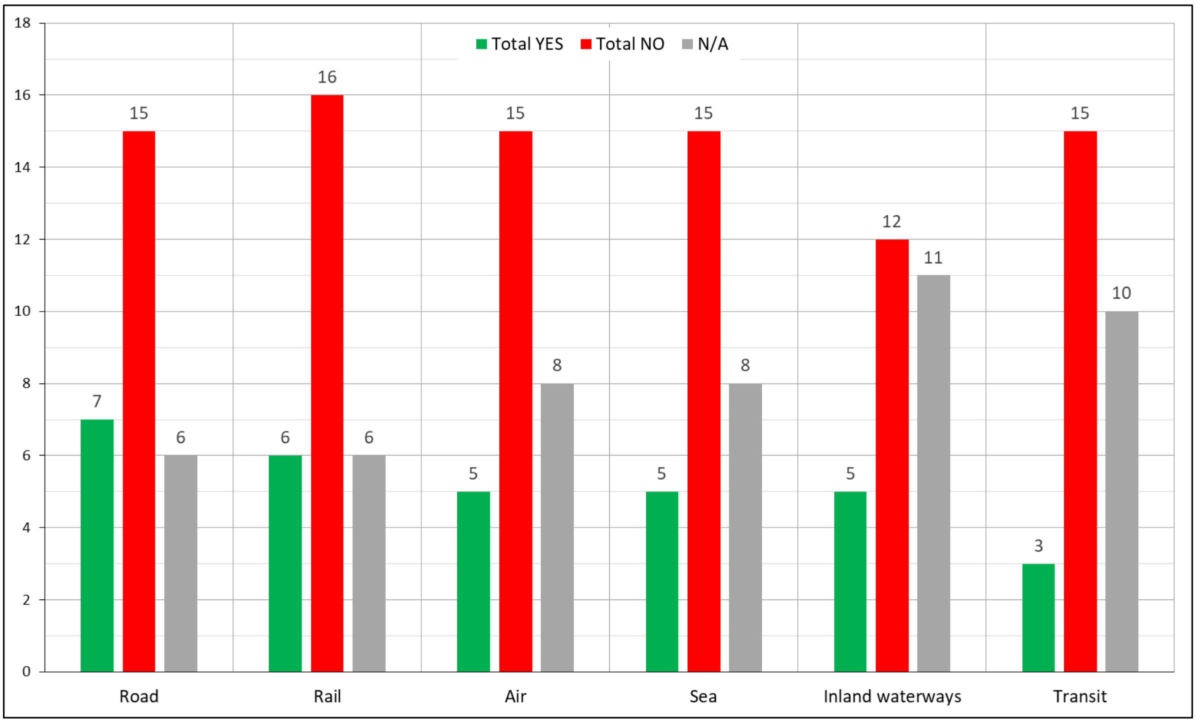


Figure 65: Do you have a registration scheme for package tests for RM in regulation?

INTERNATIONAL POWERS

The questionnaire also inquired on international powers regarding witnessing of testing. Several MS were not aware of any powers, others noted collaboration with other authorities as a practice. Some MS indicated the use of powers within their state to manage particular situations (e.g. withholding approvals if they were not satisfied). Few MS identified ADR 1.8.2.1 as a potential power to work internationally.

The potential for the open market to result in activities in an MS related to packages produced in another State is particularly important in this area. There are limited facilities where packages can be tested to regulatory standards, particularly for large packages. It is usual for parts of the compliance regime to require interface with other states.

ADR 1.8.2.1 “The Contracting Parties [in EU Member States] shall agree on mutual administrative support for the implementation of ADR.”

So, I-5 also applies here.

EVIDENCE OF TEST WITNESSING

Fifty package tests were witnessed over five years in the Community, with approximately 75% of them being in only two MS (**Table 33**). Although several MS did not provide concrete figures, one State responded N/K (not known), meaning that the regulator could not readily identify the number of tests they had witnessed.

Table 33: How many package tests were witnessed in years 2012 - 2016

How many package tests were witnessed in year:	
2012	3
2013	6
2014	7
2015	19
2016	15
TOTAL	50

NON-CA APPROVED PACKAGE WITNESSING

The testing of 20 packages that did not require Competent Authority approval were witnessed over five years, again 85% of these cases emerging in only two MS (**Table 34**). At first glance this number seems low. In the follow-up meetings the question was raised concerning the total number of tests that had been carried out compared to the number of tests witnessed — if few tests had been carried out then this number of test witnessing would be acceptable. Follow-up information gathering identified a significant rate of testing taking place over the past five years of both Competent Authority approved packages and packages not requiring Competent Authority approval. This, along with the higher testing rate in two MS, suggests variable standards being applied in the community, either by too high of a burden being placed on industry, or by failing to perform effective compliance assurance in this area.

This also leads to the application of I-5 here.

Table 34: How many packages not subject to CA approval had testing witnessed in years 2012 - 2016

How many packages not subject to CA approval had testing witnessed in	
2012	1
2013	3
2014	2
2015	7
2016	7
TOTAL	**20**

WITNESSING OF MANUFACTURE

REGULATION AND REGISTRATION

It was discovered that roughly 25% of MS require registration of the manufacturing of packages (**Figure 66**). Two MS reported varied requirements depending on the mode of transport.

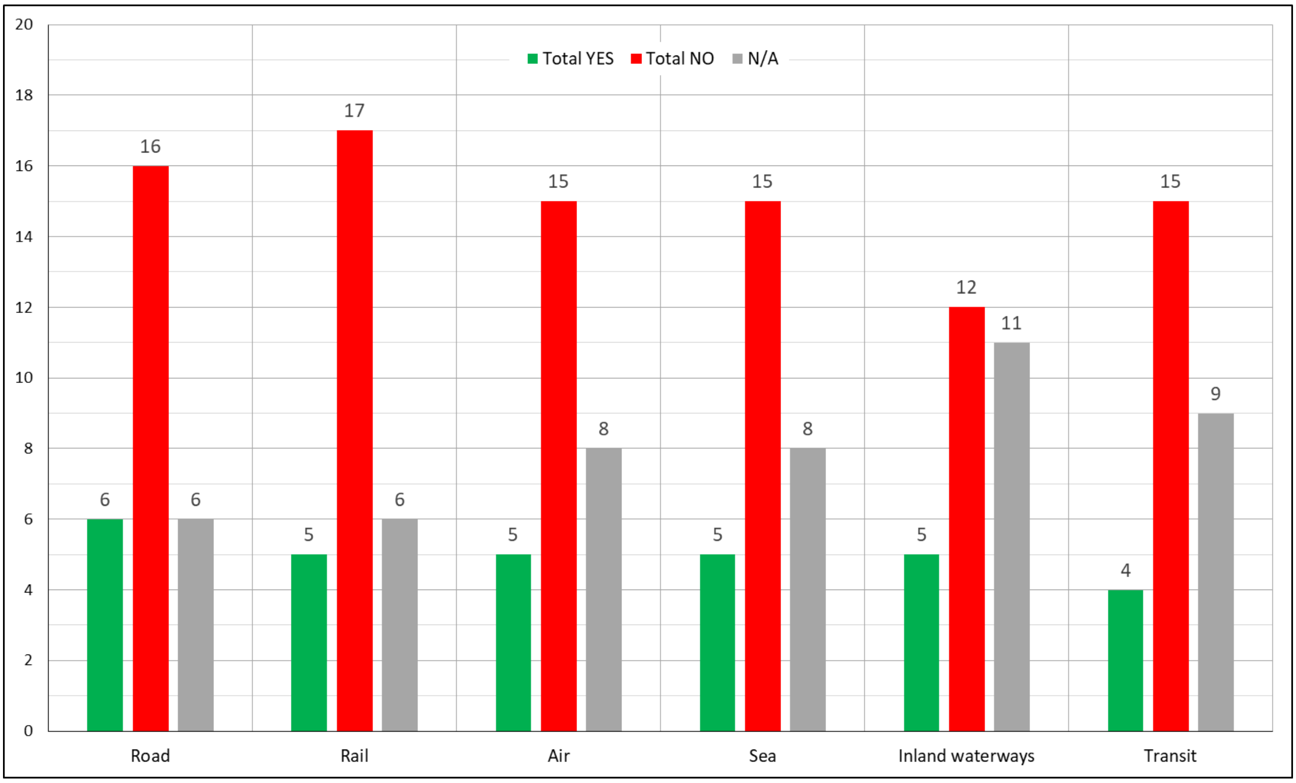


Figure 66: Do you have a registration scheme for package manufacturers for RM in regulation?

SERIAL NUMBER REGISTER

ADR 6.4.23.19 requires the notification of serial numbers to the Competent Authority that approved the design. The importance of serial numbers is to enable the identification of counterfeit packages (which have been found in the past in the EU). It is important that a register of valid serial numbers is maintained by the Competent Authority.

Less than half of MS have packages on the register, while some MS do not maintain a register. A total of 300 different Competent Authority approved packages were reported as being registered within the EU, with over 80% in three MS.

Several respondent MS were unable to report the numbers of serial numbers for each package type, however one MS reported approximately 15,000 different numbers which accounts for roughly 90% of all the serial numbers recorded in the EU. These numbers do not look consistent; and some MS reported that they had not fully implemented ADR in this area over the past five years.

I-9 It is suggested that the Union develops a packaging information system that is focused on the needs of the Union, including a register of packages and valid serial numbers. This could be extended if required.

EVIDENCE OF MANUFACTURE

Only 25% of MS reported witnessing of manufacture during the past five years (**Figure 67**). The average inspection rate in the community is around 10 CA-approved package manufacturing operations each year. Some MS identified manufacturing taking place but had not inspected manufacturing operations over the past five years.

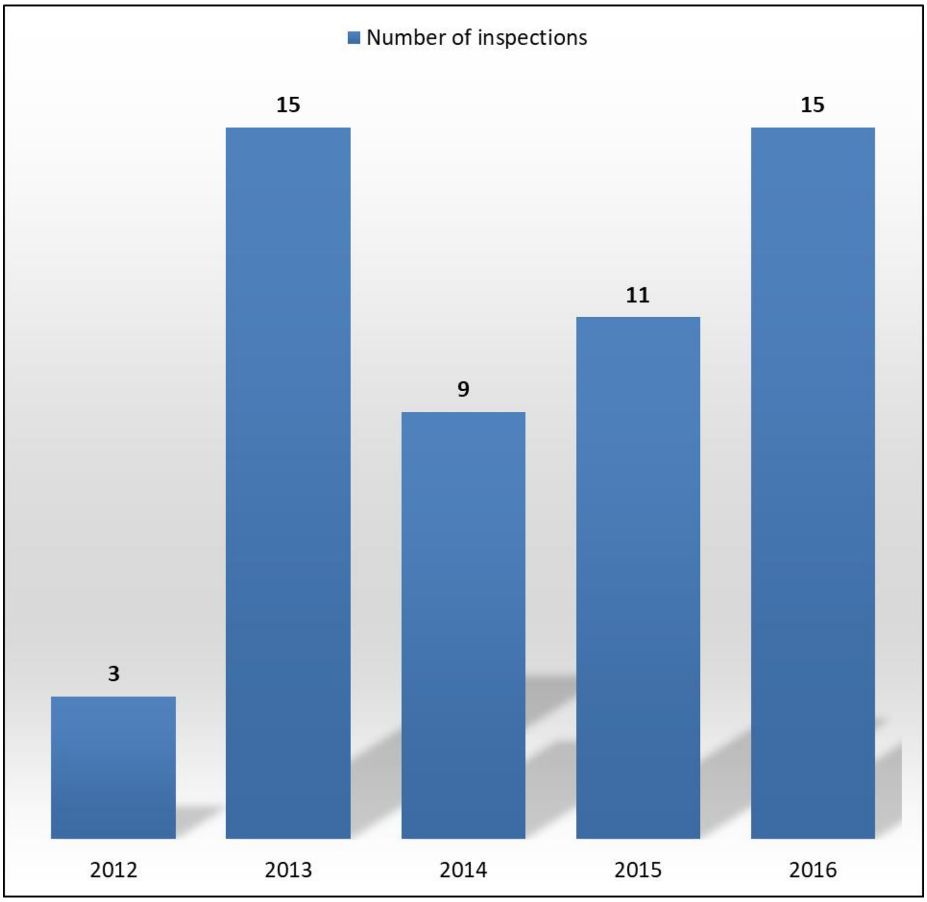


Figure 67: Manufacturing operations inspected

NON-CA APPROVED PACKAGE MANUFACTURE

Only two MS reported witnessing the manufacture of non-CA approved packages, with around 20 operations being examined in the past five years (less than 4 per year) (**Figure 68**). This suggests a low rate of witnessing of manufacture of non-CA approved packages. Many of such packages are single use, and as a result this accounts for the vast majority of the manufactured packages each year. The inspection rate appears low.

I-5 also applies in this area.

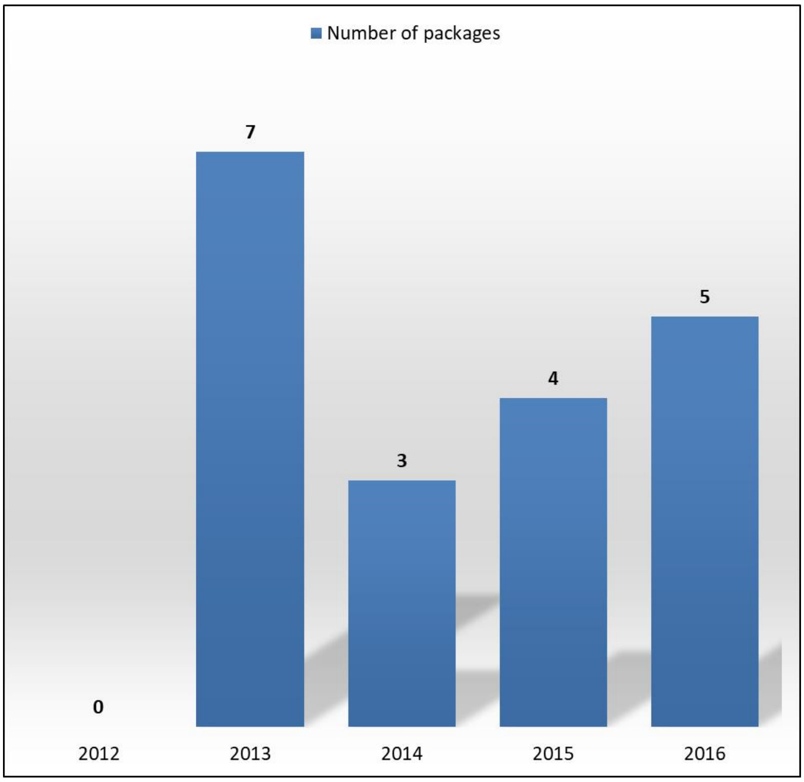


Figure 68: Manufacture of packages not subject to CA approval witnessed

EXAMINATION OF MAINTENANCE AND SERVICING

REGULATION AND REGISTRATION

Less than 25% of MS have a registration scheme for maintenance and servicing operators (**Figure 69**), but a significant proportion identified powers to inspect witnessing of maintenance. Some MS reported differences depending on the mode of transport.

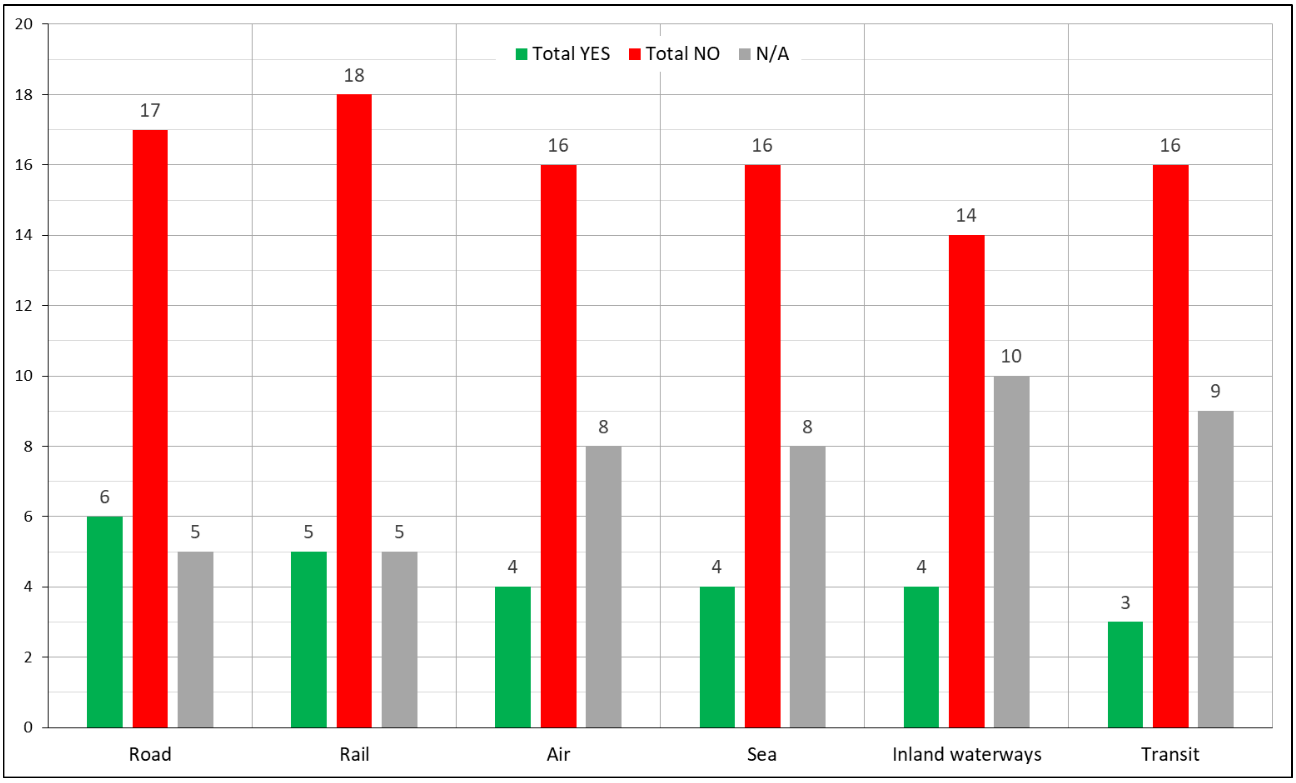


Figure 69: Do you have a registration scheme for package maintenance for RM in regulation?

INTERNATIONAL POWERS

Few MS identified established agreements with other States, but most noted it was possible. The MS requiring registration did not respond to the questions on international collaboration in a positive manner. One of the most significant transport events in the community involved maintenance responsibility in a different MS.

EXAMINATION OF RECORDS

Generally, around 200 maintenance records per year are checked in the EU, however almost 80% of inspections were limited to two MS. The two MS inspected 400 records in five years (**Figure 70**), the rest of the community averaged less than 20 inspections per year. Around a third of MS examine records.

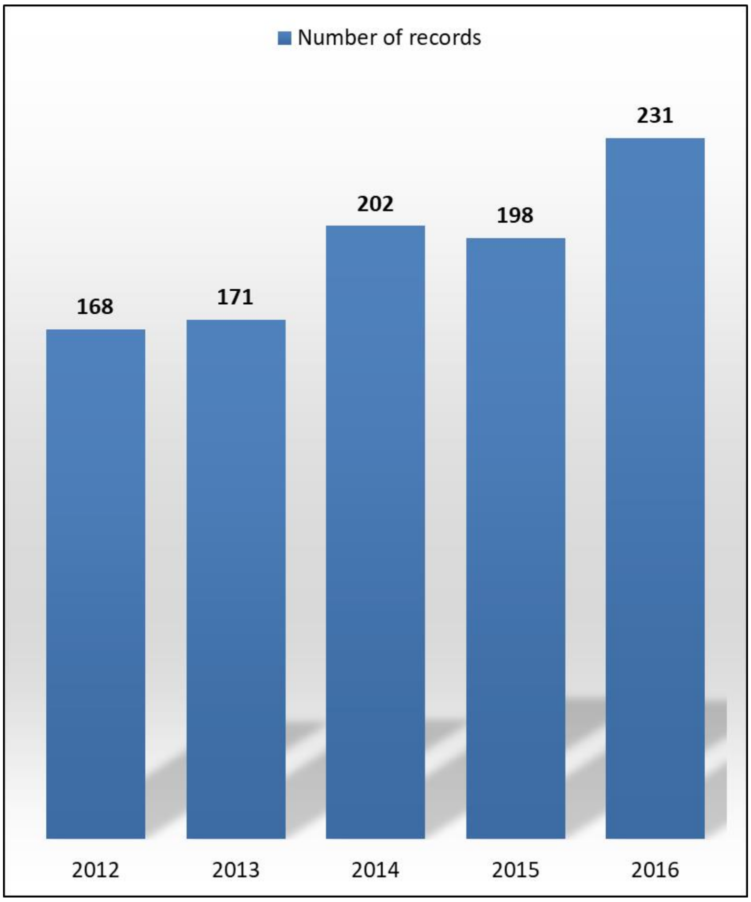


Figure 70: Maintenance records examined

EXAMINATION OF ACTIVITIES

The examination of actual maintenance operations rather than paperwork identified around 50 inspections over five years, 75% of which were in one MS (**Figure 71**). The numbers prior to 2014 were very low and only one MS reported inspections in 2012 and 2013. Only three MS (BE, FR and UK) reported examination of maintenance activities over the past five years.

There are around 300 current designs approved by Competent Authorities in the community. Around 15 operations were reviewed in recent years. Even if only Competent Authority approved packages are considered, this is a rate of 1 in 20. Considering packages not requiring Competent Authority approvals (many of which are single use so will not have servicing requirements) it is likely that some package servicing arrangements are not reviewed during the package lifetime.

I-5 also applies in this area.

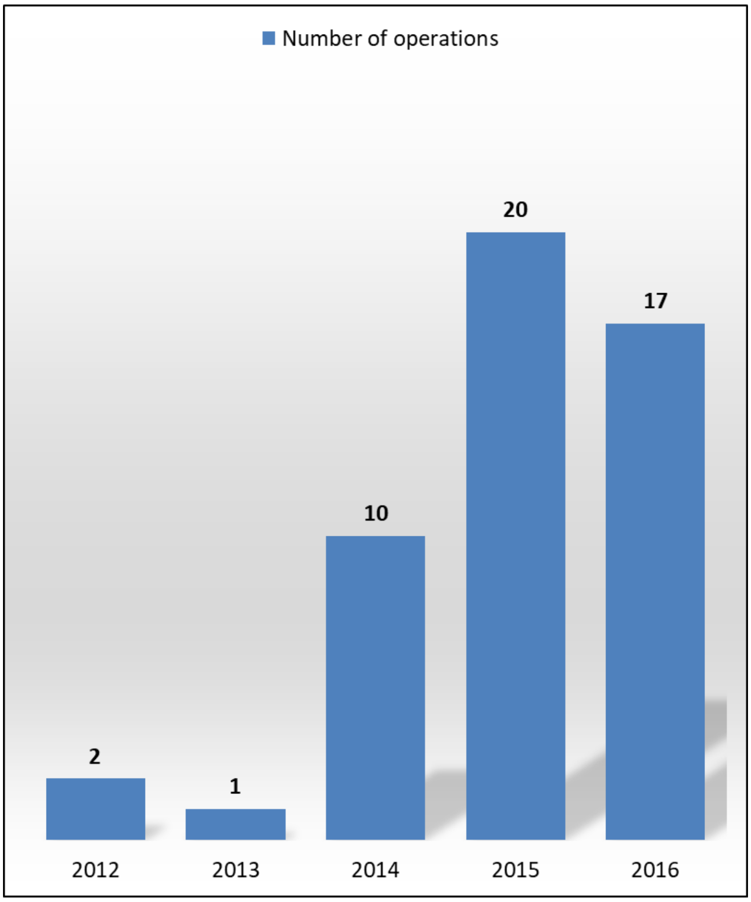


Figure 71: Maintenance operations examined

FOLLOW-UP STUDY

In the follow-up study, MS were asked about the source of maintenance and parts for gamma radiography devices. The MS where maintenance takes place or where parts are sourced are plotted in the following **Table 35:** , along with the MS responses related to the examination of servicing or maintenance. Some MS maintain or provide parts for radiography devices but failed to respond positively to the questions on how they ensure compliance in this area (marked in red).

Table 35: MS where maintenance takes place or where parts are sourced and associated compliance checks

State	Maintenance	Parts	Registration	Record checking	Inspection
Austria	YES				
Belgium	YES	YES		YES	YES
Bulgaria	YES		YES		
Croatia			YES		
Czech Republic	YES	YES	YES	YES	
Denmark					
Estonia			YES		
Finland	YES				
France	YES	YES		YES	YES
Germany	YES	YES	YES	YES	
Greece					
Hungary	YES				
Ireland	YES			YES	
Italy	YES			YES	
Latvia					
Lithuania	YES				
Luxembourg					
Malta					
Netherlands	YES	YES			
Poland					
Romania			YES	YES	
Slovenia	YES				
Spain	YES				
Sweden	YES			YES	
United Kingdom	YES			YES	YES
Other	YES	YES			
Not Known	YES	YES			

A cross-mapping of the inter-relation between MS of operation and MS where servicing or parts are sourced is shown in the **Table 36**. This clearly shows that it is important to take into account the open market when considering compliance assurance.

Table 36: Cross-mapping of MS of operation and MS of servicing or parts

		State where equipment is used																						
		Belgium	Bulgaria	Croatia	Czech Republic	Denmark	Estonia	Finland	France	Germany	Greece	Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Poland	Romania	Slovenia	Spain	Sweden	United Kingdom
State where servicing activities or parts are sourced	**Austria**																				■			
	Belgium	■	■	■									■			■	■					■	■	
	Bulgaria		■																					
	Croatia																							
	Czech Republic								■												■			
	Denmark																							
	Estonia																							
	Finland							■																
	France								■															
	Germany	■	■							■								■			■			■
	Greece																							
	Hungary			■																	■			
	Ireland											■												
	Italy												■											
	Latvia																							
	Lithuania														■									
	Luxembourg																							
	Malta																							
	Netherlands																	■						
	Poland																							
	Romania																							
	Slovenia																				■			
	Spain																					■		
	Sweden																						■	
	United Kingdom											■												■
	Other		■					■					■		■			■				■	■	■
	Not Known	■		■	■															■			■	■

EMERGENCY PLANNING AND EXERCISES

REGULATIONS AND PROCEDURES

In terms of regulations, the questions asked for three aspects of emergency arrangements planning, exercising and reviewing. These three areas are consistent with the BSS Directive (COUNCIL DIRECTIVE 2013/59/EURTOM) Article 98. The first section asked whether there were regulations requiring planning for emergencies and performing exercises (**Figure 72**).

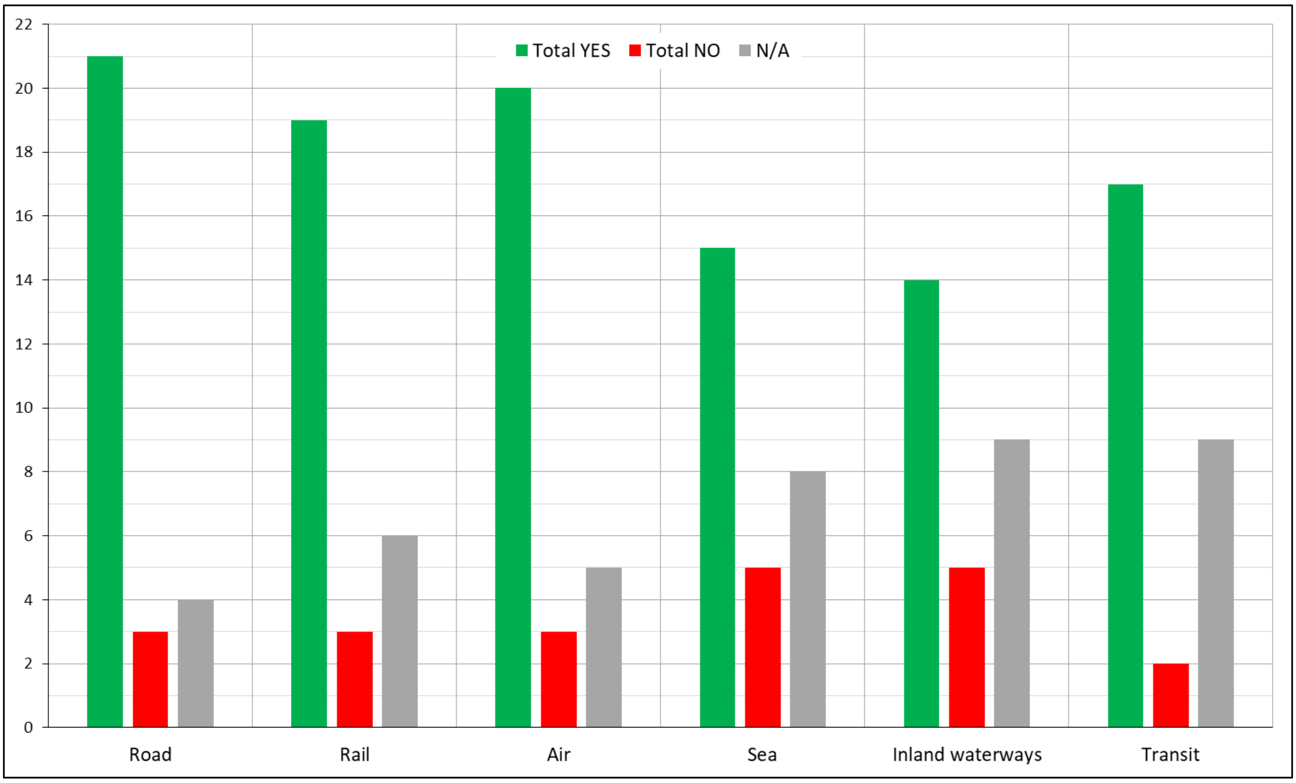


Figure 72: Are there any regulations requiring emergency planning for TRAM

Most MS identified regulations requiring planning for emergencies involving transport of radioactive materials.

In terms of responders, the MS identified the consignor, carrier, state authority, and local authority, or a combination of these. During the follow-up, a further set of questions was asked for clarification.

A review of the legal person responsible for emergency planning was carried out (legal person may include organisations). A wide variety of responsibilities were identified, these were simplified into five colour-coded groups.

Carrier
Consignor
Mixture or broadly defined
State actors only
N/A or No answer (nfi)

Hypothetical examples were considered to test the complexity of the system, namely:

- A road shipment from BE through FR to ES. The emergency planning would be the responsibility of:
  - Carrier in BE;
  - Consignor in FR;
  - State in ES.
- A road shipment from DE to IT via AT followed by a flight to EL. The emergency planning would be the responsibility of:
  - No information provided by DE;
  - No information provided by AT;
  - The prefects of provinces in IT for road transport;
  - The prefect of the airport province and the civil aviation authority for air transport in IT;
  - The carrier for transport in EL.

The situation is clearly complex, and of concern is the fact that the regulatory bodies in some MS were unable to provide answers. Some MS pointed to the international agreements for the mode of transport. The modal regulations have responsibilities for planning fairly well specified, as shown below.

- ADR 5.4.1.2.5.2 specifies that the consignor should provide the carrier with emergency arrangements.
- ADR 6.4.23.15 specifies that the certificates for packages and shipments should include the emergency arrangements that the Competent Authority believes are necessary.
- ADR 5.4.3 places requirements on the carrier to provide the driver with instructions in writing in a specified format, in all applicable languages.
- ADR 8.1.4 and 8.1.5 sets in place some of the emergency equipment that is required to be available, including PPE.
- ADR Table A provides Hazard Identification numbers that are used to guide response.
- ADR 8.2.2.3.5 includes a requirement for the driver to be trained in relation to the measures to be taken in event of an accident involving radioactive material.

From these requirements (which are compulsory under Directive 2008/68/EC) it can be deduced that emergency arrangements must be available prior to any consignment being identified, and thus placing the responsibility for planning on the carrier *only* would not seem to meet the requirements of the Directive. In addition, there are clearly prescribed regulatory requirements that can be relied on as part of emergency planning (such as the equipment available and the training of the driver).

A key issue with transport is the need to plan for the eventuality that the driver, carrier and consignor are one and the same person, and could be seriously injured in an accident. To this end the MS could be required to respond to an emergency with little input.

The result is that there is a structure that involves drivers, carriers, consignors and regulators in the development of emergency response plans which is established in Directive-backed requirements. The response that represents this in the best manner is considered to be that of the NL.

Council Directive 2013/59/EURATOM provides additional requirements based on the need for each MS to put in place an emergency management system based on potential emergency exposures:

- Article 15 1 d provides for training of workers, similar to ADR 8.2.2.3.5;
- Article 17 provides for training of emergency workers;
- Article 98 requires emergency response plans to be drawn up, incorporating specific requirements;
- Article 99 requires State to State communication in event of an international emergency.

Most MS identify a common responsibility for planning for emergency response for all modes, however several MS have different responsibilities depending on the mode of transport. The situation is overly complex (**Table 37**).

Table 37: Responsibility for planning for emergency response

State	Consignments by road originating in your state	Consignments by air originating in your state	Shipments transiting your state by road
Belgium	Carrier	Carrier	Carrier
Bulgaria	The licensee or authorization holder	The licensee or authorization holder	The licensee or authorization holder
Croatia	Responsible person	Responsible person	Responsible person
Czech Republic	Consignor	Consignor	Consignor
Denmark	nfi	nfi	nfi
Estonia	Carrier	n/a	According to ADR
Finland	Emergency services	Emergency services	Emergency services
France	consignor	consignor	consignor
Germany	nfi	nfi	nfi
Greece	Consignor	Air carrier	Carrier
Ireland	Licensee (Consignor and Carrier), Emergency Services in conjunction with the EPA	Licensee (Consignor and Carrier), Airline, Airport and Local Authority Emergency Services in conjunction with the EPA	Licensee (Consignor and Carrier), Emergency Services in conjunction with the EPA and Local Authority
Italy	The prefect of the provinces crossed by the consignment	The prefect of the province in which the consignments originating together with the Civil Aviation Authority	The prefect of the provinces crossed by the shipment
Latvia	Operator (i.e. any organization involved in transport, including the consignor, the carrier, the port operator and the consignee).	Operator	Operator
Lithuania	MoTC	MoTC	MoTC
Luxembourg	Carrier	Carrier	Carrier
Malta	RPB	RPB	Not applicable
Netherlands	1. Consignor and 2. Carrier. Obviously the Government provides the (legal) framework to the consignors and carriers, assigns EPR responsibilities and plans, prepares, tests the plans and responds to emergencies.	1. Consignor and 2. Carrier. Obviously the Government provides the (legal) framework to the consignors and carriers, assigns EPR responsibilities and plans, prepares, tests the plans and responds to emergencies.	1. Consignor and 2. Carrier. Obviously the Government provides the (legal) framework to the consignors and carriers, assigns EPR responsibilities and plans, prepares, tests the plans and responds to emergencies.
Poland	Carrier	Carrier	Carrier
Romania	Consignors	Consignors	Consignors

State	Consignments by road originating in your state	Consignments by air originating in your state	Shipments transiting your state by road
Slovenia	Carrier	Carrier	Carrier
Spain	Dirección General de Protección Civil - Ministerio del Interior	Dirección General de Aviación Civil - Ministerio de Fomento	Dirección General de Protección Civil - Ministerio del Interior
Sweden	MSB/SSM	SSM/TS	SSM/MSB
United Kingdom	Consignor and Carrier as defined in CDG Schedule 2 para 4. See ONR guide: http://www.onr.org.uk/transport/emergency-arrangements-guidance.pdf	Once airside: The Aerodrome Operator – see GM/AMC to COMMISSION REGULATION (EU) No 139/2014, AMC2 ADR.OPS.B.005(b) Aerodrome Emergency Planning AERODROME EMERGENCY PLAN DOCUMENT Once airborne: The Air Operator – see GM/AMC to Commission Regulation (EU) 965/2012 on air operations, SPA.DG.105 b) (4) The operator shall in accordance with the Technical Instructions establish operating procedures to ensure the safe handling of dangerous goods at all stages of air transport, containing information and instructions on: 4) the response to emergency situations involving dangerous goods.	Consignor and Carrier as defined in CDG Schedule 2 para 4. See ONR guide: http://www.onr.org.uk/transport/emergency-arrangements-guidance.pdf

Around 50% of MS identified legal requirements requiring emergency exercises (Figure 73). In the majority of cases the organisations responsible for planning were also responsible for exercises related to the plans. This appears to fall short of the requirements of directives.

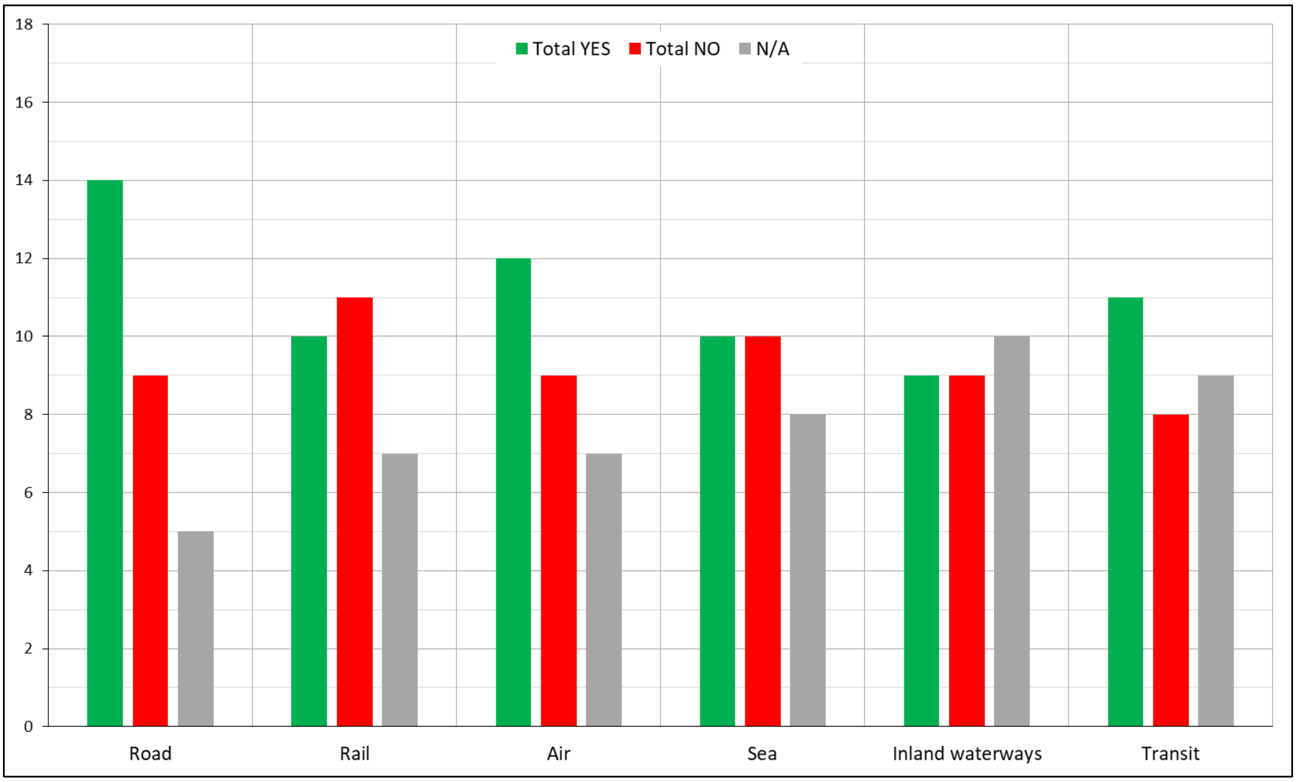


Figure 73: Are there any regulations requiring emergency exercises for TRAM

REVIEW OF PLANS

Again, the distribution of the responsibility for reviewing plans was wide, including consignor, licensee, State etc. Two MS identified over 100 reviews of plans each in 2016, mainly related to road transport. This accounts for almost all of the reviews of emergency plans in the EU (**Figure 74**).

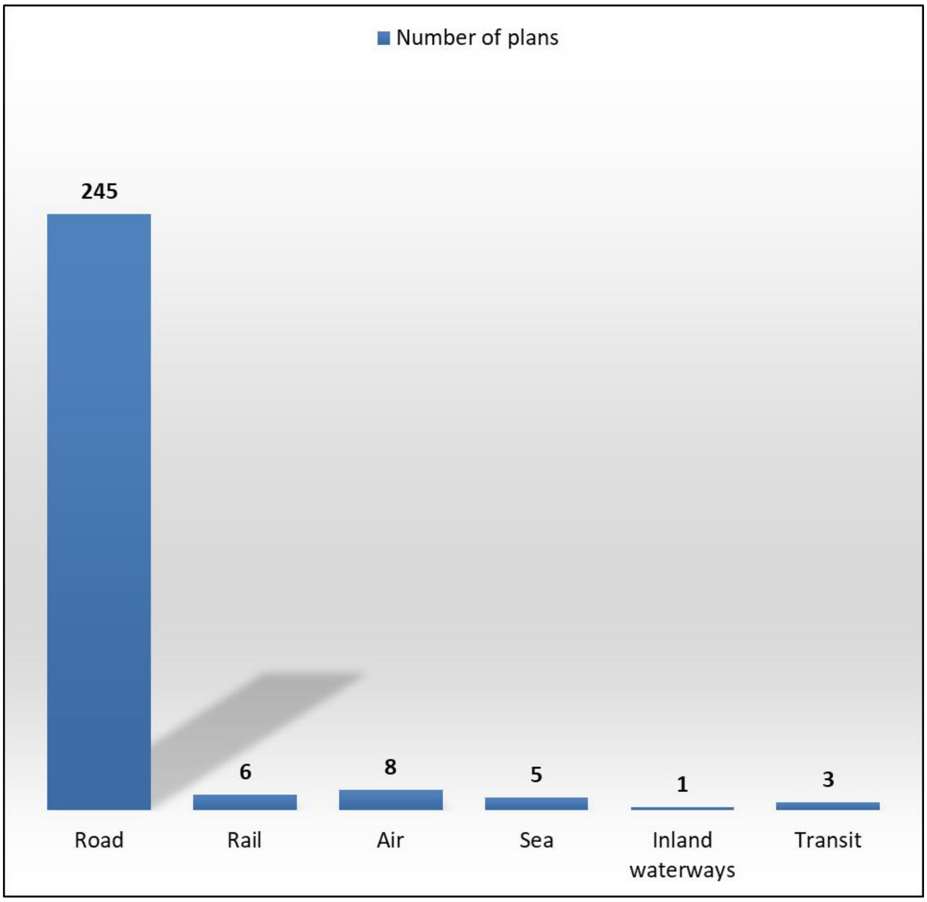


Figure 74: Number of emergency plans reviewed

WITNESSING OF EXERCISES

Generally, there was a lack of clarity over who was responsible for witnessing emergency exercises, and few such emergency exercises were witnessed in 2016 (**Figure 75**). Several MS did not identify a responsible body for witnessing exercises. The number of regulator-witnessed exercises reported for road in 2016 is below 10.

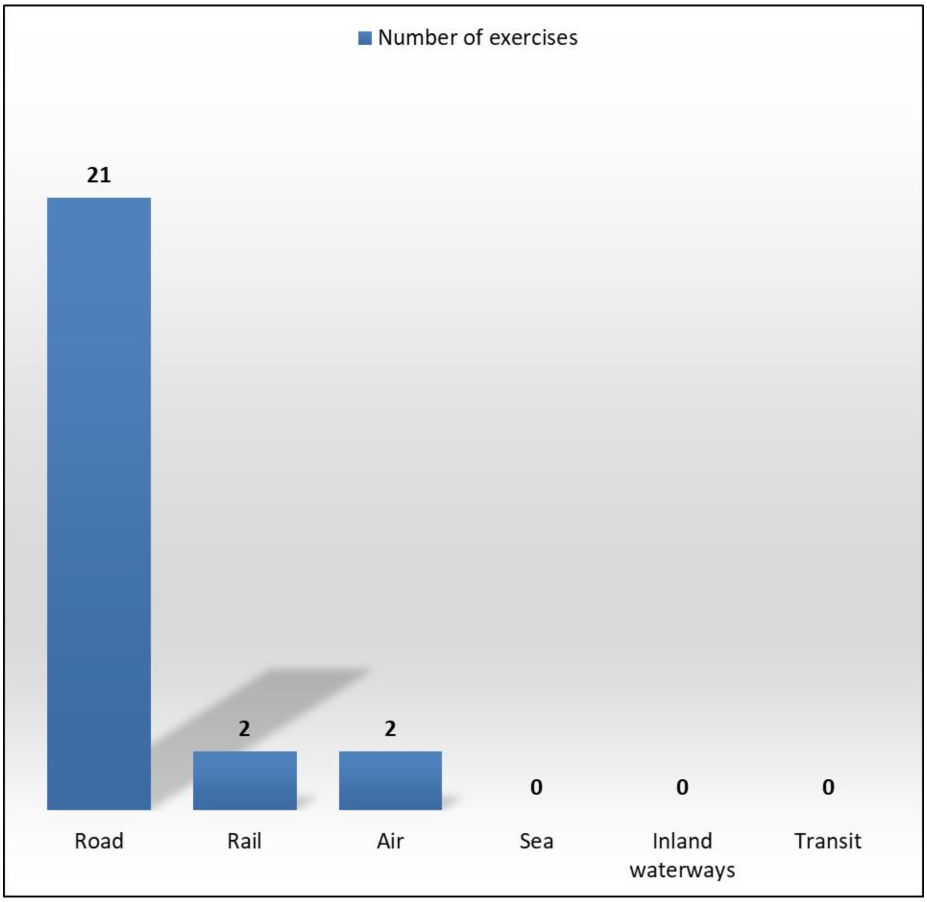


Figure 75: Number of emergency exercises witnessed

Overall, the Community standards for EPR were not set out clearly in responses either in terms of the primary activities, responsibilities or reviews. Further in-depth study of this area took place in the follow up study.

TESTING EMERGENCY PLANS

In the follow-up study, questions reviewed the legal person responsible for testing emergency plans. Using the same colour code, **Table 38** summarizes the results of the follow-up study. In addition, where the responsibility for testing is different to the responsibility for planning, the text is shown in italics.

Table 38: Legal person responsible for testing emergency plans

State	Consignments by road originating in your state	Consignments by air originating in your state	Shipments transiting your state by road
Belgium	Carrier	Carrier	Carrier
Bulgaria	The licensee or authorization holder	The licensee or authorization holder	The licensee or authorization holder
Croatia	SORNS	SORNS	SORNS
Czech Republic	Consignor	Consignor	Consignor
Denmark	nfi	nfi	nfi
Estonia	Carrier	n/a	n/a
Finland	Emergency services	Emergency services	Emergency services
France	Consignor	Consignor	Consignor
Germany	nfi	nfi	nfi
Greece	Consignor	Air carrier	Carrier

State	Consignments by road originating in your state	Consignments by air originating in your state	Shipments transiting your state by road
Ireland	Licensee (Consignor and Carrier), Emergency Services in conjunction with the EPA	Licensee (Consignor and Carrier), Airline, Airport and Local Authority Emergency Services in conjunction with the EPA	Licensee (Consignor and Carrier), Emergency Services in conjunction with the EPA and Local Authority
Italy	The prefect of the provinces crossed by the consignment	The prefect of the province in which the consignments originating together with the Civil Aviation Authority	The prefect of the provinces crossed by the shipment
Latvia	Operator	Operator	Operator
Lithuania	MoTC, MoI, RPC & VATESI	MoTC, MoI, RPC & VATESI	MoTC, MoI, RPC & VATESI
Luxembourg	Carrier	Carrier	Carrier
Malta	CPD/RPB	CPD/RPB	Not applicable
Netherlands	1. Consignor and 2. Carrier. Obviously the Government provides the (legal) framework to the consignors and carriers, assigns EPR responsibilities and plans, prepares, tests the plans and responds to emergencies.	1. Consignor and 2. Carrier. Obviously the Government provides the (legal) framework to the consignors and carriers, assigns EPR responsibilities and plans, prepares, tests the plans and responds to emergencies.	1. Consignor and 2. Carrier. Obviously the Government provides the (legal) framework to the consignors and carriers, assigns EPR responsibilities and plans, prepares, tests the plans and responds to emergencies.
Poland	Carrier	Carrier	Carrier
Romania	Carriers	Carriers	Carriers
Slovenia	carrier	carrier	carrier
Spain	Dirección General de Protección Civil - Ministerio del Interior	Dirección General de Aviación Civil - Ministerio de Fomento	Dirección General de Protección Civil - Ministerio del Interior
Sweden	MSB/SSM	SSM/TS	SSM/MSB
United Kingdom	Consignor and Carrier as defined in CDG Schedule 2 para 4. See ONR guide: http://www.onr.org.uk/transport/emergency-arrangements-guidance.pdf	Once airside: The Aerodrome Operator – see GM/AMC to COMMISSION REGULATION (EU) No 139/2014, AMC1 ADR.OPS.B.005(c) Aerodrome emergency planning There is no specific requirement for the Air Operator to test their emergency response plan.	Consignor and Carrier as defined in CDG Schedule 2 para 4. See ONR guide: http://www.onr.org.uk/transport/emergency-arrangements-guidance.pdf

RESPONDING TO EMERGENCIES

The final follow-up question on EPR considered the legal person responsible for responding to an emergency. An additional marking (underline) is included in **Table 39** to identify where the responders are different to those responsible for exercises.

Table 39: Legal person responsible for responding to an emergency

State	Consignments by road originating in your state	Consignments by air originating in your state	Shipments transiting your state by road
Belgium	Carrier	Carrier	Carrier
Bulgaria	The licensee or authorization holder	The licensee or authorization holder	The licensee or authorization holder
Croatia	Various organizations	Various organizations	Various organizations
Czech Republic	Consignor	Consignor	Consignor
Denmark	nfi	nfi	nfi
Estonia	Carrier (driver) and first responder (Rescue Board)	n/a	Carrier (driver) and first responder (Rescue Board)
Finland	Emergency services	Emergency services	Emergency services

State	Consignments by road originating in your state	Consignments by air originating in your state	Shipments transiting your state by road
France	Emergency Public Services assisted by the transport actors	Emergency Public Services assisted by the transport actors	Emergency Public Services assisted by the transport actors
Germany	nfi	nfi	nfi
Greece	Depending on the severity of the emergency: carrier, consignor, first responders, EEAE	Depends on the location of the emergency	Depending on the severity of the emergency: carrier, first responders, EEAE
Ireland	Emergency Services, Licensee (Consignor and Carrier) and the EPA	Airline, Airport and Local Authority Emergency Services in conjunction with the licensee (Consignor) and the EPA	Emergency Services, Licensee (Consignor and Carrier) and the EPA.
Italy	The fire brigade under the coordination of the prefect of the provinces crossed by the consignment	The fire brigade under the coordination of the prefect in which the consignments originating together with the Civil Aviation Authority	The fire brigade under the coordination of the prefect of the provinces crossed by the shipment
Latvia	Operator, SFRC, RSC	Operator, SFRC, RSC	Operator, SFRC, RSC
Lithuania	MoI & RPC & VATESI	MoI & RPC & VATESI	MoI & RPC & VATESI
Luxembourg	Carrier	Carrier	Carrier
Malta	CPD/RPB	CPD/RPB	Not applicable
Netherlands	1. Consignor and 2. Carrier. Obviously the Government provides the (legal) framework to the consignors and carriers, assigns EPR responsibilities and plans, prepares, tests the plans and responds to emergencies.	1. Consignor and 2. Carrier. Obviously the Government provides the (legal) framework to the consignors and carriers, assigns EPR responsibilities and plans, prepares, tests the plans and responds to emergencies.	1. Consignor and 2. Carrier. Obviously the Government provides the (legal) framework to the consignors and carriers, assigns EPR responsibilities and plans, prepares, tests the plans and responds to emergencies.
Poland	Carrier	Carrier	Carrier
Romania	Emergency response organization with support of Radiation protection team	Emergency response organization	Unified Emergencies response organizations according to Harmonized Emergency Response plan during the transport of RM
Slovenia	first responders, CORS, SNSA officer on duty, mobile units	first responders, CORS, SNSA officer on duty, mobile units	first responders, CORS, SNSA officer on duty, mobile units
Spain	Dirección General de Protección Civil - Ministerio del Interior	Dirección General de Aviación Civil - Ministerio de Fomento	Dirección General de Protección Civil - Ministerio del Interior
Sweden	First responders local rescue services/SSM TiB/ Police	First responders local rescue services/SSM TiB/ Police	First responders local rescue services/SSM TiB/ Police

State	Consignments by road originating in your state	Consignments by air originating in your state	Shipments transiting your state by road
United Kingdom	Driver, Carrier and Consignor as defined in CDG Schedule 2 para 5. See ONR guides: http://www.onr.org.uk/transport/responsibilities-in-an-emergency.pdf and http://www.onr.org.uk/transport/transport-guidance-overseas-consigners.pdf	Once airside: The Aerodrome Operator – see GM/AMC to COMMISSION REGULATION (EU) No 139/2014, GM1 ADR.OPS.B.010(a)(1) Rescue and firefighting services AVAILABILITY AND SCOPE OF RESCUE AND FIREFIGHTING SERVICES The Air Operator: AMC1 SPA.DG.105(b) Approval to transport dangerous goods PROVISION OF INFORMATION IN THE EVENT OF AN IN-FLIGHT EMERGENCY If an in-flight emergency occurs the pilot-in-command/commander should, as soon as the situation permits, inform the appropriate ATS unit of any dangerous goods carried as cargo on board the aircraft, as specified in the Technical Instructions.	Driver, Carrier and Consignor as defined in CDG Schedule 2 para 5. See ONR guides: http://www.onr.org.uk/transport/responsibilities-in-an-emergency.pdf and http://www.onr.org.uk/transport/transport-guidance-overseas-consigners.pdf

A number of paragraphs in the ADR are of particular importance, namely:

- ADR 1.4.1.2 provides that participants should inform the emergency services and provide them with information that they require in order to respond to any risk to public safety.
- ADR 1.7.1 NOTE 1 provides guidance on the use of IAEA standards in the response to an emergency.
- ADR 1.7.6 provides for notification of Competent Authorities and consignors in the event of an emergency exposure situation, and provides for carriers, consignors and consignees to mitigate the consequence of non-compliances.
- ADR 1.8.3.3 provides requirements for a “safety advisor” to monitor the implementation of emergency procedures in the event of an accident or incident.

The lack of harmony in the area of EPR is significant across the Community and does not appear to fully implement requirements.

FIRST RESPONDER TRAINING

Almost all MS reported that the responsibility for first responder training lay with a state organisation, however almost 50% of MS were unable to identify how many first responders were trained in 2016. Overall, numbers varied, with a peak value of two hundred trainees (**Figure 76**).

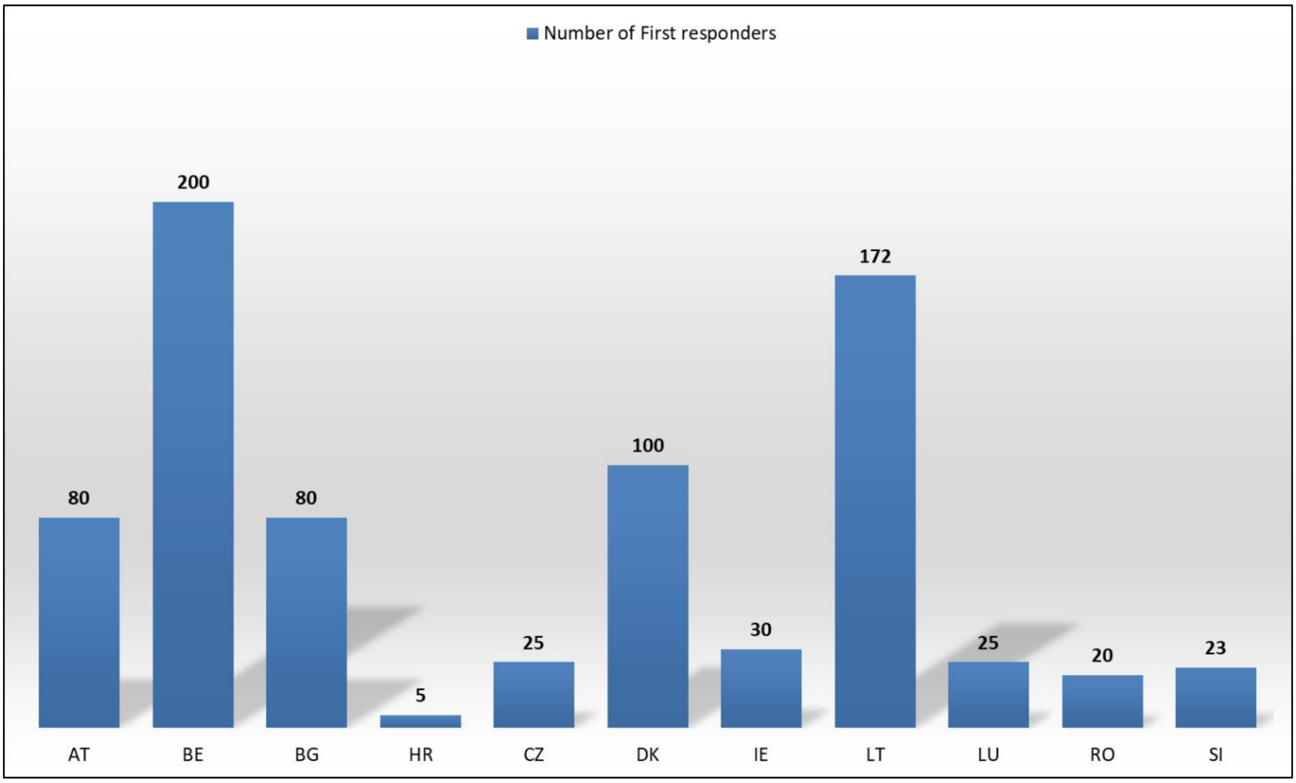


Figure 76: First responders trained in 2016

ENFORCEMENT ACTIONS AND INVESTIGATION OF INCIDENTS

REGULATION AND REGISTRATION

Three-quarters of the respondent MS identify the existence of national requirements for reporting non-compliances to an enforcement body (**Figure 77**). Some MS identified enforcement powers instead of investigation powers, but essentially there is reasonable coherence throughout the community.

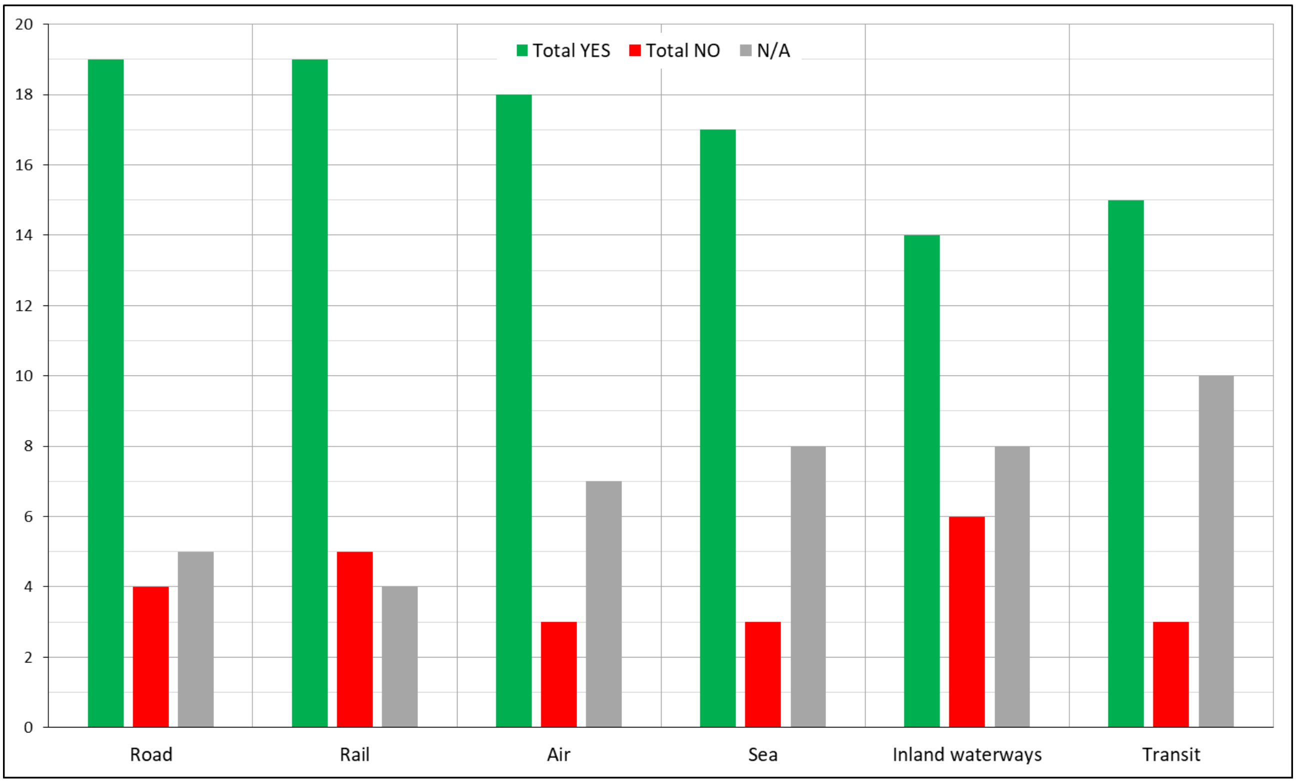


Figure 77: Requirement to report non-compliance to an enforcement authority?

TRANSBOUNDARY POWERS

Many MS identified the concept of working together with other regulatory bodies, but failed to identify the related powers in ADR. Generally, the concepts were understood. However, practical application was not in place.

ENFORCEMENT ACTIONS

There is a wide range of enforcement actions across the Community, and the rate has been relatively consistent year-on-year (**Figure 78**). Typically there are around 80 enforcement actions completed each year in the community, with over 80% originating in four MS, and one MS being responsible for 50% of enforcement actions in the community over the past five years (**Figure 79**, **Figure 80**).

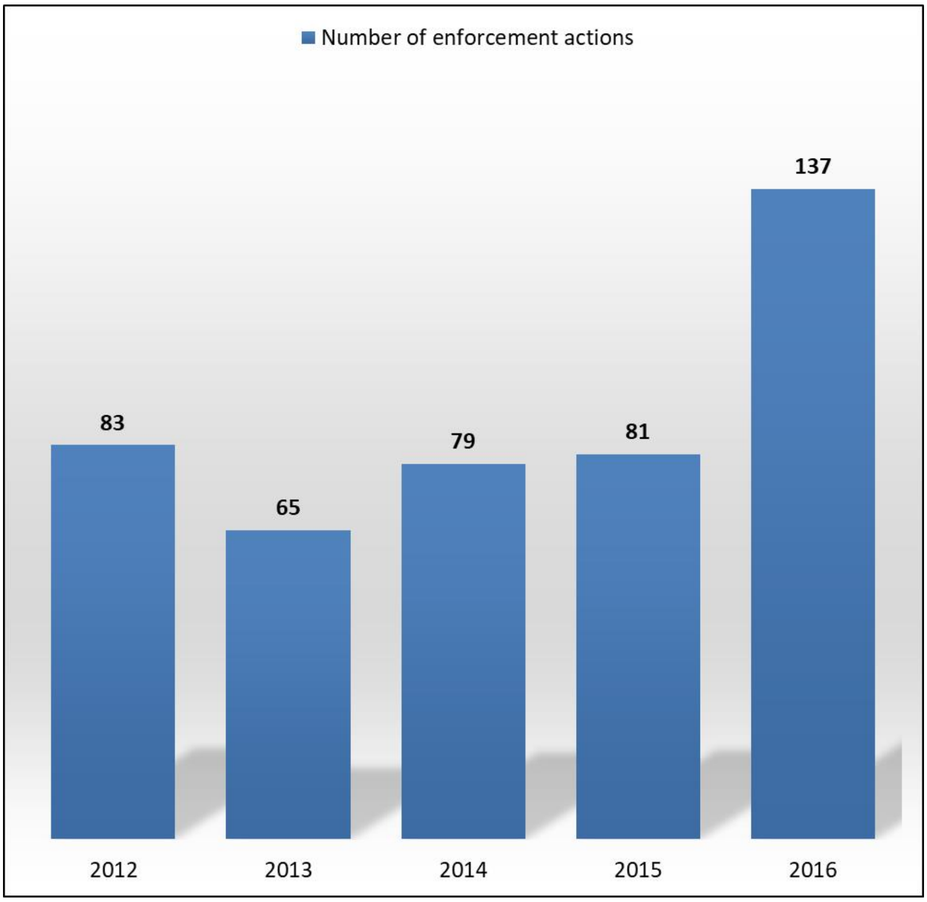


Figure 78: Enforcement actions reported 2012-2016 (EU)

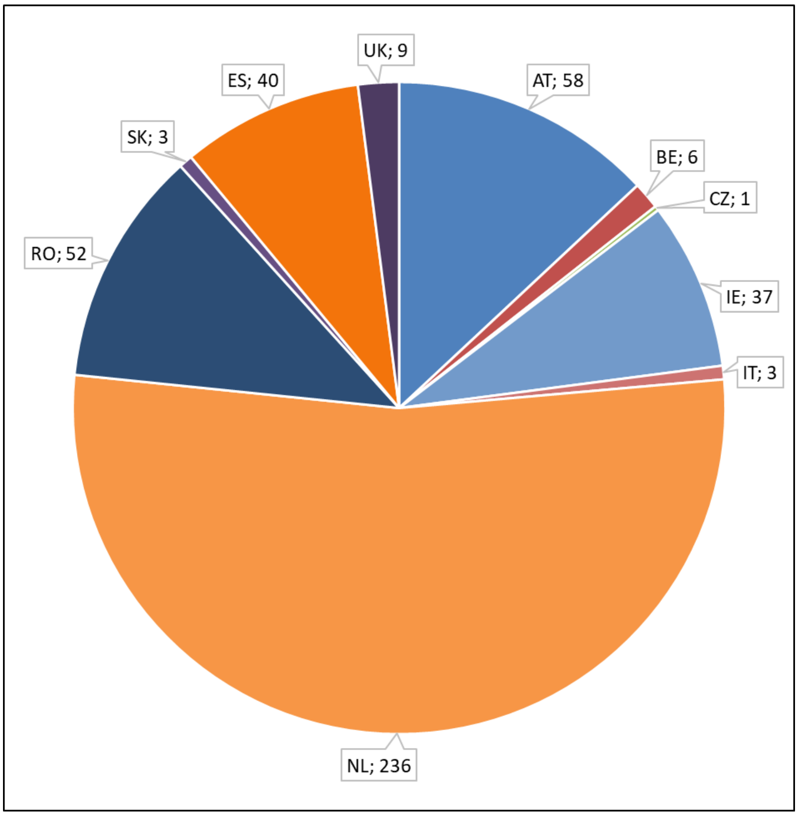


Figure 79: Enforcement actions reported by MS 2012-2016

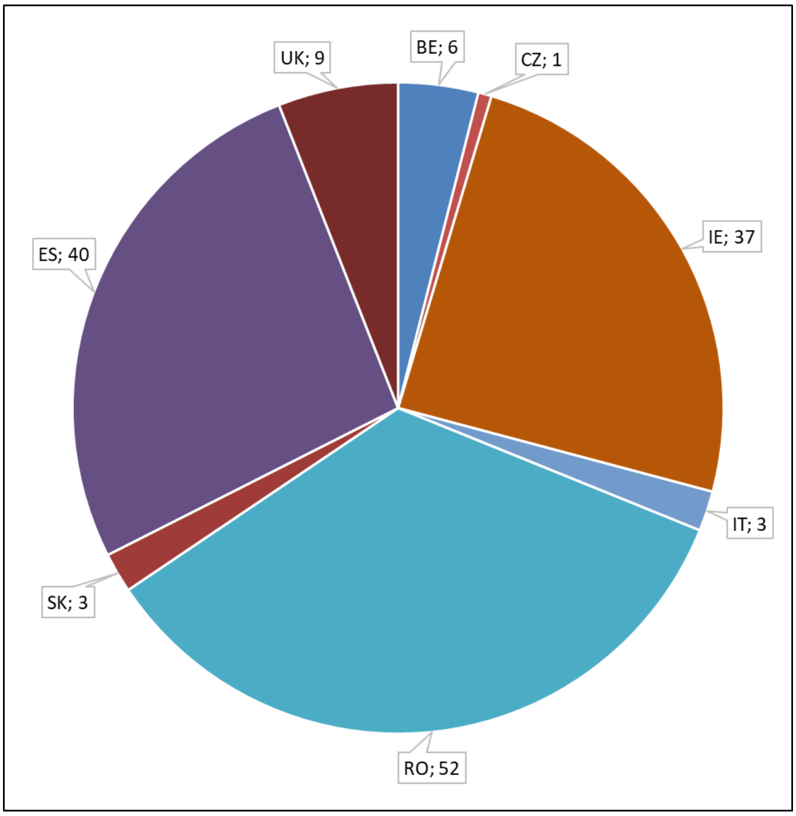


Figure 80: Enforcement actions reported by MS 2012-2016 (minus AT and NL)

INVESTIGATIONS

The number of investigations reported in the Community was around 100 each year (**Figure 81**, **Figure 82**, **Figure 83**). A comparison of the number of enforcement actions and investigations for each MS shows that certain MS have equal numbers, implying that an investigation always results in enforcement, while other MS indicated more enforcement than investigation.

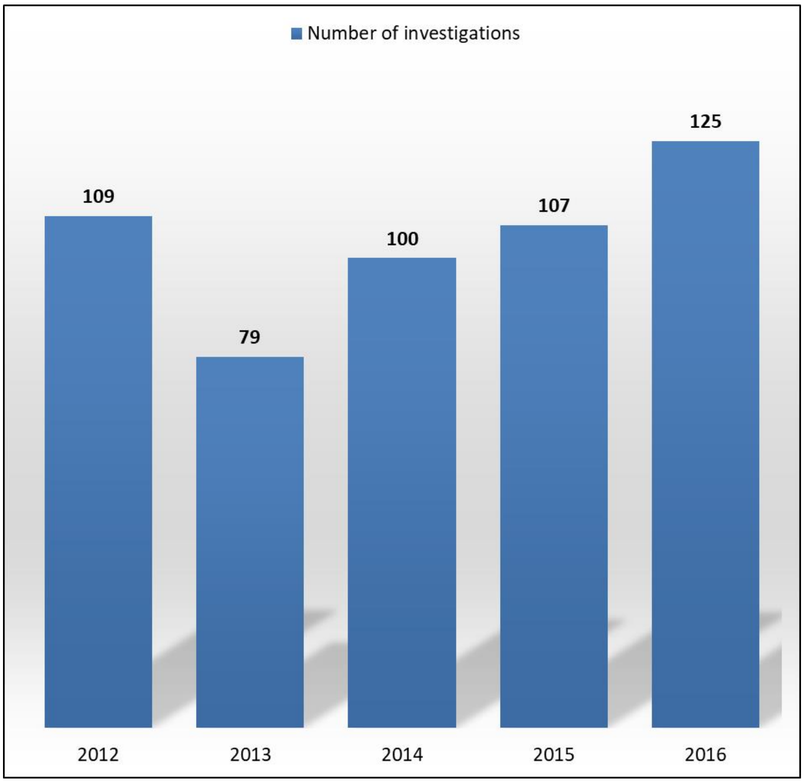


Figure 81: Investigations of non-compliance completed 2012-2016 (EU)

Generally speaking, the terminology may not be universally agreed. However, the data point to effective enforcement in the Community.

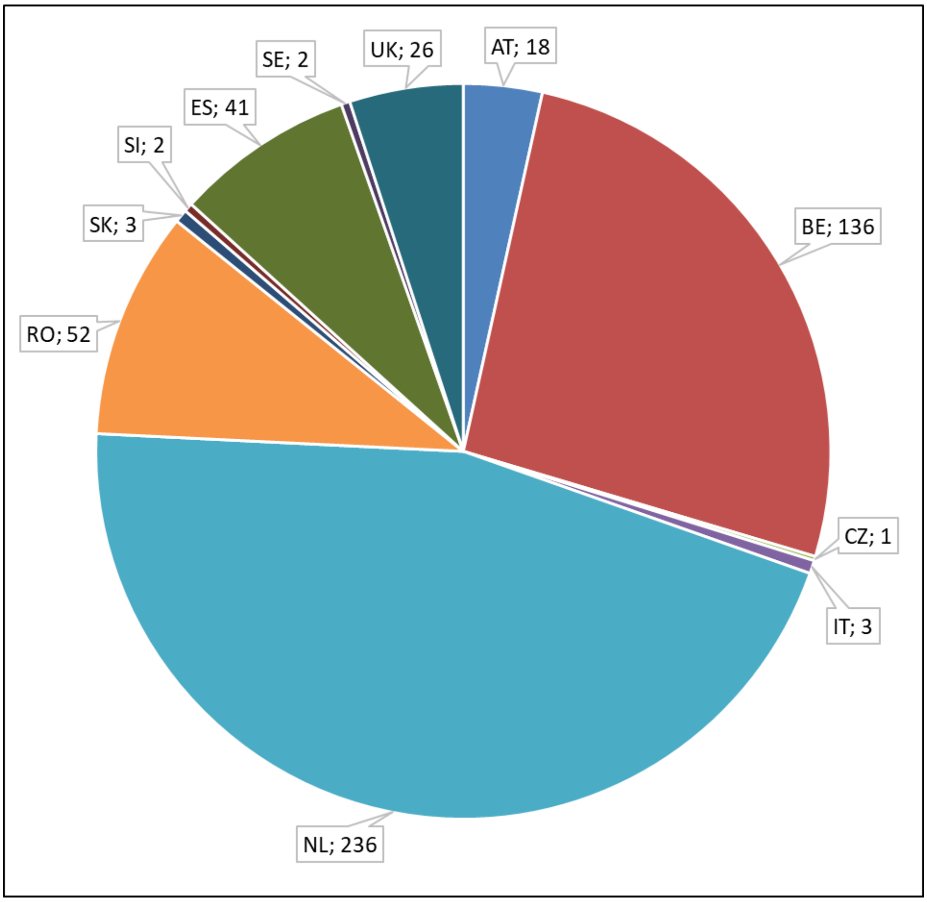


Figure 82: Investigations of non-compliance completed by MS 2012-2016

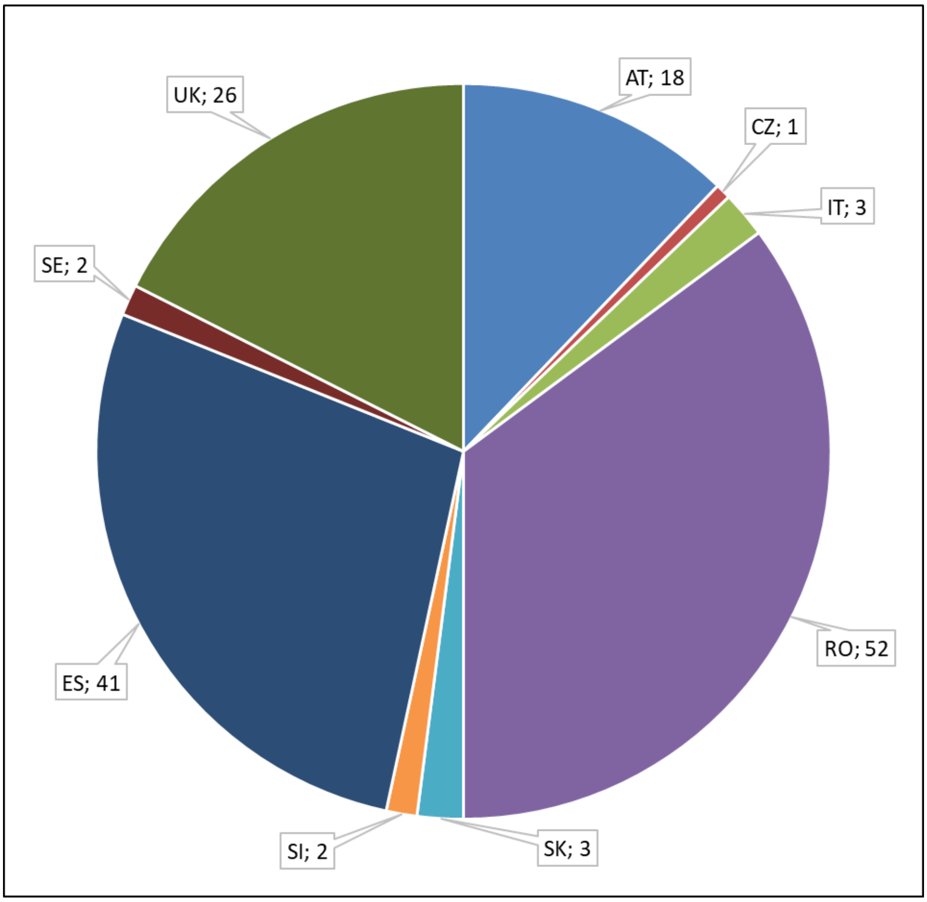


Figure 83: Investigations of non-compliance completed by MS 2012-2016 (Minus BE and NL)

PENALTIES

A wide range of penalties were applied across the Community during the interval of analysis (**Figure 84**). The main penalties were improvement notices and financial penalties. Although several answers identified withdrawal of approval as a concept that is considered appropriate, this has not been applied in practice.

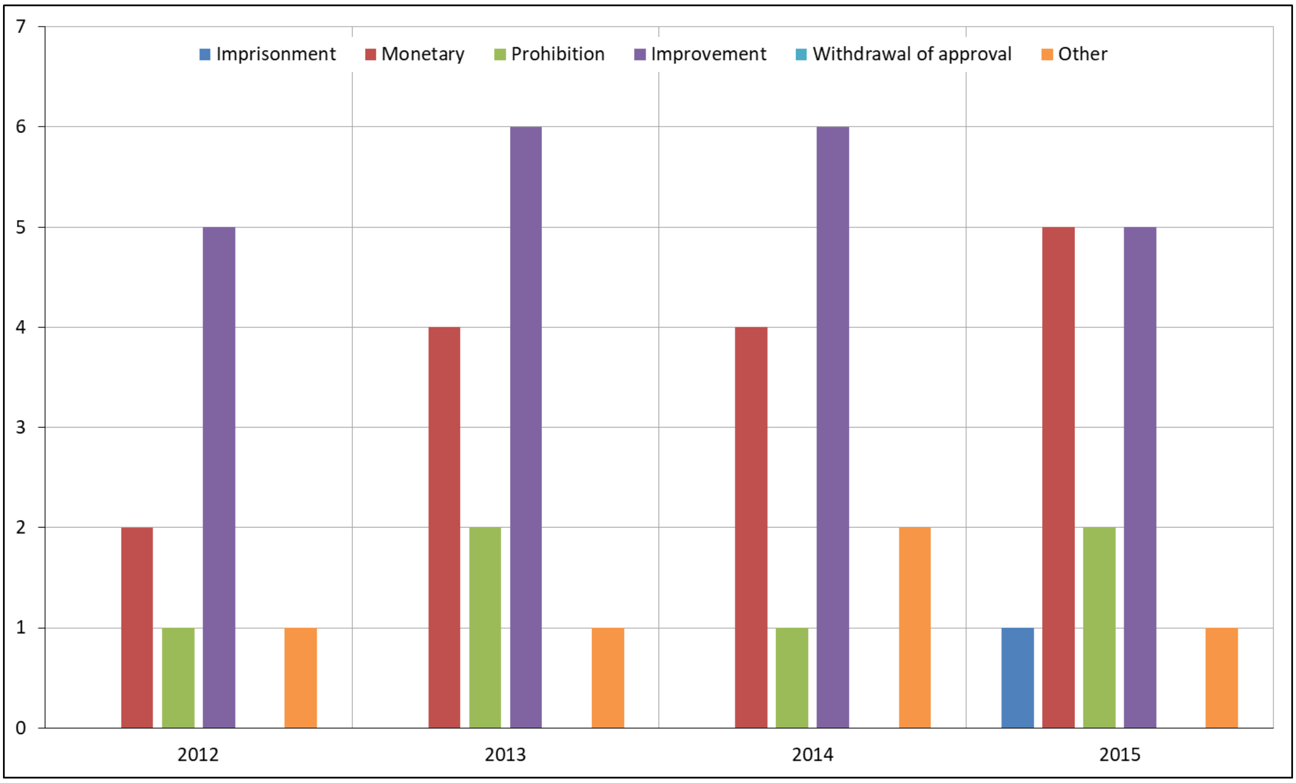


Figure 84: What penalties were applied as a result of enforcement

TRAINING AND DISTRIBUTION OF INFORMATION

NATIONAL TRAINING REGIMES

Around 70% of MS had a national training regime for carriers, while close to half (45%) have such a regime for consignors (**Figure 85**). Several MS indicated no knowledge of regulatory requirements in place for consignor training, although this is required by ADR.

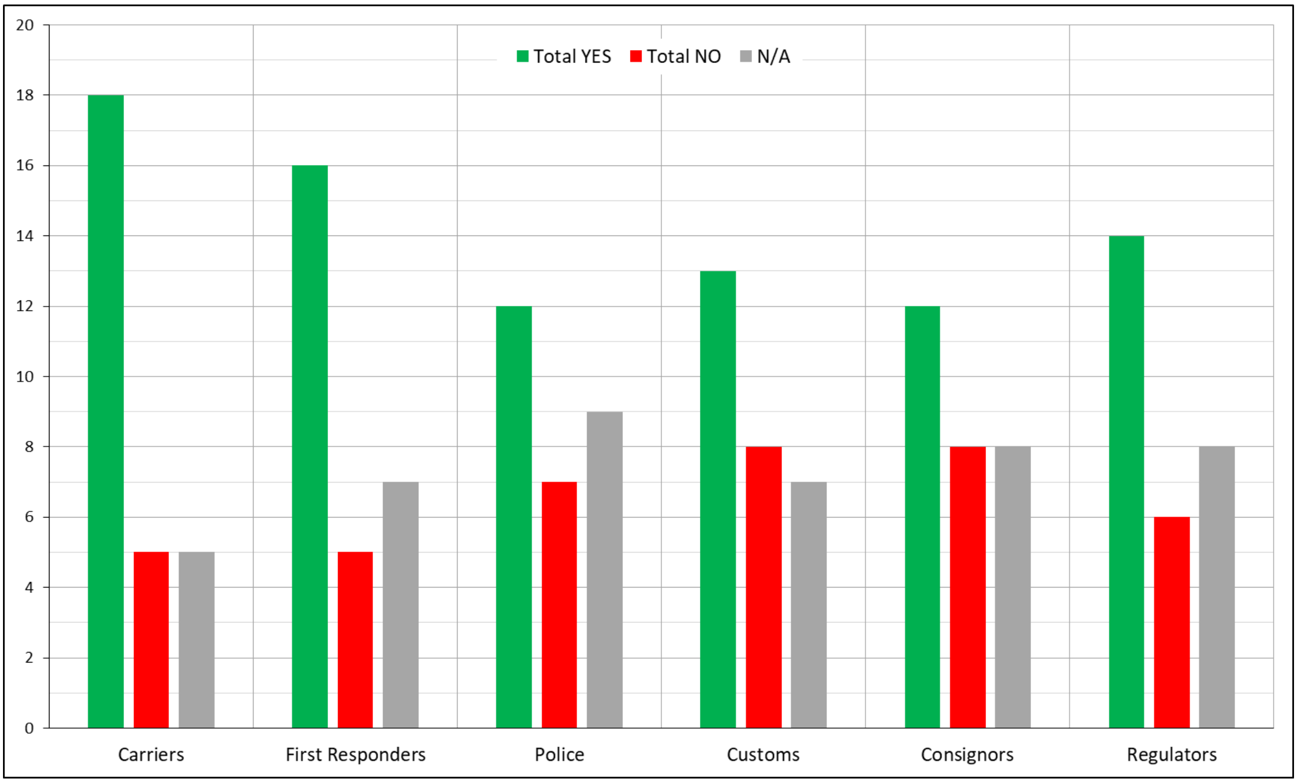


Figure 85: Is there a national training regime established related to TRAM?

Few MS have regulatory requirements relating to the training of police, customs or regulators (**Figure 86**).

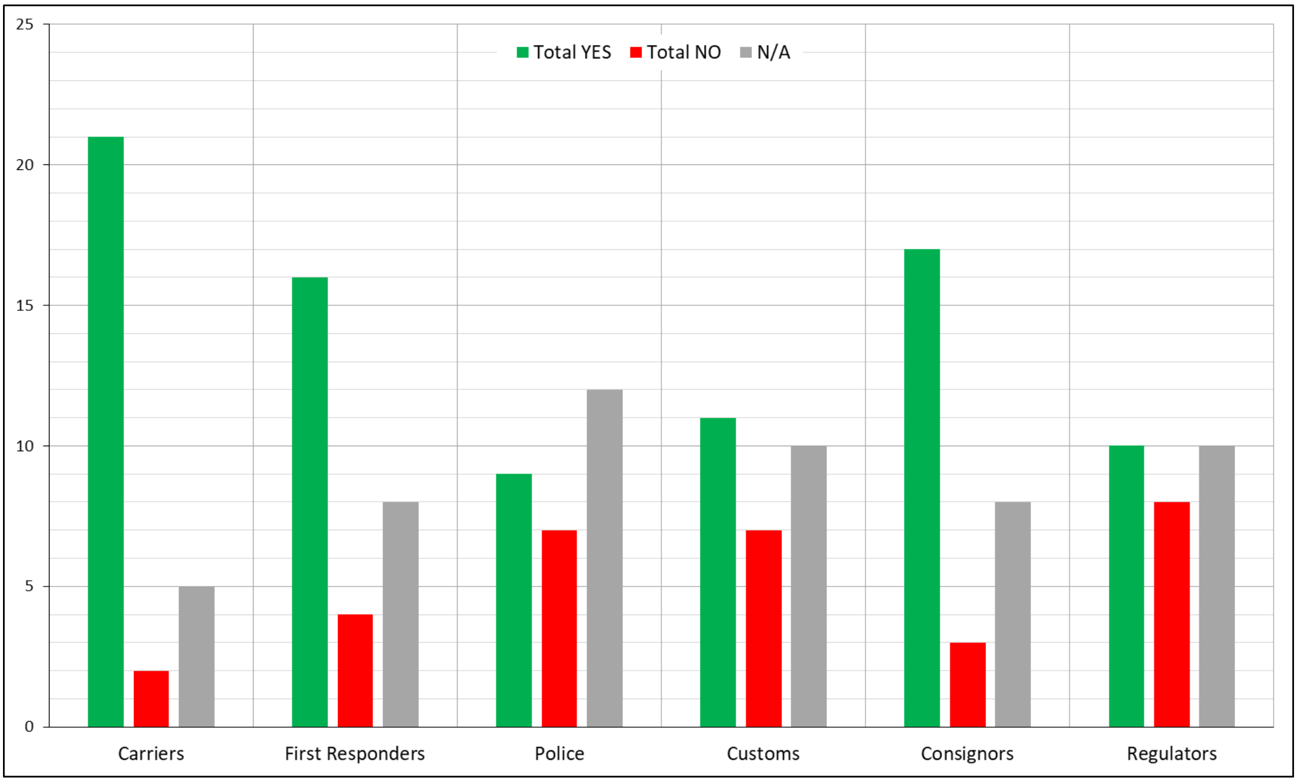


Figure 86: Are there any regulatory requirements for training?

NUMBER OF TRAINED PERSONNEL

A significant number of personnel were trained across the Community (**Figure 87**, **Figure 88**). However, the focus is different in various MS. For example, one MS is responsible for 90% of the carrier and consignor training, and another two MS are responsible for over 80% of regulator training; a fourth MS is responsible for around 50% of the police, customs and first responder training.

Overall, 45% of MS failed to report any training taking place. Two-thirds did not identify (by either failing to answer or zero answer) regulator training over the past five years, although it is true that regulatory capacity was identified as an issue in follow up meetings.

I-10 Develop an EU capacity building model based on the UK national system.

In particular, training on practical aspects of the transport infrastructure for Competent Authorities that are more familiar with facility regulation, was identified as a possible benefit.

I-11 The EU should encourage training, and potentially the IAEA on-line training platform. Consideration of the need for harmonised tests is appropriate.

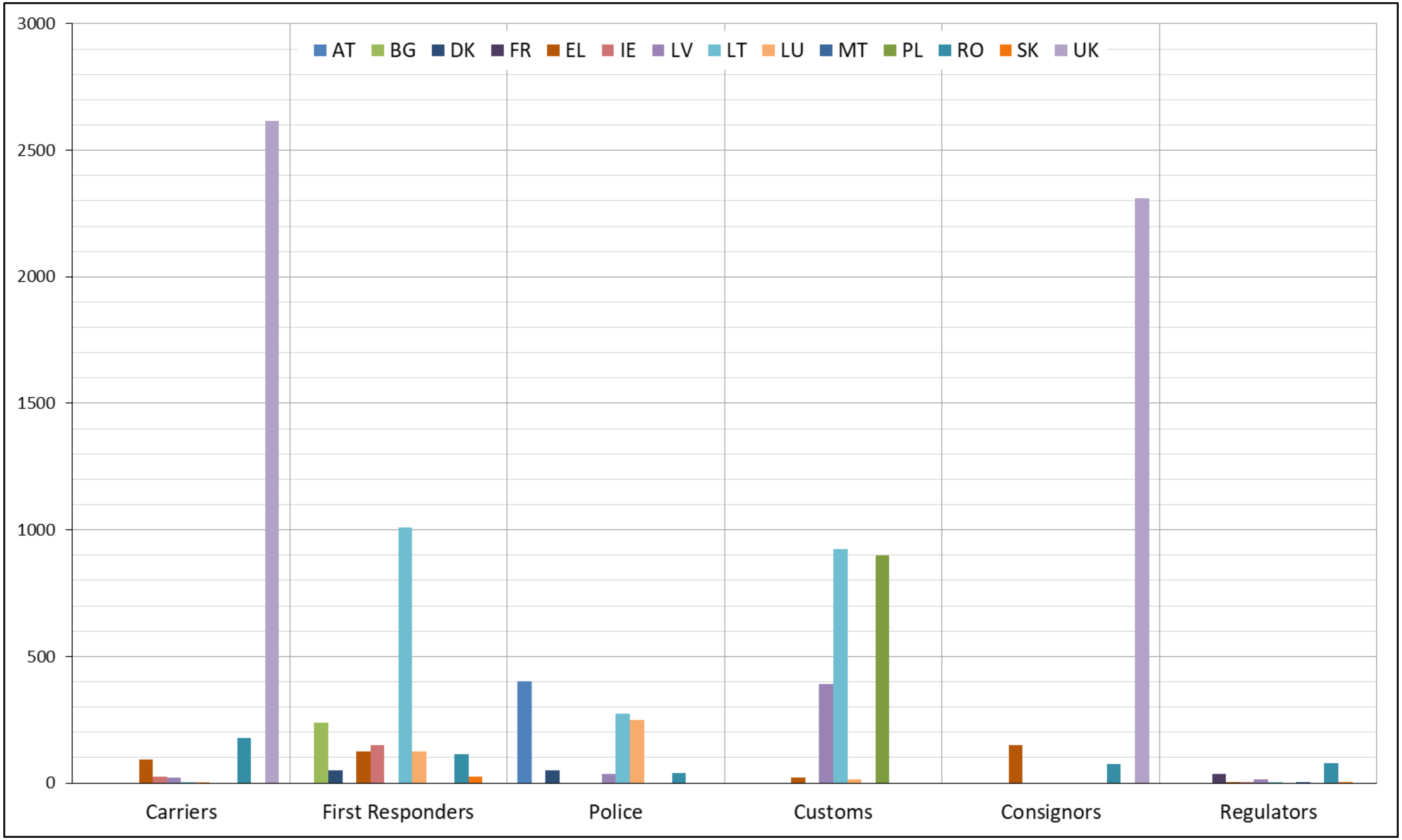


Figure 87: Number of people trained 2012-2016 (all reporting MS)

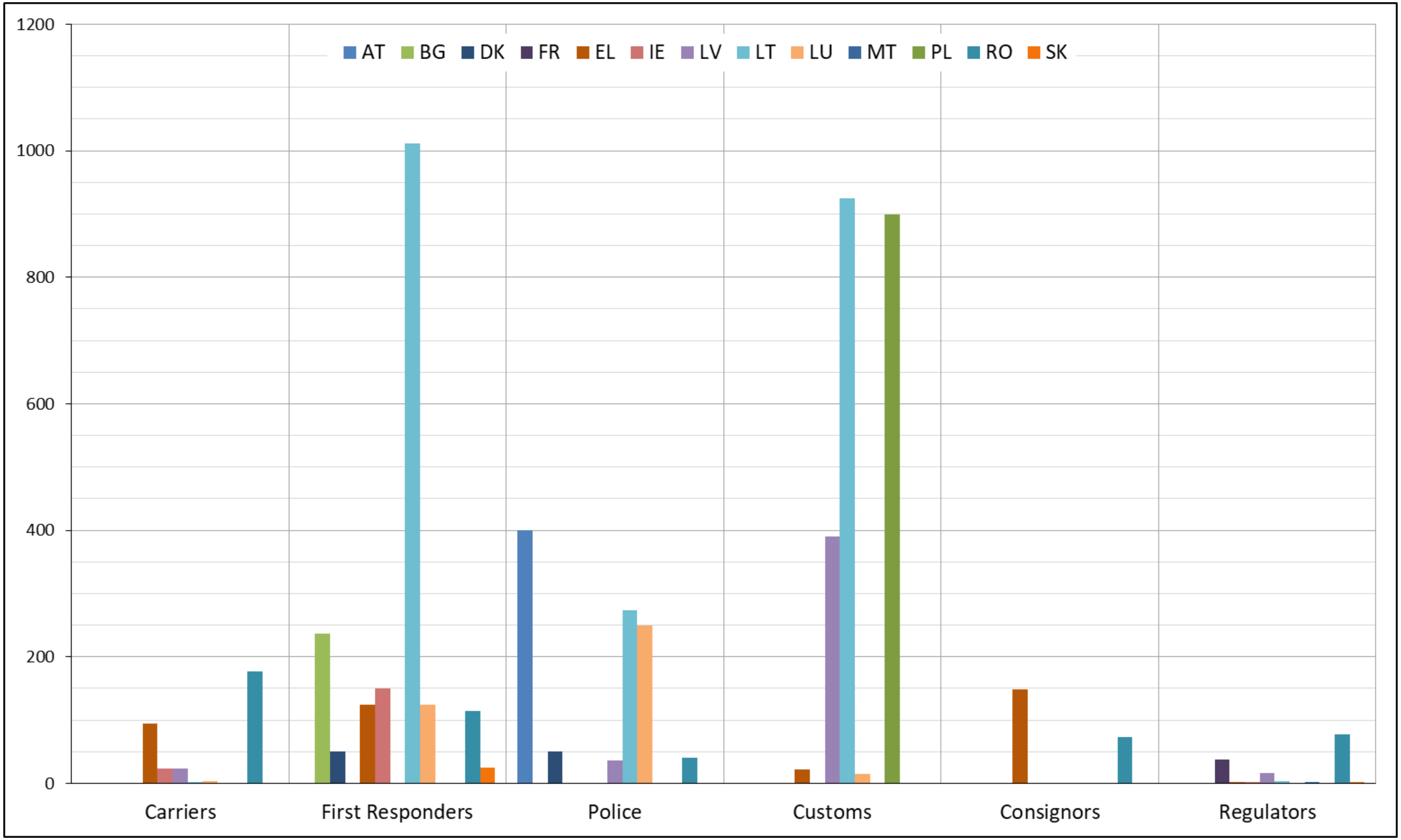


Figure 88: Number of people trained 2012-2016 (minus UK)

RECOGNITION OF TRAINING IN OTHER STATES

The majority of MS recognises training carried out in other States (**Figure 89**). This should be a standard requirement.

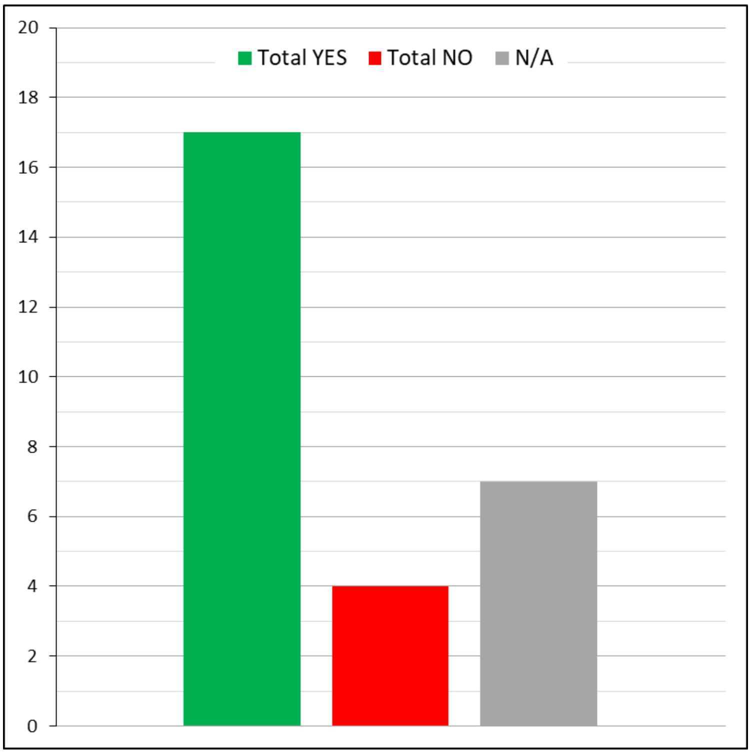


Figure 89: Is training that was carried out in other states recognised?

FOLLOW UP

In order to assist MS in sourcing training, a follow-up question was asked on the identification of training providers that could be used by other members of the Community. Some of the responses may be less helpful than others, but all are included in **Table 40**, which comprises suggested Community-wide training providers.

Table 40: Training providers in MS

Belgium
SCK-CEN
Vinçotte Controlatom
FANC
Different Belgian high schools and universities
Czech Republic
Sdružení ČESMAD BOHEMIA Nad Sokolovnou 117/1, 147 00 Praha 4 - Podolí, Czech Republic
DEKRA CZ a.s., Türkova 1001, 149 00 Praha, Czech Republic
Ing. Jiří Miletín M Konzult, Nad Statkem 177, 149 00 Praha 4, Czech Republic
Centrum dopravního výzkumu, v. v. i., Líšeňská 33a, 636 00 Brno, Czech Republic
State Office for Nuclear Safety, Senovážné náměstí 9, Praha 1, 110 00, Czech Republic

Estonia
Environmental Board organise trainings.
France
INSTN Centre CEA de Saclay F-91191 Gif-sur-Yvette
FORM-EDIT 5 rue Janssen – BP 25 F-75921 Paris Cedex 19
Le comité interprofessionnel pour le développement de la formation dans les transports de marchandises dangereuses (CIFMD) 14 rue de la republique F-92909 Paris la défense
Greece
EEAE, in RAM transport practices, radiation protection and safety, EPR
Ireland
A list of training providers in radiation protection and transport (Class 7) is on the EPA website. Their permission would have to be sought to provide community wide training. https://www.epa.ie/radiation/lic/needtoknow/training/
A list of approved General ADR Driver Training Courses is provided at http://www.hsa.ie/eng/Your_Industry/ADR_-_Carriage_of_Dangerous_Goods_by_Road/ADR_Files/ADR_driver_training_information.pdf
Latvia
Latvian University (training in radiation safety issues)
Road Traffic Safety Directorate (Issues driver license for workers transporting radioactive material. Training about transporting dangerous cargos, in that count radioactive materials).
Lithuania
Civil protection training center at Firefighters Training School (Emergency preparedness training (including regulators))
JSC Kita kompetencija (radiation protection training for workers)
Training Center Energetikai (radiation protection training for workers)
JSC Tuvlita (radiation protection training for workers)
Training Center Linava (ADR training for drivers (7 class cargo))
Netherlands
-Nuclear Research and consultancy Group NRG -Technische Universiteit Delft TUD -Boerhaave Nascholing/LUMC BN/LUMC -Rijksuniversiteit Groningen RUG -Radboudumc RUMC -TU Eindhoven TU
Other organisations offering courses on the transport of dangerous goods as required in the applicable transport regulations; ADN, ADR, ICAO-TI / IATA, IMDG, RID
Romania
The transport training course for drivers who transport radioactive materials, authorized by CNCAN
The transport training course for safety advisors with have responsibilities in the transport of radioactive materials, also authorized by CNCAN
The examination of the safety advisers in order to obtain the permit for exercise of the nuclear activities in radioactive material transport field.

Spain
Centro de Investigaciones Energéticas Mediomabientales y Tecnológicas (CIEMAT): www.ciemat.es
Sweden
MSB
Private training companies
United Kingdom
Regulatory training is delivered in-house through the ONR Academy

CAPACITY BUILDING FRAMEWORK

The concept of a simple competence framework that could be developed and utilised as part of a capacity building programme was proposed. While the competence framework identifies areas where training should be considered, the capacity building programme needs to identify resource requirements and the methodology for ensuring these requirements can be met over the long term. A simplified competence framework is set out in **Table 41** for a number of groups.

Table 41: Example of a simple competence framework

	Consignor	Carrier	Regulator	First Responders	Police	Customs
Uses of radioactive material						
Understanding radiation						
Understanding radiation protection						
Modal regulation of transport						
Freight transport regulation (all modes)						
Dangerous goods transport regulation						
Radioactive Material Transport Regulation						
Radiation protection regulation						
Consignor duties						
Carrier duties						
Compliance assurance programmes						
Physical protection of radioactive material						
EPR						

The UK regulator (ONR) identified a UK-wide capacity building process, a collaborative approach between government (including the regulatory body) and industry. This involved the establishment of the Nuclear Skills Strategy Group (NSSG) with support from industry.

The NSSG initiated research into the future needs for nuclear specialists nationally and the results are available in the report **Nuclear Workforce Assessment 2015**

http://www.cogentskills.com/media/59769/nuclear-workforce-assessment-2015_r1.pdf

This research indicated that in the next five years, an average of 8,200 new recruits would be required in the field.

Following this assessment, the NSSG in partnership with the UK Government, regulators, and trade unions have developed the Nuclear Skills Strategic Plan, (http://www.cogentskills.com/media/76258/national-nuclear-skills-strategic-plan.pdf), which covers national development of skills from schools through to experts. A number of new postgraduate nuclear courses have been set up with an increasing number of students taking up places. The strategy covers specialists suitable for work in industry and the regulatory bodies.

The key steps to be considered would be:

- Establishing Community needs.
- Establishing guiding groups, partnerships and sponsorships.
- Establishing industry and regulator supported training and development activities.
- Establishing and promulgating the basis of the safe transport of radioactive material.
- Development of transport expertise within the radiation protection specialty including:
    - Radiation protection (and nuclear) regulators;
    - Radioactive material industry (including spent nuclear fuel and radioactive waste).
- Development of knowledge on radioactive material transport within the transport industry.

In order to achieve this, it will be necessary to identify a responsible entity.

I-12 It is proposed that a Union body is established incorporating non-regulatory governmental representatives that are responsible for facilitation of the transport of radioactive material.

There is a possibility of partnerships outside of the Union, such as the modal agencies, modal industry bodies and the IAEA (for example by supporting enhancement of their technical basis document which describes how transport safety is assured).

Based on the results of this study the following areas should be given specific consideration:

- Regulators
- Transport nodes (Airports, Sea ports, border crossings)

PROVISION OF GUIDANCE

As part of the follow-up study, a collection of the suggested guidance topics that could be developed to facilitate community compliant transport is set out in **Table 42**.

Table 42: Guidance topics suggested by MS

Belgium
Management System
Radiation Protection Programme
Emergency procedures

Bulgaria
Guide "Implementation of requirements for the safe transport of radioactive materials"
Croatia
How to apply various international standards to specific situations
Finland
Questions to be answered in management system for different types of transport taking into consideration graded approach. The IAEA guidance is a bit strict.
Ireland
A summary Note that outlines what is required and how to go about applying for and complete import / export requirements / IAEA Regulator to Regulator Consent (as appropriate), EC 1493 Shipping Declarations, Port Authority approval, Consignors Note / Transport Documents, Shipment Approval Certificates, and documents such as package certification, certificate of special form sealed sources, wipe test certs for sealed sources, etc.
Italy
Guidance for labelling and marking of dangerous goods (Class 7) on package, overpack, freight container and conveyance
Guidance for certificate of compliance for non-competent authority approval packages
Latvia
Guidelines for the content of radiation safety quality assurance programme were developed by RSC SES in 2017 and published on SES website. General requirements for applicant`s management system, radiation protection officer and radiation workers, protection of workers and public are covered by these guidelines and are applicable to transport operators as well.
Netherlands
Currently the IAEA ST-G-1.2 (EPR Transport RAM) is the main guidance. This is being revised. Possibly it may be helpful to provide further practical guidance on how to implement the revised ST-G1.2 and possibly specific for the Netherlands (to make sure the EPR interfaces properly with the Dutch arrangements). "How to prepare and respond to an transport emergency involving radioactive material - by road, sea, rail, air." Main audience would be stakeholders involved, in particular consignors and carriers.
Romania
Procedure on analysis and evaluation of the approval application of radioactive sealed sources declaration between MS according to EEC Regulation no. 1493/93
The norm on elaboration of the safety report for package design for transportation of radioactive materials approved by CNCAN President Order no. 223/2017
The norm on elaboration and implementation of the radiation protection programme for transport activity of radioactive materials approved by CNCAN President Order no. 222/2017
Slovenia
We propose to develop a guidance in a form of a checklists
There should be list of simple formulated requirements with references to the SSR-6 or specific modal regulations
List of requirements should be specific for consignors, consignees, carriers and others if necessary
A kind of guiding for the carriers could be also the Annex (1) of the »Rules on uniform procedures for checks on the transport of dangerous goods by road« that include the uniform minutes and standard reviewing themes to be ticked off (by the CA, inspection control) – being an orientation of the most important themes and issues to be reviewed and complied with.
Spain
A Guidance similar to the IAEA Safety Guide SSG-33, but focused in European regulations: ADR. A similar guide has been published by the CSN (Safety Guide 6.5), just focused in ADR. It may be found (in Spanish) in www.csn.es

Sweden
MSB Transport handbook for dangerous goods
United Kingdom
IAEA guidance on emergency response. ONR have developed our own guidance in this respect. http://www.onr.org.uk/transport/guidance.htm ONR would appreciate that ONR guidance is taken into account if any new guidance is produced, so as to avoid any conflicting guidance.
A guidance document that aggregates all emergency response and security guidance produced by different member states into a single document. This would allow consignors and carriers to readily see the requirements of the different member states that they intend to transport through / to.
Resurrection of the PACKTRAM Database on National Competent Authorities' Approval Certificates for Package Design, Special Form Material and Shipment of Radioactive Material

A number of conclusions can be drawn from this list:

- Guidance should be specific to the types of transport packages;
- Guidance should be specific to the target audience;
- Guidance should take into account the graded approach;
- Summaries of the situation in each MS helps understanding.

It is proposed that initial guidance identifies MS responsibilities for carriers and consignors, covering safety and security.

INTERDEPARTMENTAL LIAISON AND COOPERATION

REGULATORS RELEVANT TO TRANSPORT

MS identified situations with a varying amount of complexity regarding the regulatory structure. However, many MS use informal contacts rather than formalised meetings for coordination between regulatory bodies. The guidance provided suggests a list of potentially interested officials, such as:

- Agencies with responsibilities for transport;
- Agencies with responsibilities for dangerous goods;
- Agencies with responsibilities for health and safety;
- Agencies with responsibilities for radiation protection;
- Legal authorities;
- Police;
- Customs officials;
- Post offices;
- National research institutes and institutes for materials testing;
- Institutions that provide training and education.

I-1 also applies in this case.

For example, the TranSAS reports of UK and FR both identify more than 5 regulatory bodies with direct relevance to the transport of radioactive material. A wide range of additional bodies are identified as having a special interest in the responses for this report for both of these MS. A list compiled by both MS alone would be more comprehensive than that available in the current guidance. There is a suggestion that EACA might be working on such a list.

REGULATORS IN OTHER STATES

Regulators identified good relationships with regulatory bodies in other states. There is clear evidence of this through the existence and activity of two networks of regulators in the region, and this good cooperation was demonstrated during the follow up meetings.

JOINT ACTIVITIES

A number of initiatives were identified for this topic, including:

- Joint inspections;
- Exchange of assessment information;
- Meetings for information exchange;
- Good practice sharing;
- Regulatory review;
- Examination of safety advisors and drivers;
- Joint training;
- Peer review.

A6 CASE STUDIES

A6.1 URGENT MEDICAL SHIPMENT

1) SCENARIO

A shipment of a radiopharmaceutical in a Type A or excepted package from a distribution facility in the UK to a hospital in IT.

Packages transported by air will leave the manufacturer and be delivered in most cases the next morning at the end users' premises for use by the consignee.

A) WHO

Describe the organisation or person responsible for carrying out the activity, including any alternative scenarios. Include any links to others responsible for other processes.

B) WHAT

Describe the activities that will be carried out under the what section.

C) WHEN

Describe when the activity will be carried out in relation to the shipment. Include any repeat actions (such as reviews of design approvals).

D) WHERE

Describe where the activity occurs.

E) COST

i) Industry

Describe the cost to industry excluding any work required for demonstration of compliance with regulation. You can use generic terms such as "store documents for 10 years" rather than monetary terms.

ii) Regulatory

Describe the costs associated with regulatory compliance, including any repeat costs.

Separate the costs by activity, so if a package design is checked during a roadside check this would relate to carrying. If a package design is checked by a visit to the consignor this cost is associated with consigning.

2) INTRODUCTION

Thousands of radiopharmaceutical packages are transported daily worldwide. This demand is primarily driven by the requirements of the health care industry (the diagnosis or treatment of diseases). Most radiopharmaceuticals are short half-life gamma or hard beta emitters, i.e. iodine-123 (13.2 h half-life) and molybdenum-99 (66 h). The final product needs to be delivered on the correct day and at the correct time for the administration to the patient. Compared with over the counter pharmaceuticals, all radiopharmaceuticals are made by specific order for the end patient. The entire supply chain works just in time from the raw products from cyclotrons and reactors, through the production and final delivery and administration to the patient, fishing with the scan for diagnosis. The patient, in many cases, will be an out-patient only visiting the hospital on the day of the procedure. It is vitally important that the radiopharmaceutical product is delivered at correct date and time otherwise the patient cannot be treated with a loss of time and money for the hospital and the patient.

Stage	Who	What	When	Where	Cost
2) Package Development	Developer of the product. Sets out what the product is (nuclide, activity, chemical and physical state).	Specify the contents to be carried. Any design requirements due to the nature of the product. Example: • temperature sensitive • any other hazards.	The package design will start as the product is determined to be a viable product and as changes to product or packaging are made.	Research Chemical Laboratories	**Industry** Meeting costs for determining the packaging. The keeping of records and decisions for the type of packaging. **Regulatory** Not Applicable at this stage?
	Designer of the package.	Design the package: The package can be: • one use from the manufacturer to the end user; • one use but packaging re-used to return the shielded primary package back to the manufacturer for recycling; • multiple use packages. Most radiopharmaceuticals are short half-life gamma or hard Beta emitters. For the gamma emitters it is required that the product will need to be shielded to reduce the radiation surface dose and the radiation dose at 1 m. Beta emitters may need to be shielded to reduce bremsstrahlung. The maximum activity at despatch and the physical form of the material are used for determining the type of package (excepted or Type A). The maximum radiation dose for the package needs to be determined (may be an excepted quantity of radioactive material but the radiation surface dose moves the package into a Type A category). The determination of the primary packaging is dependent on the physical form and chemical composition of the contents. The type of shielding (plastics, lead, steel etc.) required to reduce the radiation dose is determined from the nuclide and the maximum activity. Depending on one use or multiple use, the type of secondary packaging to be used for the transport of the primary package needs to be determined. Need to determine whether there is a package combination already available that can be used without going through the package development process. Need to take into consideration any other regulatory requirements for the material or the packaging including: • environmental requirements; • pharmaceutical regulations; • any import or export requirements; • other hazard (packaging or the material).		Package designers office(s)	
	Outside consultants	If involved, for the package design.			
	Marketing	For any trademark design on the packaging.			
	Transport	Any requirements for the transport, example time constraints (very short lived nuclides), handling (weight) and loading.			

Stage	Who	What	When	Where	Cost
	Regulatory	Other hazards, customs control of the product (drug requirements) and drug licencing.			
3) Package Approval	Designer of the package.	Full manufacturing specifications **of all parts** that make up the package. This includes • inner containment system; • outer packaging; • sealing system (example: sealing tape for the package). A system to determine that specification changes are minor (no effect that may compromise the package) or major (re-testing of the package) is necessary.	Throughout the design process. System of design ensures: • verification that the manufacturer can produce the separate components to the specification; • any failure leads back through the process of redesign, manufacture and testing.	Package design office	**Industry** Meeting costs for determining the packaging. The keeping of records and decisions for the type of packaging. **Regulatory** Not Applicable at this stage
	Tester of the package.	All the documentation and supporting evidence that supports the testing of the package type.		Testing centre	Keeping the test records.
	Manufacturer of the components.	Documentation for the design specifications and ensuring system in place to be able to track updates.		Manufacturers of the components premises	Keeping manufacturing records.
	Quality Control (QC).	Testing (QC) requirements and sample sizes for the receipt of the finished components for the package.	Testing that the package meets the requirements of the regulations.		Keeping the QC test reports.
	Manufacturer of the final product.		Liaison with the manufacturer of the Final Product that the package design can be handled.	Manufacturer of the product.	Records of the decisions of the manufacturer.
4) Consignment	Manufacturer.	Manufacturer will perform: • preparation of the product with Receipt of order with delivery date and delivery point; • QC of the radioactive and pharmaceutical properties; • dispensing, packaging, labelling, dose and weight checks.	Stock products picked from stock on the day. Made to order or short lived product picked on the day.	Manufacturers Premises	Records of the manufacture of the product. QA Systems. Control of computer systems to ensure the systems are validated and changed only under strict change control. Control of individual's radiation dose. Controlled areas for packing, storage and despatch.
	Consignor	Consignor will perform: • booking of transport company/airline/tunnel/ferry; • production of all transport documents for the package; • checking of vehicles before despatch to ensure compliance to the regulations.	Packaged on the day of despatch. Handed to carrier on day of despatch.	Consigning area/warehouse	Systems to ensure that the packages meet the regulatory requirements. Records of the consigning of the product, with hand over signatures. Control of individual's radiation dose. Controlled areas for packing, storage and despatch.
	Carrier	Accept the consignment ensuring compliance with the applicable regulations.	At the handover of the consignment from the consignor to the carrier.	At the consignors premises	Control of individual's radiation dose.
	Forwarder who will book airline/ferry, etc.	Bookings for transport on the day of despatch with confirmation of consignment to airlines, ferry, tunnel and customs (when applicable). System to ensure management of delays and failures are in place.	As required to ensure the correct delivery times as required by the consignor.		Keeping of records.
	Ferry, airline or tunnel operator	Ensuring that the mode specific conveyance is loaded in compliance with any regulatory requirements.	At time of receipt.	Operators premises	Control of individual's radiation dose.

Stage	Who	What	When	Where	Cost
					Keeping of the records of hazardous goods.
	Consignee	Ensure the correct delivery point and date is transmitted to the consignor.			
	Dangerous Goods Safety Advisor (DGSA)	Informed of any accidents or occurrences. Inform Competent Authorities of reportable incidents.	If an incident occurs.	DGSA premises	Keeping of records for the annual report.
	Radiation Protection Advisor	Ensuring control of radiation doses to personnel	Ongoing	Manufacturers and consignors premises	Keeping of records. Instigating reviews if doses are exceeded.
	Competent Authorities	Informed if any accidents or occurrences. Inspections.	As required	Manufacturers and consignors premises	
5) Carrying	Road Carrier	Receipt of correct number of packages for direct delivery or delivery to a distribution hub. Sorting packages for onward delivery. Ensuring correct handling and loading to keep radiation doses as low as practicable.	When unloading, storing and reloading vehicles.	At carrier premises	Keeping of records. Redirecting consignments when delayed or redirected due to weather, strikes and technical issues. QA system. Controlled sorting/checking area and controlled storage area.
	Airline	Dangerous goods check (airlines). Putting into storage before the packages are taken out to the aircraft. Ensuring these are directed on the correct vehicle/aircraft. Ensuring that packages are loaded onto the vehicle or aircraft to minimise dose. Ensuring that documentation accompanies consignment to the end destination.	At the receipt of the packages at the airline/agent.	At airline or agent's warehouse	Keeping of records. Redirecting consignments when delayed or redirected due to weather, strikes and technical issues. Controlled sorting/checking area and controlled storage area.
	Ferry (vehicle only)	Receiving notification of the packages that are being carried by the vehicle.	Before receipt of vehicle at the docks.	Docks	Keeping of records.
	Tunnel (vehicle only)	Receiving notification of the packages that are being carried by the vehicle.	Before receipt of vehicle at the terminal.	Terminal	Keeping of records.
	DGSA	As per the consignment requirements.			
	Radiation Protection Advisor	As per the consignment requirements.			
	Competent Authorities	As per the consignment requirements.			
6) Cross Internal Border (Option1)	Consignor	When required producing the correct paperwork for any inspection.	Before shipment.	With Competent Authorities as required	Having a system in place to identify when licences or authorisations are required.
	Carrier	Having the correct licences or authorisations in place prior to shipment.	Before shipment.	On carriers vehicle	Ensuring correct licences or authorisations in place.
7) Cross External Border (Option 2A incoming – Option 2B outgoing)	Consignor	When required producing the correct paperwork for any inspection.	Before shipment.	With Competent Authorities as required	Having a system in place to identify when licences or authorisations are required.
	Carrier	Having the correct licences or authorisations in place prior to shipment.	Before shipment.	On carriers vehicle	Ensuring correct licences or authorisations in place.
8) Delivery	Consignor or agent	Consignor ensures with consignee correct delivery point and checks that it is correctly indicated on the delivery paperwork and package.	At order input		As consignor.
	Carrier	Delivery to the correct destination within the consignee's premises. Delivery secured by signature or other agreed system to the correct end delivery point.	At the time agreed by the consignee and the consignor or their agent. At the consignee's delivery point.	As per the paperwork and package address	Keeping records of the delivery. Systems in place to ensure packages are not lost.

Stage	Who	What	When	Where	Cost
	Consignee	Consignee to ensure the correct delivery address with consignor. Reporting back when expected deliveries are not received.	At point of making the requisition of the product. When package is believed missing.	Consignee's premises	Keeping paperwork for suspected loss of package.
9) Returns of used package for reuse or recycling	Consignor	Need to follow the return instruction provided by the owner of the package. May be returned as inactive, excepted or Type A package. Completing any paperwork that needs to be included with package.	Before consigning the package to the carrier.	Consignee's premises	Keeping records of the despatch.
	Carrier	As per Consignment.			
	Consignee	As per Consignment.			
	Owner of the package	Ensuring the return instructions are with each returnable package and reflect the requisite regulations. Ensure that those packages that must be returned are returned and tracked. Returned package must be checked to ensure that it meets the design specification prior to reuse.	Prior to packages being returned.		Keeping despatch and return data. Carrier costs for the return of the package.
	DGSA	As per Consignment.			Impact if a package is lost or damaged during transport.
	Radiation Protection Advisor	As per Consignment.			

This covers just one route. Many larger cities have a number of nuclear medicine departments and therefore a number of vehicles may need to be used for the deliveries in any one day. It is impossible to have all deliveries in one city at say 08.00h, therefore routing and control of the transports is very important. Many Patients may have to make long and expensive journeys as the Nuclear Medicine departments tend only to be in larger hospitals.

A cost for the manufacturer is the constant monitoring of delayed shipments. This is to ensure the end customer, the hospital/patient know when the product will be delivered. Delays can be caused by weather, malfunctions, strike, regulatory changes and even misunderstanding.

3) SHIPPING PROBLEMS

A number of issues were identified regarding the transport of urgent medical shipments. Nevertheless, the industry indicated that generally there was adequate access and capacity for air freight. The industry provided detailed reports of problems shipping in confidence, asking that no action should be taken in response to the reports.

One issue identified was that a number of European airlines refuse to carry radioactive materials, which results in more complex routes for delivery (KLM and BA were mentioned in particular).

Another issue related to the length of time required for the packages to be available at the airport prior to the flight. For some urgent products (such as I-123) this can be almost a full half-life at some airports. Adding this to the lack of availability of some airports because airlines refuse to carry radioactive materials, the result is a significant increase in the amount of material that needs to be consigned for the same number of patients.

The segregation limits and Transport Index (TI) limits for each aircraft can cause problems where multiple consignments are booked on the same flights. This report and others previously have identified that there is enough data to suggest the TI limits should be relaxed. This would assist medical product delivery.

The understanding of carriers and staff of the importance of the medical products and general information regarding their transport can be poor and lead to problems. This suggests that improved transparency would be a positive benefit. This study identified that few MS have a specific body responsible for the promotion of the industry (transport of radioactive material). Establishing national and Union bodies for this purpose might be a potential solution in this area.

The frequent changing of regulations, including some minor administrative changes (such as the need for a 2 mm line around the Class 7 diamond label) also represents a challenge. While the IAEA has adopted a cost benefit assessment as part of their regulatory development leading to infrequent updates and rejection of numerous “nice to have” changes, this has not been implemented by either UNECE in relation to the Orange Book or in relation to the modal bodies. The EU provides guidance on the acceptability of these changes. It may be beneficial for the EU to apply a cost benefit review to proposed changes to all requirements related to the transport of dangerous goods.

Other developments, such as security portals, can result in delays to shipments. Many requirements do not consider the very short time-lines associated with medical products. Brazil has dealt with this by providing a list of urgent medical isotopes that should be facilitated. This might be a potential solution that could be adopted in the EU.

4) CONCLUSIONS

The key items identified in the study include:

- The manufacture and transport are related to specific patient needs and the product must be delivered just in time;
- While the packages might appear to be simple boxes, in some cases the specification can be very detailed (e.g. specification of the type of sealing tape to be used);

- Transport is often booked on the day of shipment.

Overall, the impression from the case study is that lives depend on transport being able to be carried out with little or no advance planning. This type of shipment is the most common in the community, and the effect of shipping problems on human lives should be kept in mind when considering transport of radioactive material.

The industry identified that, at the present time, there was enough capacity for delivery of products, although delays could require shipment of more than double the isotopes due to decay en-route.

The limit to infrastructure suggests that neither safety nor security of transport can be fully optimized. Longer journeys increase vulnerability in terms of security, while additional activity and transport time increases exposure of workers and the public (although these are normally well within limits).

Specific examples of existing barriers were identified by the industry.

The response to the draft report suggested that there was a desire for the administrative burden associated with medical shipments to be reduced.

I-12 also applies in this case.

The methodology for the air segregation limits is provided as an example in IAEA guidance, along with the values assumed in the calculations. The data provided for this report (and values identified in recent studies) suggests that the values assumed were pessimistic by around an order of magnitude, particularly for the type of air shipments commonplace in Europe.

I-24 The air segregation limits were identified as being potentially over restrictive.

A6.2 NORM

1) SCENARIO

A small shipment of low quality tantalite is coming from Santos, Brazil, to Dresden, Germany. The material has an average activity of 5 Bq/g and is carried in 30 drums in an ISO container. It is carried on a ship calling at Santos, New York, Cherbourg and Hamburg. The ship carries an Antigua and Barbuda flag.

A) WHO

Describe the organisation or person responsible for carrying out the activity, including any alternative scenarios. Include any links to others responsible for other processes.

B) WHAT

Describe the activities that will be carried out under the what section.

C) WHEN

Describe when the activity will be carried out in relation to the shipment. Include any repeat actions (such as reviews of design approvals).

D) WHERE

Describe where the activity is occurring.

E) COST

i) Industry

Describe the cost to industry, excluding any work required for demonstration of compliance with regulations. You can use generic terms such as ‘store documents for 10 years’ rather than monetary terms.

ii) Regulatory

Describe the costs associated with regulatory compliance, including any repeat costs.

Separate the costs by activity, so if a package design is checked during a roadside check this would relate to carrying. If a package design is checked by a visit to the consignor this cost is associated with consigning.

2) INTRODUCTION

Tantalite is a mineral containing the valuable metal tantalum (Ta), and it is transported from mines to facilities that can extract the metal from the mineral. There is typically also naturally occurring thorium and uranium present in the mineral matrix that cannot be removed prior to transport, with total parent radioactivity concentrations ranging from 5 to 50 Bq/g, in some cases more than 100 Bq/g. It is typically shipped as a dry mineral (<0.5% moisture) with a grain size below 5 mm. As a dry product, handling it loose is dusty and presents a typical inhalation hazard due to the presence of e.g. silica, and the natural radionuclides thorium and uranium and their daughters.

The total world market involves the transport of the order of 10,000 tonnes of tantalite mineral annually, or approximately 500 ISO containers. Most of this requires transport as Class 7 radioactive material, although where the radioactivity concentration is below 10 Bq/g (such as this worked example), the material is exempt from transport regulations for radioactive materials, including IAEA SSR-6, IMDG Code Class 7, and ADR Class 7. Exempt material can be transported as general cargo.

The packaging used for this package of tantalite consists of 30 drums, stowed in an ISO container. The drums will typically be new steel drums with separate lids held in place by a steel band, which may be secured with a bolt or a clip, and optionally fitted with one or more security seals made of thin plastic, metal wire or similar.

The drums may alternatively be made of recycled metal drums, with separate or welded lids, or of plastic drums. Less often the material may simply be packaged in new or recycled 1 t bulk bags, or 50 kg plastic bags. The material may be stowed unpackaged in an ISO container. However, this is not done for commercial reasons of impracticality and risk of material loss.

Due to the density of tantalite, a 20 t shipment of tantalite will not fill the entire volume of an ISO container, and sometimes smaller shipments of 10 or 15 t are made. The packages (i.e. drums or bags) may be stuffed centrally in the ISO container, or at one end, with the voids filled with wooden dunnage to prevent shifting of cargo during transport and damage to packages. An ISO container may sometimes simply contain one single layer of drums in order to maximise security against cargo shifting.

The ISO container will typically be a standard 20 foot sea-land container, with no special features, sealed with one or more metal bolts, plastic clips, etc.

A shipment of tantalite from Santos/Brazil is already travelling along its transport route. The consignor (producer) and location where the tantalite was prepared for shipment are located elsewhere in Brazil. Therefore, the material in Santos may have been stored for a longer period in a warehouse in or out of the port area, or may recently have arrived from the consignor.

As the material can travel as general cargo, as long as the package remains on the sea-going vessel, ports of call including New York and Cherbourg should not have impact on the package transport.

Stage	Who	What	When	Where	Cost
2) Package Development	Material producer	No involvement in package development, as the material producer will use any one of a variety of new or second-hand packaging, readily available on the market.	-	-	**Industry** Design and construction of drum and container. The keeping of records and decisions for the type of packaging. **Regulatory** Not Applicable at this stage.
	Producer of the package	The producer of the packaging (drums and containers) will develop the design, choice of materials and construction method. The drum manufacturer designs, constructs, inspects and approves the packaging, potentially based on ISO standards. The drum producer will be targeting a general market, where the metal or plastic drum may be used for a variety of solid and/or liquid contents. Generic steel drums are not designed for corrosive contents or environments. Drums intended for the transport of hydrocarbons (*e.g.* fuel and lubricants) will have one or two small openings with screw cap fittings, instead of a removable lid. The ISO (sea-land) container producer will also be targeting a general market, and the container will use a standard steel construction, a plywood floor and a number of vents in the upper corners, with the design needing to meet criteria set by the International Maritime Organisation.	Any time prior to the shipment, potentially 10+ years before the shipment.	Packaging producer premises.	
	Outside consultants	If called for, for the package design.			
	Intellectual Property Department	For any trademark design on the packaging.			
3) Package Approval	Producer of the package	Specifications of all parts that make up the package, ensuring verification that the manufacturer can obtain or produce the separate components to the specification.	Throughout the design process.	Packaging producer premises.	**Industry** Administrative process of selecting and procuring packaging (consignor, and possibly consignee). Packing process of 30 drums, loading into container, and final package approval: half a day with 2-3 workers. (consignor, and possibly 3rd party warehouse). **Regulatory** Potentially: approval of container design by independent standards body and/or regulator.
	Consignor	The consignor selects and approves the packaging for its shipment, and approves the completed package.	Packaging selection: on-going process by consignor, ahead of package preparation. Approval may be on the day of shipment or weeks before if package is kept in temporary storage.	Consignor premises.	
	3rd party warehouse	A 3rd party warehouse may be involved in repacking the package, and approving the repacked package.	Prior to repacking.	If repacked, at 3rd party warehouse, most likely located at the discharge port of Hamburg.	
	Consignee	The consignee may stipulate the type of packaging in which the material is to be delivered.	Any packing stipulations will typically be made as part of agreeing a contract.	Consignee premises.	
4) Consignment	Consignor	Consignor will perform: • Packaging and weighing the product, with dose check as required by national licencing for companies handling radioactive materials (above 1 Bq/g). • QC of the radioactive properties to confirm exemption from Class 7.	Prior to the material departing Santos.	Consignor facilities, prior to delivery to Santos warehouse (in or out of the port area).	Consignor payment of: • Administrative fee for CNEN export licence. • Administrative fee to warehouse operator for

Stage	Who	What	When	Where	Cost
		• Apply to the national competent authority CNEN for a licence to export material containing Th and/or U from Brazil (there may be a lower exemption level). • Book transport as general cargo, potentially *via* freight forwarder. • Production of all transport documents for the package, including analysis certificate and explanatory note to demonstrate exemption from Class 7.			releasing material from storage. • Freight forwarder, or local haulage company directly, for transport from warehouse to port. QC records of the product analysis. Control of individual's radiation dose at the consignor facility. Potentially controlled areas for packing and storage at the consignor facility.
	Radiation Protection Advisor (separately for consignor and for warehouse)	Ensuring control of radiation doses to consignor's and warehouse's personnel	On-going	Consignor and warehouse premises	Keeping of records. Instigating reviews e.g. due to spillages.
	Regulators: Brazilian national Competent Authority CNEN	Prior to consignment, an export of material containing Th and/or U from Brazil, requires an export licence by the national competent authority CNEN (there may be a lower exemption level). Informed of any accidents or occurrences. Inspections at consignor and warehouse.	As required	Consignor and warehouse premises	CNEN review of export application by consignor.
	Warehouse operator	The consignor will issue instruction to the warehouse to release the package from storage, and allow it to be loaded onto road transport for the short journey to the vessel. In case of longer storage in warehouse, the warehouse may prepare or re-package the material for onward transport, in coordination with the consignor.	Immediately prior to transport	Warehouse in or out of port area	Warehouse record keeping and administration of packages, and for facility licencing and radiation protection. Potential re-packing, in new or second-hand packaging, as instructed by the consignor.
5) Carrying	Maritime carrier, port operator / stevedores, road and/or rail transport operator	Maritime carrier from Santos to Hamburg. Port operator / stevedores, within port of Hamburg. Road or rail transport operator, from Hamburg to Dresden. If repacked: road transport to/from third party warehouse.	During transport. Maritime transport 2 weeks, port operations 10-30 minutes, possible warehouse operations 4 hours plus storage time, road/rail transport 8 hours. Rail transport may involve temporary storage in rail sidings.	Along respective part of transport route, including port areas, vessel, public roads (including parking areas and service stations), and potentially warehouse for temporary storage and/or rail sidings and along railway	**Industry** Consignor payment for carriage to destination. **Regulatory** Nil.

Stage	Who	What	When	Where	Cost
				station platforms.	
6) Cross Internal Border		No internal EU borders are crossed for this shipment arriving by sea in Hamburg and being delivered to Dresden. Even if an internal EU border was crossed, *e.g.* to final destination Czech Republic, no particular additional actions would be expected for this exempt material.			
7) Cross External Border	Freight forwarder acting for consignor. Customs authority in Hamburg port. Authority operating radiation detectors in Hamburg port, e.g. Customs, or Fire Department of emergency services.	Customs clearance of documentation. Screening package for radiation, whether using handheld monitors or a fixed portal monitor.	Following discharge of sea-land container package from the seagoing vessel, while the container is still in the port area.	In the port area.	**Industry** Consignor preparation of documentation (prior to shipping), including analysis results for radioactivity concentration of the material in the package in order to demonstrate exempt status. **Regulatory** Operation of monitoring equipment, dealing with potential 'false positives' such as this material containing 5 Bq/g, which may trigger a response by the equipment operator, due to radiation dose rates slightly higher than natural background. Review of consignor documentation to verify that the material is in fact exempt from transport regulations.
	German Competent Authority, Bundesamt für kerntechnische Entsorgungssicherheit (BfE)	Ensure regulatory regime requires relevant personnel of port authority, Customs and emergency services, to be trained in radioactive materials transport regulations, including the application of exemptions.	As required.	Where training is delivered.	Each authority's cost of ensuring training for the personnel responsible for applying the radioactive materials transport regulations, including the application of exemptions.
8) Delivery	Carrier	Delivery to the correct destination within the consignee's premises.	At the consignee's delivery point.	As per the paperwork and package address	Keeping records of the delivery. Systems in place to ensure packages are not lost.
	Consignee (assuming consignee is located at the destination in Dresden)	Checks package and documentation on arrival for acceptance, on the basis of criteria set in the commercial contract with the consignor, as well as any quality control procedures at the consignee. Even if the package containing 5 Bq/g is exempt from transport regulation, a consignee receiving material above 1 Bq/g is required to have a radiation protection programme. The package will also be inspected on arrival by static	On arrival of the package at the consignee's facility.	At the consignee's goods incoming entrance, generally by road transport	Setting up, training and maintaining a quality assurance system and radiation protection programme, in order to handle and process any materials above 1 Bq/g.

Stage	Who	What	When	Where	Cost
		portal radiation monitors or handheld radiation monitors in order to verify and record the radiation dose rate.		and potentially by rail.	Notifying the national competent authority of the activities undertaken with radioactive materials (materials at 5 Bq/g are unlikely to lead to worker exposures requiring registration or licencing). Maintaining records as required by national legislation, typically 5-10 years.
	German Competent Authority, Bundesamt für kerntechnische Entsorgungssicherheit (BfE)	Maintaining a system of regulatory control that assures that regulatory obligations are suitably discharged. Inspections of consignee facilities.	Regulatory system on-going. Inspections as required.	Regulator's and consignee's facilities.	Maintaining a system of notification, registration and licencing, as required for a particular facility. Review and approval as required of applications. Performing inspections and record keeping.
9) Returns of used package for reuse or recycling		Not applicable to exempt material: the packaging is not considered to have contained radioactive material for the purposes of transport. As soon as the ISO container is emptied and cleaned (as required by consignee procedures), it is collected by the freight forwarder and released into general circulation. Any bag packaging is generally disposed of as waste, as not being fit for reuse. Drum packaging may be disposed of as waste, or reused for other purposes *e.g.* storing process residues or waste for disposal.			

This example covers one route of numerous actual or potential routes into the European Union. In addition to Brazil, material (whether exempt or Class 7) may come from Bolivia, Colombia, Nigeria, Namibia, DR Congo, Egypt, Ethiopia, Somaliland, Uganda, Rwanda, Burundi, Zambia, Zimbabwe, Malawi, Russian Federation, China, Thailand, Malaysia, Australia. Potential destinations in the European Union include Austria, Czech Republic, Estonia, Germany and the United Kingdom. Some material originates within the European Union, in France, and there are plans to reopen mines in Spain.

An additional cost for the consignor is the monitoring of and resolution of delayed shipments, particularly where these are caused by human factors, including regulatory changes or the misapplication of transport regulations to exempt materials.

A number of companies in the niobium and tantalum industry worldwide thought of as likely to be transporting NORM, were contacted regarding their experience with transport. Below is a summary of those that responded, followed by some of the separate individual responses.

Companies that responded	Country	Response
A&M Minerals and Metals	United Kingdom	No longer transports any NORM in/through/out of the European Union, due to the difficulty of obtaining transport.
Buss & Buss Spezialmetalle	Germany	No longer transports any NORM in/through/out of the European Union, due to the difficulty of obtaining transport.
HC Starck Tantalum & Niobium	Germany	See attached form. Three cases: one regarding a Spanish port denying access for a vessel with Class 7 containers leading to Denial of Shipment (DoS) recently by the carrier for future shipments. Another carrier has a policy of accepting “tantalite mineral concentrate” ONLY if declared as Class 7, even if it is technically exempted, thus increasing the transport cost. A third carrier no longer accepts “tantalite“, after an incident at a German port, where port police demanded a re-declaration of the exempt cargo as Class 7 for road transport and the carrier was fined. The number of carriers accepting tantalite cargo is at a very crucial point, threatening Europe´s supply of tantalum and niobium raw materials, as mergers between carriers have reduced the number of independent companies considerably, the choices are running out to find carriers prepared to accept IMDG class 7. The status of UN2910 for certain very low activity NORM material does not help. All attempts to convince a carrier that the NORM does not represent a radiation problem during carriage to anybody involved with transport and loading / unloading, based on a multi-country exposure study (IAEA TECDOC-1728), did not change the decision by the carrier to deny transport. At EU level, it would be helpful to establish and implement EU-wide port acceptance standards: any port open to international business with non-EU countries should adhere to a rule, not to deny transhipment for ships carrying any type of Dangerous Goods on to other destinations. They may refuse unloading certain IMDG-type cargo. In order to reduce the general attitude among carriers of DoS, it would help tremendously inside the EU jurisdiction to prevent local port policies (including those due to local city council politics) to strangle world trade and EU-critical raw materials supply.
Imerys Ceramics France	France	See attached form. There are difficulties in foreign ports in obtaining transit authorisation, with demand for new documents every time a new route is tested, *e.g.* demand for an export licence because the buyer has an import licence and the authorities expect a matching export licence, or demand for “Original” documents or certified documents by mail instead of e-mail. Political decision in Pakistan denying transit in their port for Class 7 cargo bound for India, it’s the shortest route but instead cargo must go to Malaysia and be transhipped to India. Insurance company often required to post insurance certificate directly from their office to port authorities. It would help to have: a worldwide procedure and documentation for products with low radioactivity; a Guideline about specific request in each port for this kind of material; experts available to help quickly if there is a problem in obtaining authorisation.
Krome Commodities	United Kingdom	No longer transports any NORM in/through/out of the European Union, due to the difficulty of obtaining transport.
Neo Performance Materials	Estonia	See completed form. No longer transports any NORM in/through/out of the European Union, due to the difficulty of obtaining transport. Attempting to ship as Class 7 results in carriage costs 10x that of general cargo, and ship’s masters sometimes deny loading of Class 7 containers due to personal perception of risk to other general cargo *e.g.* foodstuff. The main difficulty is in maritime transport, with maritime carriers and in loading of vessel. More specifically with carrier’s commercial and/or DG departments, or Ship’s Master.
Specialty Metals Resources	Belgium	See completed form. No longer transport any NORM in/through/out of the European Union, due to the difficulty of obtaining transport. Purchasing minerals with lower radioactivity concentration restricts the materials that are available, and can mean lower grades of tantalum content, however, the lower value of the material and inefficiency of transport is offset by avoiding Class 7 transport.
Stapleford Trading	United Kingdom	Difficulty in transporting high grade tantalum raw material from Europe, due to problems inside and outside Europe. Awaiting clearance to provide further details.
Thailand Smelting and Refining	Thailand	See completed form. No longer transports any NORM in/through/out of the European Union, due to the difficulty of obtaining transport. The tantalum slags produced from tin smelting now have deliberately low radioactivity concentrations below 10 Bq/g by adapting the process. These are exported to a company in Germany that further processes the slags to extract the tantalum. The low radioactivity is an intentional goal in the process, in order that sales and export of the slags are not subject to Class 7 regulation. This is partly due to the negative perception radioactive materials would have locally to the smelting plant, as it is located amongst hotels in a tourist area. It is also partly due to the historic experience by the company in the difficulty of obtaining Class 7 transport. The lowered radioactivity concentration also results in lower grade of tantalum content, however, the lower value of the material and inefficiency of transport is offset by avoiding Class 7 transport.
Treibacher	Austria	May be able to share information at a future date.

EUROPEAN COMMISSION STUDY ON COMPREHENSIVE EXAMINATION AND ANALYSES OF THE SITUATION OF TRANSPORT OF NUCLEAR MATERIALS

The Commission is carrying out a study of the transport of all radioactive materials being moved in, through or out of the European Union, *i.a.* in order to identify and address difficulties experienced in such transports.

This study includes all Naturally Occurring Radioactive Materials (NORM), also that which is below the exemption level for transport as radioactive material, *i.e.* in the range of 1 to 10 Bq/g, as these low level NORM can also experience difficulties in transport due to their radioactive properties, despite being exempted from regulations for transport of radioactive material.

As your company may be a consignor and/or consignee in the transport of NORM in the European Union, you are invited to contribute specific examples of difficulties in transport, whether before, during or after the transport, and any barriers or restrictions that you have experienced.

Any matters related to confidentiality of information should be made clear in the response provided and these will be taken into account.

Your assistance and cooperation is highly appreciated.

Responding company:	H.C.Starck Tantalum & Niobium GmbH
Company representative:	Christian Cymorek, Radiation Protection Officer
Date of response:	Dec. 20th, 2017______________

Concrete examples of difficulties, barriers and limited availability
Case 1: Carrier (A) has accepted UN2912-cargo with origin South America for many years; now (from November 2017 onwards), a Spanish port denies access for a vessel with IMDG class 7 containers destined for a German customer; this led to Denial of Shipment (DoS) recently by this Carrier. Result: the attitude of the Spanish port blocks raw material supply from South America. Case 2: Carrier (B) has a policy of accepting the cargo (tantalite mineral concentrate) ONLY if declared IMDG class 7. The cost per container thus is higher at a factor of about 15 times (!) as compared to standard cargo. This is de-facto a refusal of service via pricing. Case 3: Carrier (D) has this year declared DoS for tantalite cargo, based on one incident at unloading at a German port: port police checking incoming goods demanded a re-declaration of the incoming standard cargo into IMDG class 7 for road transport. The Carrier was informed of this fact (due to EU-required harbour information system), and was fined. The number of Carriers accepting tantalite cargo is at a very crucial point, threatening Europe´s supply of Tantalum and Niobium raw materials.
How often do these problems occur
The issue with Denial of Shipment (DoS) is: it is highly effective by the first application, as it is a matter of Carrier´s policy change. And: as mergers between Carriers have reduced the number of independent companies considerably, the choices are running out to find Carriers prepared to accept IMDG class 7. Sadly, the status of UN2910 for certain very low activity N.O.R.M. material does not help.
Examples of what is done to avoid problems
All attempts were made to convince carrier (D) that the N.O.R.M.-cargo would not represent any radiation expose problem along the whole carriage to anybody involved with transport and loading / unloading, based on a multi-country exposure study some years ago (published as IAEA-paper). The factual absence of physical risk, however, was not valued in decision-making at Carrier´s headquarter at all.

We have no solution to what we as company can do.
Suggestions for improvement
On EU-level, it would be helpful to establish and implement port acceptance standards EU-wide: any port open to international business with non-EU countries should adhere to one rule: not to deny transhipment for ships carrying any type of Dangerous Goods on to other destinations. They may well refuse unloading certain IMDG-type cargo; however, in order to reduce the pro-Denial-of-Shipment attitude among Carriers, it would help tremendously to, at least inside the EU jurisdiction, prevent locals port policies (induced by any sort of local city council politics) to strangle world trade and EU-critical raw materials supply.
Reference to stage of transport and persons involved
Sorry, due to time constraints no cross-check with Carriers, and no acceptance for being cited in this survey, could be done.
Further relevant information

EUROPEAN COMMISSION STUDY ON COMPREHENSIVE EXAMINATION AND ANALYSES OF THE SITUATION OF TRANSPORT OF NUCLEAR MATERIALS

The Commission is carrying out a study of the transport of all radioactive materials being moved in, through or out of the European Union, *i.a.* in order to identify and address difficulties experienced in such transport.

This study includes all Naturally Occurring Radioactive Materials (NORM), also that which is below the exemption level for transport as radioactive material, *i.e.* in the range of 1 to 10 Bq/g, as these low level NORM can also experience difficulties in transport due to their radioactive properties, despite being exempted from regulations for transport of radioactive material.

As your company may be a consignor and/or consignee in the transport of NORM in the European Union, you are invited to contribute specific examples of difficulties in transport, whether before, during or after the transport, and any barriers or restrictions that you have experienced.

Any matters related to confidentiality of information should be made clear in the response provided and these will be taken into account.

Your assistance and cooperation is highly appreciated.

Responding company:	IMERYS CERAMICS FRANCE
Company representative:	Pierre SIERAK
Date of response:	20/12/2017

Concrete examples of difficulties, barriers and limited availability
Difficulties in foreign port to have transit authorisation Demand for new documents every time we are testing a new route Demand for export licence because our client have an import licence and authorities are expecting an export licence to match with it Reception of “Original” documents or certified documents by mail and not by e-mail Delay on authorisation obtention Political decision from Pakistan, which not allow us to transit by their port to go to India. It’s the shortest route but we have now to go to Malaysia and them transbord to go to India
How often do these problems occur
For every shipments (3-4 times a year for now should increase in the coming years)
Examples of what is done to avoid problems
Ask our Insurance to send by mail from their office our insurance certificate to port authorities as e-mail version are sometimes rejected Avoiding Pakistan to go to India Working with French companies like Areva which are used to handle this kind of product (with low results)
Suggestions for improvement
Worldwide procedure and documentation for product with low radioactivity Guideline about specific request in each port for this kind of material Experts available to help quickly if any problem to obtain authorisation
Reference to stage of transport and persons involved

Further relevant information

EUROPEAN COMMISSION STUDY ON COMPREHENSIVE EXAMINATION AND ANALYSES OF THE SITUATION OF TRANSPORT OF NUCLEAR MATERIALS

The Commission is carrying out a study of the transport of all radioactive materials being moved in, through or out of the European Union, *i.a.* in order to identify and address difficulties experienced in such transport.

This study includes all Naturally Occurring Radioactive Materials (NORM), also that which is below the exemption level for transport as radioactive material, *i.e.* in the range of 1 to 10 Bq/g, as these low level NORM can also experience difficulties in transport due to their radioactive properties, despite being exempted from regulations for transport of radioactive material.

As your company may be a consignor and/or consignee in the transport of NORM in the European Union, you are invited to contribute specific examples of difficulties in transport, whether before, during or after the transport, and any barriers or restrictions that you have experienced.

Any matters related to confidentiality of information should be made clear in the response provided and these will be taken into account.

Your assistance and cooperation is highly appreciated.

Responding company: Neo Performance Materials

Company representative: Tiit Vau

Date of response: 20-Dec-2017 (by telephone)

Concrete examples of difficulties, barriers and limited availability
Columbites and tantalites of higher grades often have radioactivity concentrations of 20-50 Bq/g. Attempting to ship as Class 7 results in carriage costs 10x that of general cargo, and ship's masters sometimes deny loading of Class 7 containers due to personal perception of risk to other general cargo e.g. foodstuffs.
How often do these problems occur
Every attempted shipment of Class 7.
Examples of what is done to avoid problems
The company currently does not source any Class 7 material. It only sources NORM below the transport exemption level of 10 Bq/g, despite the generally lower grade.
Suggestions for improvement
Reference to stage of transport and persons involved
Maritime transport, maritime carriers, loading of vessel. Carrier's commercial and/or DG departments, Ship's Master.
Further relevant information
The company is licenced in Estonia to receive, handle, store and dispose of NORM.

EUROPEAN COMMISSION STUDY ON COMPREHENSIVE EXAMINATION AND ANALYSES OF THE SITUATION OF TRANSPORT OF NUCLEAR MATERIALS

The Commission is carrying out a study of the transport of all radioactive materials being moved in, through or out of the European Union, *i.a.* in order to identify and address difficulties experienced in such transport.

This study includes all Naturally Occurring Radioactive Materials (NORM), also that which is below the exemption level for transport as radioactive material, *i.e.* in the range of 1 to 10 Bq/g, as these low level NORM can also experience difficulties in transport due to their radioactive properties, despite being exempted from regulations for transport of radioactive material.

As your company may be a consignor and/or consignee in the transport of NORM in the European Union, you are invited to contribute specific examples of difficulties in transport, whether before, during or after the transport, and any barriers or restrictions that you have experienced.

Any matters related to confidentiality of information should be made clear in the response provided and these will be taken into account.

Your assistance and cooperation is highly appreciated.

Responding company: Specialty Metals Resources

Company representative: Quentin Lamarche

Date of response: 21-Dec-2017 (by telephone)

Concrete examples of difficulties, barriers and limited availability
The company specifically avoids purchasing any minerals above 10 Bq/g, in order to avoid difficulties in transporting Class 7.
How often do these problems occur
Examples of what is done to avoid problems
Purchasing minerals with lower radioactivity concentration restricts the materials that are available, and can mean lower grades of tantalum content, however the lower value of the material and inefficiency of transport, is offset by avoiding Class 7 transport.
Suggestions for improvement
Reference to stage of transport and persons involved
Further relevant information

EUROPEAN COMMISSION STUDY ON COMPREHENSIVE EXAMINATION AND ANALYSES OF THE SITUATION OF TRANSPORT OF NUCLEAR MATERIALS

The Commission is carrying out a study of the transport of all radioactive materials being moved in, through or out of the European Union, *i.a.* in order to identify and address difficulties experienced in such transport.

This study includes all Naturally Occurring Radioactive Materials (NORM), also that which is below the exemption level for transport as radioactive material, *i.e.* in the range of 1 to 10 Bq/g, as these low level NORM can also experience difficulties in transport due to their radioactive properties, despite being exempted from regulations for transport of radioactive material.

As your company may be a consignor and/or consignee in the transport of NORM in the European Union, you are invited to contribute specific examples of difficulties in transport, whether before, during or after the transport, and any barriers or restrictions that you have experienced.

Any matters related to confidentiality of information should be made clear in the response provided and these will be taken into account.

Your assistance and cooperation is highly appreciated.

Responding company: Thailand Smelting and Refining Co.,Ltd

Company representative: Warit Choovaree

Date of response: 21-Dec-2017 (by telephone)

Concrete examples of difficulties, barriers and limited availability
The tantalum slags produced from tin smelting now have deliberately low radioactivity concentrations below 10 Bq/g by adapting the process. These are exported to a company in Germany that further processes the slags to extract the tantalum.
How often do these problems occur
Examples of what is done to avoid problems
The low radioactivity is an intentional goal in the process, in order that sales and export of the slags are not subject to Class 7 regulation. This is partly due to the negative perception radioactive materials would have locally to the smelting plant, as it is located amongst hotels in a tourist area. It is also partly due to the historic experience by the company in the difficulty of obtaining Class 7 transport. The lowered radioactivity concentration also results in lower grade of tantalum content, however the lower value of the material and inefficiency of transport, is offset by avoiding Class 7 transport.
Suggestions for improvement
Reference to stage of transport and persons involved
Further relevant information

3) CONCLUSIONS

This study examines the transport of material which is exempt from outside of the EU to supply essential industry within the EU. One of the complexities with this type of material is that the packagings used for transport are generally packagings that exist already for the transport of other materials. The ability of a regulator to oversee the manufacture of such packages, when the carriage of radioactive material is not considered at the time of manufacture, is clearly impossible. The emphasis on the activities of the consignor are clear for this type of shipment. The amount of document checking for the shipment is significant. It appears that this could be an area where duplication of effort exists.

Industry supplied lists of specific problems, including four companies that identified they no longer ship to/from Europe due to problems shipping radioactive material. One key issue is port acceptance. Where ships call at a scheduled sequence of ports it only requires one to prohibit the material to result in carriage to all ports on the route to be affected. The issue of ensuring port acceptance of goods complying with the IMDG code should be considered.

Some companies identified problems with regulators, many regulators do not accept there is a problem. A simple expert resolution system might benefit cases where there is a perception of inappropriate regulatory action.

In this case the ability of an entity to provide resolution of differences of opinion between the transport industry and the infrastructure operators and Competent Authorities is essential. For this reason, the entity needs to be outside of the normal transport chain.

Restrictions in ports are reported to have resulted in industry being unable to operate in Europe in some cases. Some states identified less than 10% of ports as accepting radioactive material. The importance of these restrictions on other states is explained in the main report, and as a result greater clarity is important in this area.

A6.3 DUAL PURPOSE CASKS

Following the responses to the follow-up questions on dual purpose casks it was decided to present this as a small case study to set out some specific issues. A dual purpose cask is designed for both transport and storage. Generally, it is designed in one state that may use the package for transport and/or storage. It is also exported to other users who initially use the package for storage with the intention of transporting the package after many tens of years.

A significant question is how there can be an assurance that transport can take place after 30, 50 or even 100 years of storage. Industry is keen to ensure that the regulatory system will guarantee the transport can take place. New provisions in the IAEA transport regulations seek to provide some assurance based on new requirements for ageing management.

The scenario to be considered is that a package is developed in MS A by company AA, initially for use at facility AB by company AC for use in a MS B at facility BB for eventual transport by company BC to site BD.

The first step is the design, testing and manufacture in State A by company AA. This may simply be transport approval, since the facility safety case is more likely to be the appropriate means of gaining approval for storage. Transport approvals are partly transferrable to other States, however facility approvals are not. This process can take many years.

After a time, company AA sells casks to facility BB in MS B for use as a storage package. At no time does a loaded package require transport in MS B. The approval required in MS B is simply for storage at facility BB as part of the facility safety case. Until the time that transport takes place in MS B there is no legal requirement for a transport approval to be given. As a result, the ageing management requirements in the transport regulations need not be applied in MS B. Given that transport approval costs can average tens of thousands of Euros per year there is clearly no incentive in requesting an approval that is not essential.

Although transport approvals are essentially transferable with validations, there is a risk, particularly if the initial approval in different States is many years apart, that best practice will have changed and the safety case will differ in MS A and MS B.

At no time does ownership of design change hands, and thus when transport finally takes place in MS B the design authority (company A) will be responsible for the approval. The questions that need to be answered in this respect are:

- Does company A still exist (Competent Authority in MS B can have no control over this);
- Can company A be sure of the effective ageing management in MS B.

In addition to this, the performance and regulation of servicing of the package need careful consideration. Whether there can be any real assurance that regulations can be stable over a period of 50 years is questionable (this is comparable to the lifetime of the current regulations).

The risk of not having an effective regulatory system in place that can remain stable for the lifetime of storage is that loaded packages will be at an unsuitable interim storage site and will not fully meet the transport requirements at the time they are to be moved. The pressure on the Competent Authority might then be unacceptable, particularly if the safest option would be to move a sub-standard transport package to a different location.

For the dual purpose cask to be an effective international product, two regulatory improvements are required:

- A common, transferable EU standard for storage casks is required;
- This standard needs to incorporate ageing management regulation.

In practice, Competent Authorities provided assurance at the workshop that they are each, independently, implementing approval requirements before storage, although this is not clearly required in regulation. This was not consistent with the information provided as part of the follow up study.

FOLLOW-UP STUDY – AGEING

The issue of ageing is part of the dual purpose cask project. A Coordinated Research Project (CRP) was completed by the IAEA several years ago, but it is unpublished. A follow-up project is in place, but it is not clear whether it is operational.

Transport approvals are based on current regulations and typically last for five years. At the end of approval, a renewal takes place against the regulations in place at that time. Generally, the regulations recognise that changes should only be imposed on existing packages if there is a significant safety need. However, the regulations apply a transition system that currently limits packages to around 45 years old, and apply additional restrictions to the older packages.

The IAEA regulatory system has only been in existence for around 50 years, and dual purpose casks are intended to be transported in 50 years time. It is not realistic to assume any guarantee can be given regarding the regulatory infrastructure at that time based on what is a limited experience of the stability of regulations.

Dual purpose casks are transport packages (approved in the country of design) and storage packages (approved in the country of storage). There are two additional complexities, the multilateral nature of the transport approval and the potential for a delay before any transport takes place in a state.

These packages tend to be multilateral in nature, and as a result the transport approval needs to be reviewed in every State that the package is transported in. This means that the package will need to be approved for transport and storage in every State they are used. The storage approvals are State based and, although they may have a common safety case, are not dependant on each other. Should the original State stop using the packages for transport and the primary transport approval lapse, then all transport approvals will cease to have effect.

Off the record information was passed to the Consultant that dual purpose packages are being located at facilities and loaded for storage purposes, but no transport is taking place at this time and as a result the MS involved is not being asked to give a multilateral approval at this time. The issue with this is that the transport approval normally incorporates the aspects of ageing management required to ensure the package remains acceptable for transport in the future. As a result, there is a potential that approval will not be possible for transport in the future because of a lack of through life transport regulatory oversight.

Follow-up questions investigated this issue and identified at least one case in the Community where a dual purpose cask was used for storage in an MS where there was no transport approval. Since transport approval is required to bring the requirements for long term monitoring of transport packages into effect, this means that the necessary requirements for control are not in place. Should this continue the pressure on Competent Authorities to allow transport of substandard transport packages after tens of years of storage could be unacceptably high. As a result a means of ensuring that dual purpose casks are not used for storage without transport approval should be considered.

CONCLUSIONS

This case study was introduced to demonstrate specific issues. The current regulatory infrastructure places ageing management standards in the transport requirements. However, these are not required to be applied until transport takes place.

There is no universal standard that is applied in a harmonised manner for approval of packaging for storage. Without this there are safety risks involved in the international trade in dual purpose casks.

It is important to ensure that there is a coordinated system of compliance assurance for dual purpose casks, taking into account the potential impact of State decisions on the continued use of nuclear power and other issues that might impact on long term approval renewal, maintenance and compliance.

Given that all Competent Authorities believe that they are implementing an acceptable system of transport approval prior to use it would seem this is an area where EU standards would be a good option.

There are few package design authorities that have survived for 50 years. Cases where original package designers have closed business while packages have still been in use have caused problems in the past. It would be sensible to review the potential need for an assurance system for dual purpose casks that provides a backstop for this event.

The potential for ageing requirements to be different in different States for the same package design could provide problems when considering ongoing package approval. For example, if the primary approval is in MS A for transport, and the package is maintained in MS B for storage in a manner not consistent with the views of the Competent Authority A, then a separate design approval from first principles might end up being required in MS B. To this end the Competent Authorities for transport and long term storage in all States would benefit from cooperation.

A6.4 RADIOISOTOPE SAMPLES

Initially, the intention was to include a case study on the transport of radioisotope samples. However, information on typical shipments was scarce. After multiple requests, two examples were provided by the CTF. These identified some specific issues, most of which are included in the main report. However, they are extracted here to ensure they are contained in a stand-alone report.

The first example identified an issue with the ability to transport a radioisotope sample through some MS. A few MS prohibit certain shipments, but there are often practical work-arounds. Otherwise the shipment was routine, and similar to most other shipments of radioactive materials, with no specific issues that could be examined further.

The second example involved problems shipping a small sample of fissile material. Several minor issues can be identified from this case, but many potential solutions were rejected at the second workshop.

The regulatory changes have resulted in small amounts of fissile material being classified as fissile, rather than fissile excepted. This regulatory change may have taken place following initial planning of the work. The change was administrative in nature and has resulted in significant additional costs for shipping these materials (particularly approval costs). In the main report the suggestion is made that this change should be reviewed, and this has been accepted.

A further issue was related to how to classify samples being shipped for identification. While the use of the term 'SAMPLE' can be used for other dangerous goods, it cannot be used for radioactive materials. An option would be to permit the use of the term 'SAMPLE' for radioactive materials. However, there is an alternative option, which is to use the unknown radionuclide values for the radioactive sample.

The ability to identify packages suitable for the 'SAMPLE' designation proved difficult, and the suggestion of a European Package Information System in the main report would be an effective solution for this issue.

Overall, there were several minor issues identified that could affect shipments of samples, but the solutions were already identified in the main body of the report.

A7 WORKING METHOD

The methodology behind this report was to start with a broad basis of potential challenges and, through interface with the SG and CTF, reduce these to a manageable list of items where action is recommended. Initially the Consultant developed a questionnaire and shared this with contact points in MS, all of whom were members of the SG. Results were collated and areas where the answers were not clear were followed up. At the same time, the Consultant reviewed public documents, previous relevant reports and legislation. Using this information and the results of the questionnaires, a draft report was drawn up. This report identified all areas where the information that was readily available was limited or which identified potential gaps. These challenges were identified in the report. The report was shared with the CTF and SG and comments gathered prior to holding a workshop where the challenges were discussed.

At the workshop, several areas were identified where further information was considered available and, as a result, a follow-up questionnaire was produced and circulated after the workshop. Based on responses to this, as well as comments at and after the workshop by the CTF and SG, the report was significantly revised. It is important to note that the report was shared with all the CTF and SG, not just those who attended the workshop, and comments were welcomed from all members.

This revised report was shared with the CTF and the SG and comments obtained in preparation for a meeting with the CTF and a second workshop with the CTF and SG members. The revised report reduced the number of areas of interest and put forward suggestions of actions that could be taken related to the remaining areas.

At the workshop each of these areas were considered in turn and the information gathered related to the potential need for action. In several cases the CTF and/or the SG were able to identify current actions that are under way and deal with some of the areas of concern. In other cases, plans of actions were discussed, and bodies were identified that were considered responsible for the action area and were expected to take up the actions. Following the workshop, an extended period was allowed for the SG and CTF to add final comments on these areas.

This process has resulted in only a few areas where recommendations were considered necessary. Overall, the result from the study suggests that the transport of radioactive materials is safely regulated. Although there was no generic need for facilitation, there were individual areas where problems in shipping still exist, and of note was the suggestion by the environmental civil society that some areas could benefit from reduced administrative burden.

All these comments were taken into consideration and a final draft was prepared for consideration by the CTF, which provided comments that have been incorporated into this version of the report.

Although the report contains only a few areas where recommendations were produced, the process examined a wide range of areas and identified a significant amount of positive evidence that there were no problems. In order to ensure a record is maintained for future reference of the areas considered where positive evidence was provided through the workshops this annex has been developed.

In summary, the process involved the Consultant collecting information through questionnaires, reviewing documents/legislation and interfacing with the SG to obtain an overview of the status of transport of radioactive materials. Based on this information, the Consultant identified several challenges or areas where the collected information left room for interpretation. This was presented to the SG and CTF through draft reports, presentations and discussions in two workshops, and gradually the challenges/areas were refined by grouping in the following way:

- There was sufficient information to show that the current situation was acceptable.
- There were processes in place with bodies responsible for overseeing an area that was currently being managed.
- There were bodies responsible for areas, and they could be expected to take action on issues (considering a graded approach).

- There was a need for encouraging improvements in this area.
- There was a need for urgent EU/Community action to remedy problems.

The vast majority of the challenges identified through the consultations fell in the first three groupings, and none of them fell into the final grouping. The overall conclusion is that the transport of radioactive materials continues to have an excellent safety and security record. Although issues have been identified, there is clear evidence of effective regulatory and industry response, and no evidence of significant accidents.

There is effective response to problems involved in shipping radioactive materials globally, although specific concerns remain. If implemented, the recommendations in this report will, as an added benefit, reduce the barriers to shipments of radioactive materials.

Although the study generally identified the situation as being positive, the one area that would seem to offer room for improvement was that of transparency (for example, information on exposures to workers and the public was not readily-available).

At the first workshop, the Competent Authorities proposed the prioritization of actions in relation to safety. Considering this aspect and considering other driving factors, three markers for improvement have been set: safety, transparency, and burden. All three represent important aspects of demonstrable oversight of safety. Safety issues speak for themselves, while transparency provides for the demonstration that the oversight is active in achieving its goal.

The issue of the burden is often less obvious, but probably one of the most significant in terms of implementation. Considering the extent and diversity of the industry, an important aspect of safety is voluntary compliance by the industry, which is only investigated by the Competent Authorities. Should the burden of compliance with legislation be disproportionate to the safety benefits of compliance, there is a risk that the non-compliance rate in industry will increase as the regulations come into disrepute. This is not a desirable output of the regulatory infrastructure.

The major vectors for improvement identified by the study are:

- Regulatory:
  - Improving the implementation of Directives affecting the transport of radioactive material;
  - Potential Directive enhancements.
- Transparency:
  - Lack of information readily available to MS;
  - Lack of information shared by MS.
- Economic:
  - Administrative costs to the transport industry are disproportionate with regard to benefits and risks;
  - Regulatory costs unreasonably high;
  - Synergies not being fully utilised.

The detailed recommendations and action plans are set out in this annex, and those that are recommended to be taken forward as specific actions are summarised here. At the request of the SG, this annex also includes details of activities that are either under way or expected to be managed by an identified body, as well as challenges that were identified through the review process as currently being actively managed.

A7.1 WORKSHOP 1

A number of areas where gaps in the readily available information led to discussions during the first workshop are set out here. Some of these were dealt with or modified as a result of further investigations/SG response.

A7.1.1 PRIME RESPONSIBILITY FOR SAFETY

Some MS require carrier registration, some consignor registration; this extends to how MS carry out inspections. This could result in different responsibilities, depending on shipment direction between MS. This could result in a lack of clarity of primary responsibility for safety. There seems little justification for a different focus in different MS, and this has been a long-standing issue identified by the European Parliament as a matter requiring solution.

A7.1.1.1 POTENTIAL SOLUTION

Guidance/regulation identifying primary responsibility and, if desired, who should be subject to any registration requirement.

A7.1.2 INSPECTION REGIME

Over 90% of consigned packages are non-CA approved. There is almost no verification assessment of design carried out by CA. Only one-third of MS report reviewing design assessment of non-CA approved packages. The verification of the accuracy of the information presented in the paperwork related to the design of non-CA approved packages may not be taking place on a sufficiently regular basis.

A7.1.2.1 POTENTIAL SOLUTION

Verify whether the current system has a gap. If necessary, fill the gap based on the graded approach, possibly look at harmonisation of the IAEA and UN package certification process.

It is important to be mindful of the graded approach. Access to information is essential for this. Utilise roadside checks to identify packages that exist and request information on inspection issues from FANC.

A7.1.3 PUBLIC EXPOSURE

Around 25% of MS reported a programme for assessing public exposure from the transport of radioactive materials. Assessing the exposures of the public is consistent with IAEA Safety Standards Series No. SSR-6 and the BSS Directive, and is essential in judging the effectiveness of the regulatory system and any changes to it.

A7.1.3.1 POTENTIAL SOLUTION

Ensure assessments are carried out on public exposure on a sufficiently regular basis.

Agree a community review frequency. Share information on methodology with a goal on having a common methodology. Share information on dose reduction. Coordinated collection of data at community level or IAEA level.

A7.1.4 REGULATORY REVIEW POLICY AND PROCESS

Most MS participate in the IAEA review and revision process. Regulation is set at EU level. There are EU views over the suitability of international regulatory change. However, there is no routine EU review of the need to change the IAEA requirements.

A7.1.4.1 POTENTIAL SOLUTION

Verify that there is a policy in each MS. Establish an EU level policy and process for review if there are significant issues.

A7.1.5 COMPLIANCE STANDARDS

Compliance assurance in some areas is patchy, some MS focusing on some areas, others in different areas. Generally, inspection rates seem low for testing, manufacture, maintenance and servicing. Roadside checks may not be the most cost-effective solution for these areas.

A7.1.5.1 POTENTIAL SOLUTION

Develop guidance to support compliance. Competent Authorities could adopt a version of IAEA Safety Standards Series No. TS-G-1.5, adapted to assist MS in achieving a consistent level of compliance. Examine the issue of multiple regulatory responsibilities (e.g. cross-border).

A7.1.6 CAPACITY BUILDING

There were a number of indicators that related to an apparent need for improved capacity building. A number of MS privately communicated the need for either transport or radiation protection training for Competent Authorities.

A7.1.6.1 POTENTIAL SOLUTION

Develop and or identify targets for capacity building in the EU and ensure training is provided to meet these needs. Request UK to provide information on capacity building (cf. joint convention report). Consider training non-transport inspectors in transport issues. The EC could investigate whether transport is addressed in their report on capacity building.

A7.1.7 COLLABORATION

There is no formal EU wide collaboration agreement. The existing networks do not have a mandate to operate in a collective manner. There is good evidence of informal interfaces between MS. A number of MS suggested they would cooperate on an ad-hoc basis if required, particularly related to incidents/emergencies.

A7.1.7.1 POTENTIAL SOLUTION

A comprehensive agreement between MS based on ADR 1.8.2.1. Identify areas of specialism (package assessment, package testing, carrier inspection). Draft and sign an agreement. Identify this as a solution to capacity building.

A7.1.8 PEER REVIEW

A number of MS have had an IAEA IRRS review, including the transport module. Few of the respondents knew about the other reviews of their State (e.g. by ICAO, which has reviewed every MS). The findings of the IRRS missions identify consistent regulations (as expected), but tend to provide guidance on implementation that does not drive consistency. The areas of transport that the EU is most involved with (road, rail and inland waterway) have no modal based peer reviews.

A7.1.8.1 POTENTIAL SOLUTION

Establish a review system for road and rail that aims to encourage harmonised compliance. Update the IAEA TranSAS question set – consider Implementing the mini-TranSAS in the EU.

A7.1.9 AIR SEGREGATION CALCULATIONS

The radioactive traffic factor (RTF) based on the data collected and the European Statistical database is 0.01, as opposed to the value used in IAEA Safety Standards Series No. SSG-26 (which is 0.1). PHE report PHE-CRCE-006 suggests that the RTF factor may be overestimated in many cases even when only considering the airlines that carry radioactive material.

A7.1.9.1 POTENTIAL SOLUTION

Submission of the revised Appendix III to the upcoming IAEA revision process. PHE to raise the issue at TRANSSC at a technical group.

A7.2 OTHER FINDINGS

A number of additional findings were identified in the report.

- The difference between replies and the implementation record suggests there may be internal communication issues in some MS.

- The EU may wish to consider how to ensure effective input to the development of SMGS by all potentially affected States.
- There would appear to be enough information to suggest a legal review of implementation should be carried out.
- It may be appropriate for the EU to revise some of the details of 95/50/EC to focus on checks and data appropriate for radioactive materials.
- The potential for EACA and the related Mediterranean Regulatory Network to influence regulatory improvement in Europe; how this can be supported at the Community level may be worth exploring.
- Consideration of the interface between regulatory update, approval time and certificate lifetime.
- Consideration should be given as to what extent activities related to a package take place in more than one MS, and how a fixed agreement between MS could help comprehensive compliance.
- The potential for a gap in EPR is significant. A more detailed review of responsibilities in an emergency should be carried out.
- Overall, the community standards for EPR were not set out clearly in responses either in terms of the primary activities, responsibilities or reviews. Further in-depth study of this area is suggested.
- Development of a more comprehensive list based on the experience of all MS.
- The EU should consider whether a combined EU report should be made publicly available regularly.
- The question as to whether the requirements relating to transfer of regulatory responsibility should apply within MS and whether the transport aspects of the corresponding directives remain valid may produce better regulation if considered.
- Community based guidance on areas which could lead to material coming within the regulations should be considered.
    - Guidance to support each of these industries in understanding the potential for coming under radioactive transport and waste regulations should be considered.
- While most MS are happy with current regulatory requirements related to ageing in the IAEA Transport Regulations, there may be a need for consideration of the practical implementation in multiple MS.
- Simple guidance on how to complete transport documentation may help to reduce problems shipping radioactive materials and should be considered.
- At this point there would seem to be conflicting evidence related to whether denials of shipment are justified; further examination is warranted.
- Since IAEA requirements are effectively adopted as EU legislation in this field, there is a question as to whether there should be a requirement for the EC to produce an impact assessment on proposed changes to IAEA requirements.
- It may be sensible to revise the standard document (shipment directive) making use of transport expertise to avoid creating duplication of effort and potential security risks, and to ensure that the document is updated to reflect EU transport legislation.
- The complexity of shipment documentation and notification requirements could benefit from a comprehensive review with the objective of harmonisation.

Findings related to the issues identified above

- The EU might benefit from a common policy and harmonised procedure related to review of the regulations for the transport of radioactive materials.
- Consideration of whether a standardised Community approach to registration/authorisation of dutyholders would seem appropriate.
- Consideration of a guide to appropriate sampling rates for each of the areas of compliance assurance could be beneficial.
- Consideration should be given to the appropriate sampling rate for review of non-CA approved packages, and the extent of verification of the documentary evidence provided.
- It is possible that a European approval body could reduce duplication of effort in Europe, and it should be investigated as an alternative to recognition of other European certificates.
- The potential for an EU based serial number register might be worth considering to support compliance checking.
- Given the fact that different MS specialise in different areas of training, it may be sensible to look at an EU based capacity building programme for State officials.
- It may be sensible to examine whether a system of self-assessment focusing on implementation of compliance assurance can be developed and used as a peer review or audit system for MS.

A7.3 WORKSHOP 2

Following consultation and review, the report was updated. The issues identified in the revised report (Chapters 7–10) were used to establish potential action areas for future activities. However, it is important to note that some will be long term at best because of their degree of difficulty. The workshops stressed that it was important not to treat the information in a scientifically statistical manner. The generation of these action areas is not based on a statistical analysis of the responses provided, but is more a result of a global impression after reviewing all of the data. Nevertheless, an attempt has been made to link the major issues identified in the report to an action area.

Table 43 summarises the proposed action areas. The final column shows the action areas following the discussions during the second workshop. Where the final column is struck out the workshop participants decided that the action was not justified as a result of the evidence they had, or that was presented at the workshop. Action areas in RED text are those areas where current activities are under way that cover any challenges in that area.

Table 43: Workshop 2 review of action areas

	Action Area	Items in report	Action Areas following Workshop 2
AA1	Review the legal basis of IAEA BSS Footnote 18, and the need for it in the BSS Directive	I-3; I-35; I-39; I-40; I-41	~~Review the legal basis of IAEA BSS Footnote 18, and the need for it in the BSSD~~
AA2	Review the clearance levels (technically) and apply a fixed level for the community	I-44	~~Review the clearance levels (technically) and apply a fixed level for the community~~ EXPLAIN IN FINAL REPORT
AA3	Re-establish the community research programme	I-7; I-43; I-31	~~Re-establish the community research programme~~
AA4	Propose updates to the air segregation limits	I-48	The air segregation limits were identified as being potentially over restrictive
AA5	Update the administrative means for controlling material that used to be termed fissile-excepted	I-29	Update the administrative means for controlling material that used to be termed fissile-excepted
AA6	Review Directive 95/50/EC with the goal of introducing harmonised consignor inspection checks	I-6	Review the need for additional information requirements for roadside checks for radioactive material and guidance for consignor checks
AA7	Review Directive 2006/117/Euratom and the single standard document with the consideration of simplification to focus on transfer of location/ownership of waste and increase in scope to include in-state transfers	I-23; I-32; I-33	Review the various directives including Directive 2006/117/Euratom and the single standard document with the consideration of simplification of notification requirements
AA8	Review the administrative burden related to variation of application between MS taking into account all the legislation applying to the transport of radioactive material.	I-3; I-36; I-39	Identify all the legislation applying to the transport of radioactive material.
AA9	Consider the use of freight transport licencing and dangerous goods transport licencing and training as a means for delivering notification/registration and licencing equivalent to the BSS Directive	I-34	~~Consider the use of freight transport licencing and dangerous goods transport licencing and training as a means for delivering notification/registration and licencing equivalent to the BSSD.~~
AA10	Facilitate compliance assurance that involves the inter-dependency between Competent Authorities, particularly in the areas of design, testing, manufacture and servicing	I-5; I-7; I-9; I-11	Facilitate compliance assurance that involves the inter-dependency between state regulators, particularly in the areas of design, testing, manufacture and servicing (EACA?)

	Action Area	Items in report	Action Areas following Workshop 2
AA11	A standard set of carrier and consignor responsibilities should be delivered	I-4; I-43	Guidance on carrier and consignor responsibilities should be developed for radioactive material
AA12	Clarification of the EPR responsibilities taking into account the all-hazard approach to transport accidents	I-13; I-14	~~Clarification of the EPR responsibilities taking into account the all-hazard approach to transport accidents~~
AA13	Clear interpretation on the classification of material destined for recycling. Consideration should be given to removing the radioactive exemption to ADR 5.4.1.1.3 as part of this review.	I-25	Clear interpretation on the classification of material destined for recycling. ~~Consideration should be given to removing the radioactive exemption to ADR 5.4.1.1.3 as part of this review.~~
AA14	An interpretation of how to resolve this conflict caused by different definitions of the graded approach in transport should be produced	I-35	~~An interpretation of how to resolve this conflict caused by different definitions of the graded approach in transport should be produced~~
AA15	Guidance on how compliance with the Union requirements for transport of radioactive material provides equivalence to compliance with the BSS Directive should be produced	I-36; I-39; I-40;	~~Guidance on how compliance with the Union requirements for transport of radioactive material provides equivalence to compliance with the BSSD should be produced~~
AA16	Guidance on how to licence an activity involving multiple processes (e.g. storage processing and transport) would be beneficial, particularly if this made clear that it is the activity that requires licencing rather than the entities carrying it out.	I-37; I-38	~~Guidance on how to licence an activity involving multiple processes (e.g. storage processing and transport) would be beneficial, particularly if this made clear that it is the activity that requires licencing rather than the entities carrying it out.~~
AA17	Produce guidance on the application of compliance assurance in each of the twelve areas of the compliance circle, including how to apply the graded approach to determine a suitable sampling regime.	I-5; I-9	Produce guidance on the application of compliance assurance in each of the twelve areas of the compliance circle, including how to apply the graded approach to determine a suitable sampling regime. (IAEA producing guidance)
AA18	Guidance would be beneficial, including examples of a process that could be adopted by member states to manage the review of activities that can bring material within the BSSD (e.g. based on the process in Ireland).	I-24	Guidance would be beneficial, including examples of a process that could be adopted by member states to manage the review of activities that can bring material within the BSSD (e.g. based on the process in Ireland). (Reference in report)

	Action Area	Items in report	Action Areas following Workshop 2
AA19	Simple guidance with examples of how to complete the standard transport document could provide valuable support to industry compliance.	I-27	Simple guidance with examples of how to complete the standard transport document could provide valuable support to industry compliance (WNTI)
AA20	Guidance should be produced on how to achieve harmonised application of the BSSD to transport	I-35; I-36; I-39; I-40; I-43	~~Guidance should be produced on how to achieve harmonised application of the BSSD to transport~~
AA21	A simple annual report for the Union should be produced annually.	I-19	~~A simple annual report for the Union should be produced annually.~~
AA22	It is proposed that a Union body is established incorporating non-regulatory governmental representatives that are responsible for facilitation of the transport of radioactive material.	I-17; I-30; I-46	It is proposed that a Union body is established incorporating non-regulatory governmental representatives that are responsible for facilitation of the transport of radioactive material (IAEA)
AA23	A review of barriers to maritime transport including “special” conditions applied by ports and how these might affect the ability of the Union to compete globally should be produced.	I-49	A review of barriers to maritime transport including “special” conditions applied by ports and how these might affect the ability of the Union to compete globally should be produced (WNA)
AA24	It is suggested that the Union develop a packaging information system that is focussed on the needs of the Union, including a register of packages and valid serial numbers. This could be extended to include information on inspections that are carried out that might have cross Union interest.	I-12	It is suggested that the Union develop a packaging information system that is focussed on the needs of the Union, including a register of packages and valid serial numbers. This could be extended if required.
AA25	Develop a Union capacity building model on the basis of the UK national system	I-15; I-16	Develop a Union capacity building model on the basis of the UK national system
AA26	The Union should encourage training, utilising the list of trainers provided as part of this study, and potentially the IAEA on-line training platform.	I-15	The Union should encourage training, ~~utilising the list of trainers provided as part of this study~~, and potentially the IAEA on-line training platform. Consideration of the need for harmonised tests.
AA27	Consideration of extending the Union involvement in SMGS	I-2	Consideration of extending the Union involvement in SMGS
AA28	Consideration of establishing a single approval body in the Union for approval of radioactive material transport	I-10	Encourage cooperation between competent authorities in the assessment of packages

	Action Area	Items in report	Action Areas following Workshop 2
AA29	Requirements for storage of material in dual-purpose casks should be developed, incorporating the need for transport approval prior to use	I-26; I-49; I-50	Dual-purpose casks are being managed in the Union by ensuring transport approval prior to loading
AA30	Consideration should be given to the need for Union impact assessments of changes to regulatory requirements (including consideration of the potential costs to transport of a lack of harmonisation in implementation)	I-31; I-46	~~Consideration should be given to the need for Union impact assessments of changes to regulatory requirements (including consideration of the potential costs to transport of a lack of harmonisation in implementation)~~
AA31	Involvement of transport experts in processes looking at review of the BSSD and Shipment directive should be assured	I-44	Involvement of transport experts in processes looking at review of the BSSD and Shipment directive should be assured
AA32	Gather more statistics using a low-impact system	I-19	~~Gather information important to safety using a low-impact system~~
AA33	Information should be made public on the outcome of inspections	I-20	Information should be made public on the outcome of inspections in line with BSSD requirements
AA34	Consideration should be given to publishing information based on self-review of peer review based on a system such as the IAEA mini-TranSAS.	I-22	Consideration should be given to publishing information based on self-review or peer review based on a system such as the IAEA mini-TranSAS in the event that the IRRS does not cover transport.
AA35	A comprehensive set of interested parties should be developed by states, and more extensive sharing of information between regulators should be assured	I-1; I-18	A comprehensive set of interested parties should be developed by states, and more extensive sharing of information between regulators should be assured (refine wording to sound like Slovenian example)
AA36	Cross-regulatory familiarisation between radiation protection and transport regulators should be implemented	Workshop 1	Cross-regulatory familiarisation between radiation protection and transport regulators should be improved where necessary (taking the example of France as good practice)
AA37	A means of speeding up assessments or slowing regulatory change should be considered	I-8	~~A means of speeding up assessments or slowing regulatory change should be considered~~
AA38	Consideration should be given as to how the existing grouping of member states for Europe and the Mediterranean region can link to community initiatives	I-7	Consideration should be given as to how the existing grouping of member states for Europe and the

	Action Area	Items in report	Action Areas following Workshop 2
			Mediterranean region can link to community initiatives (already happening)
AA39	Member states identify a non-regulatory governmental entity to deal with industry promotion and denial of shipment reports that is not a regulator	I-28;	Member states identify a non-regulatory governmental entity to deal with industry facilitation and denial of shipment reports that is not a regulator (Side event at IAEA GC) - improve wording
AA40	Industry should cooperate on learning from incidents	I-21	Industry should cooperate with each other on learning from significant events (through the competent authority)

A7.3.1 WORKSHOP DISCUSSION ON PROPOSED ACTION AREAS

A7.3.1.1 ACTION AREA 1

Review the legal basis of footnote 18 in the IAEA BSS, and the need for it in the BSS Directive.

This action area was considered by the SG and the CTF, and the view expressed was that this should not be a priority.

A7.3.1.2 ACTION AREA 2

Review the clearance levels (technically) and apply a fixed level for the Community.

This action area was not considered a priority by the SG and the CTF. However, given the time scales for amending and updating these values it would be unusual for amendments within ten years, and more likely 15 years. As a result, initial work on the next update is likely to start soon. Consideration of the potential need to provide guidance to any foundation work could be important in ensuring changes are not made without appropriate justification.

A7.3.1.3 ACTION AREA 3

Re-establish the Community research programme.

The CTF was unable to commit to such a broad proposal, but would be open to specific proposals later.

A7.3.1.4 ACTION AREA 4

Propose updates to the air segregation limits.

This was amended in the workshop to read "The air segregation limits were identified as being potentially over restrictive". The methodology for the air segregation limits is provided as an example in IAEA guidance, along with the values assumed in the calculations. The data provided for this report (and values identified in recent studies) suggest that the values assumed were pessimistic by around an order of magnitude, particularly for the type of air shipments commonplace in Europe.

A7.3.1.5 ACTION AREA 5

Update the administrative means for controlling material that used to be termed 'fissile excepted'.

The proposal here does not involve making any change to the technical basis for safety, simply reviewing the administrative processes for applying the controls (in particular the proper shipping names) since these have significant effects in terms of approval (multilateral/unilateral) and willingness to carry material.

A7.3.1.6 ACTION AREA 6

Review Directive 95/50/EC with the goal of introducing harmonised consignor inspection checks.

This was updated during the workshop to read: "Review the need for additional information requirements for roadside checks for radioactive material and guidance for consignor checks". The change in effect avoids changing the current directive, which works well for other dangerous goods. The result is to look at providing additional guidance for information on radioactive material checks at the roadside, and guidance that can be used to support consignor based inspections.

A7.3.1.7 ACTION AREA 7

Review Directive 2006/117/Euratom and the single standard document with the consideration of simplification to focus on transfer of location/ownership of waste and increase in scope to include in-state transfers.

This was generalized at the workshop to: “Review the various directives including Directive 2006/117/Euratom and the single standard document with the consideration of simplification of notification requirements”.

The workshop participants did not consider the application of the Directive within the MS as a desirable option.

A7.3.1.8 ACTION AREA 8

Review the administrative burden related to variation of application between MS taking into account all the legislation applying to the transport of radioactive materials.

This was simplified at the workshop to read: “Identify all the legislation applying to the transport of radioactive material”.. During the workshop some MS identified legislation that others were not familiar with. Clarity over all the legislation applicable was considered a suitable first step.

A7.3.1.9 ACTION AREA 9

Consider the use of freight transport licencing and dangerous goods transport licencing and training as a means for delivering notification/registration and licencing equivalent to the BSS Directive.

The workshop participants did not consider that removal of this duplication of licencing was a priority issue.

A7.3.1.10 ACTION AREA 10

Facilitate compliance assurance that involves the interdependency between State regulators, particularly in the areas of design, testing, manufacture and servicing.

During the workshop there was a suggestion that this could be taken up by one of the regulatory associations.

A7.3.1.11 ACTION AREA 11

A standard set of carrier and consignor responsibilities should be delivered.

This was amended during the workshop to read: “Guidance on carrier and consignor responsibilities should be developed for radioactive material”. This has been an outstanding issue for 30 years and was identified as being relatively simple to solve by some participants at the workshop.

A7.3.1.12 ACTION AREA 12

Clarification of the EPR responsibilities taking into account the all-hazard approach to transport accidents.

This was not considered a priority area by the workshop participants.

A7.3.1.13 ACTION AREA 13

Clear interpretation on the classification of material destined for recycling. Consideration should be given to removing the radioactive exemption to ADR 5.4.1.1.3 as part of this review.

This was simplified to: “Clear interpretation on the classification of material destined for recycling.” at the workshop. The workshop participants felt that the use of ADR 5.4.1.1.3 should be retained.

A7.3.1.14 ACTION AREA 14

An interpretation should be produced on how to resolve the conflict caused by different definitions of the graded approach in transport.

The CTF and the SG did not consider this a priority issue.

A7.3.1.15 ACTION AREA 15

Guidance should be produced on how compliance with the EU requirements for the transport of radioactive material provides equivalence to compliance with the BSS Directive.

The CTF and the SG did not consider this a priority issue.

A7.3.1.16 ACTION AREA 16

Guidance would be beneficial on how to licence an activity involving multiple processes (e.g. storage processing and transport), particularly if this made clear that it is the activity that requires licencing rather than the entities carrying it out.

The CTF and the SG did not consider this a priority issue.

A7.3.1.17 ACTION AREA 17

Produce guidance on the application of compliance assurance in each of the 12 areas of the compliance circle, including how to apply the graded approach to determine a suitable sampling regime.

During the workshop it was noted that the guidance document was being updated by the IAEA and might include this. This was identified as an area where work was currently ongoing.

A7.3.1.18 ACTION AREA 18

Guidance would be beneficial, including examples of a process that could be adopted by MS to manage the review of activities that can bring material within the BSS Directive (e.g. based on the process in Ireland).

Little work was required in respect to this action area, in that the workshop participants indicated that this report contained a reference to the method used in Ireland. This was identified as an area where work was currently ongoing.

A7.3.1.19 ACTION AREA 19

Simple guidance with examples of how to complete the standard transport document could provide valuable support to industry compliance.

During the workshop it was indicated that an organization such as WNTI might be appropriate to carry out this action.

A7.3.1.20 ACTION AREA 20

Guidance should be produced on how to achieve harmonised application of the BSS Directive to transport.

The CTF and the SG did not consider this to be a priority area.

A7.3.1.21 ACTION AREA 21

A simple annual report for the EU should be produced annually.

The CTF and the SG did not consider this to be a priority area.

A7.3.1.22 ACTION AREA 22

It is proposed that an EU body be established incorporating non-regulatory governmental representatives who are responsible for facilitation of the transport of radioactive materials.

It was noted during the workshop that the IAEA was hosting a special event during its annual General Conference on this subject, and may be identifying such a body at the international level. This was identified as an area where work was currently ongoing.

A7.3.1.23 ACTION AREA 23

A review should be produced of barriers to maritime transport including ‘special’ conditions applied by ports and how these might affect the ability of the EU to compete globally.

The workshop found that the WNA might be the appropriate body through which an appropriate person could be identified to carry out this activity.

A7.3.1.24 ACTION AREA 24

It is suggested that the EU develop a packaging information system that is focused on the needs of the EU, including a register of packages and valid serial numbers. This could be extended to include information on inspections that are carried out that might have cross-EU interest.

This was generalized at the workshop to say: “It is suggested that the EU develop a packaging information system that is focused on the needs of the EU, including a register of packages and valid serial numbers. This could be extended if required”. While some members of the workshop did not understand the benefits of the system, others identified extensions that could be of benefit, and as a result the focus on the needs of the EU was considered important.

A7.3.1.25 ACTION AREA 25

Develop an EU capacity building model on the basis of the UK national system.

This was accepted by the workshop participants based on the links provided.

A7.3.1.26 ACTION AREA 26

The EU should encourage training, utilising the list of trainers provided as part of this study, and potentially the IAEA on-line training platform.

This was shortened to: “The Union should encourage training, and potentially the IAEA on-line training platform. Consideration of the need for harmonised tests”. due to concerns over being seen to recommend a limited set of training providers. However, the need for harmonized tests where there were directive requirements for people to pass a test was noted as an important extension (to avoid drivers sitting tests in the MS with the lowest test standard – since tests are accepted in all MS.

A7.3.1.27 ACTION AREA 27

Consideration of extending the EU involvement in SMGS.

This was accepted, with the note that SMGS currently is in line with RID.

A7.3.1.28 ACTION AREA 28

Consideration of establishing a single approval body in the EU for approval of radioactive material transport.

This was simplified during the workshop to: “Encourage cooperation between Competent Authorities in the assessment of packages” on the basis that some cooperation was already taking place.

A7.3.1.29 ACTION AREA 29

Requirements for storage of material in dual purpose casks should be developed, incorporating the need for transport approval prior to use.

This was simplified to: “Dual-purpose casks are being managed in the Union by ensuring transport approval prior to loading”; however, guidance in the proposed IAEA advisory material does not fully support this view.

A7.3.1.30 ACTION AREA 30

Consideration should be given to the need for EU impact assessments of changes to regulatory requirements (including consideration of the potential costs to transport of a lack of harmonisation in implementation).

This was not considered to be a priority area by the workshop participants.

A7.3.1.31 ACTION AREA 31

Involvement of transport experts in processes looking at review of the BSS and Shipment Directives should be ensured.

The importance of all areas of expertise sharing views with each other was accepted by the workshop participants. This was identified as an area where work was currently ongoing.

A7.3.1.32 ACTION AREA 32

Gather more statistics using a low impact system.

This was not considered to be a priority by the workshop participants.

A7.3.1.33 ACTION AREA 33

Information should be made public on the outcome of inspections.

This was expanded at the workshop to: “Information should be made public on the outcome of inspections in line with BSS Directive requirements”, ensuring the link to the form of the information and the legal requirement for it was included.

A7.3.1.34 ACTION AREA 34

Consideration should be given to publishing information based on self-review of peer review based on a system such as the IAEA mini-TranSAS.

This was amended at the workshop to: “Consideration should be given to publishing information based on self-review or peer review based on a system such as the IAEA mini-TranSAS in the event that the IRRS does not cover transport”. This was taken into account the fact that some MS had chosen to include transport in the scope of their IRRS.

A7.3.1.35 ACTION AREA 35

A comprehensive set of interested parties should be developed by MS, and more extensive sharing of information between regulators should be ensured.

During the workshop the particular relevance of the Slovenian example was highlighted: "learn from incidents within the community …, as well as sharing good practices with the aim at improving both safety and security during different modal transports; this group would deal also with occasional concerns of industry on denial of shipment."

A7.3.1.36 ACTION AREA 36

Cross-regulatory familiarization between radiation protection and transport regulators should be implemented.

This was amended at the workshop to say: "Cross-regulatory familiarization between radiation protection and transport regulators should be improved where necessary (taking the example of France as good practice)". The example of France was added as offering good practice.

A7.3.1.37 ACTION AREA 37

A means of speeding up assessments or slowing regulatory change should be considered.

This was not considered a priority at the workshop participants.

A7.3.1.38 ACTION AREA 38

Consideration should be given as to how the existing grouping of MS for Europe and the Mediterranean region can link to Community initiatives.

During the workshop it was noted that this was already happening.

A7.3.1.39 ACTION AREA 39

MS identify a non-regulatory governmental entity to deal with industry promotion and denial of shipment reports that is not a regulator.

This was updated at the workshop to read: "MS identify a non-regulatory governmental entity to deal with industry facilitation and denial of shipment reports that is not a regulator". It was further noted that this would be an issue taken up at the IAEA General Conference.

A7.3.1.40 ACTION AREA 40

Industry should cooperate on learning from incidents.

This was updated during the workshop to: "Industry should cooperate with each other on learning from significant events (through the Competent Authority)", adding the clarification that the BSS Directive suggests that there should be regulatory involvement in the process.

An area that is difficult to provide a recommendation on is the charges levied by regulators, which vary both in size and target. The difficulty arises from the fact that a recommendation can be seen as interfering in taxation; however, the differences are so significant that this could cause barriers to transport.

The individual recommendations have been consolidated into a series of solutions with associated action plans, graded in accordance to their perceived difficulty.

A7.3.2 PROPOSALS FOR IMPROVEMENT

Each of the action areas were considered carefully to develop a reduced number of proposals that could be used to develop a manageable number of action plans. These were initially grouped in terms of their difficulty. The workshop reviewed these and provided guidance on action plans where appropriate.

The proposals developed by the consultants are summarized in **Table 44**.

Table 44: Proposals developed by the consultants

Proposal	Action Area
A	Shipment Directive
B	Clearance levels
C	BSSD implementation, in particular for transport
D	Emergency preparedness and response
E	European Regulatory Body
F	European Package Information System and the Open Market
G	Capacity building
H	Interface between transport, radioactive waste and radiation protection communities
I	Barriers to the open market
J	Data gathering
K	Report production
L	Regulatory input
M	Guide production

A7.3.2.1 PROPOSAL A — SHIPMENT DIRECTIVE AA7

Challenges raised

- Covers a small fraction of shipments between MS;
- Covers a tiny fraction of all shipments;
- A standard document for transport is already established internationally, backed by the Directive for ALL shipments of dangerous goods, including radioactive material — Shipment Directive standard document duplicates many of these items;
- Approach reinforces the concept of internal borders;
- Shipment Directive standard document contains errors (e.g. reference to outdated IAEA documents rather than relevant EU directives);
- Shipment Directive standard document requires information that could be security sensitive in some States;
- Does not ensure regulatory cover where there are multiple regulators in a MS (national responsibility of the CA).

Potential solution

The essential need is to ensure continuity of regulatory cover when radioactive materials are moved and/or ownership is transferred. The proposal is to both reduce and extend the scope of the directive. To extend the directive to cover all changes of location or ownership of radioactive materials (some exemptions would be required for medical and radiography businesses, for example, by only requiring quarterly notification). To reduce the scope to only require information related to ownership and location (not transport).

Directive 2008/68/EC implements the ADR, which sets out legal requirements for transport documentation for road transport.

This includes:

- UN Number;
- Proper shipping name;
- The number "7" for radioactive materials;
- The number and description of the packages;
- The radionuclides;
- Physical and chemical form;
- Maximum activity (or mass in g for fissile material);
- Package category;
- Transport index;
- Information on fissile material if present;
- Identification mark of every CA certificate applicable.

These must be in the order given with no information interspersed:

- The total quantity of material;
- The name and address of the consignor;
- The name and address of the consignee;
- Any special agreement declaration;
- Any assigned tunnel restriction code.

Additional documentation provided by the consignor should include:

- Loading, stowage, carriage, handling and unloading instructions and heat dissipation requirements or a statement confirming these are not required;
- Restrictions on mode of carriage;
- Emergency arrangements.

This includes a significant amount of information required in the standard document for the supervision and control of shipments of radioactive waste and spent fuel and the use of the mandatory transport document as a standard attachment to the standard document could simplify information provision, avoid duplication and avoid errors.

In addition to this the current standard document contains information that is:

- Outdated:
    - Reference to old IAEA documents (newer versions include a specific package for large waste shipments).
- Potentially of limited relevance to the purpose of the directive:
    - Mode of transport.
- Potentially of concern to security:
    - Locations of transport hubs and dates of shipments.

Action plan

- Outline goals for the simplification of reporting requirements.

A7.3.2.2 PROPOSAL B - CLEARANCE LEVELS AA2

Challenges raised

- The BSS Directive allows different levels in different MS:
  - This opens the door to cross-border dumping of material (see discussion in Chapter 9.3.2 under BSS Directive Article 25);
  - This causes legal issues since cleared material need not be notified (it is not obvious whether clearance in another MS needs to be accepted, but it probably does).
- An in-depth check of the models deriving the different levels (clearance, exemption, codex) suggests that there are at best typos, and certainly logical inconsistency. The precision probably gives a false impression of accuracy;
- Clearance levels are at the lowest level of safety significance, but the variable approach results in the greatest regulatory complexity in the community.

Potential solution

The IAEA is apparently about to carry out a review of the clearance levels; strong Community input to the review is proposed. Although there is opposition to harmonised clearance levels between MS, the goal should be to determine levels acceptable in all MS.

Action plan

Following the second workshop, this solution was not taken forward at this time.

A7.3.2.3 PROPOSAL C – BSS DIRECTIVE IMPLEMENTATION, IN PARTICULAR FOR TRANSPORT AA1 AA9 AA14 AA15 AA20

Challenges raised

- The IAEA BSS contains a footnote exempting transport from notification and registration, except where this is implemented through the transport requirements (the concept is that the transport requirements should implement the BSS in transport). This has not been explicitly included in the BSS Directive and, as a result, may leave room for interpretation;
- The BSS Directive concept of the graded approach appears to be significantly different from that of the IAEA in that it does not permit graded application of regulation;
- Licencing for the transport of dangerous goods is already well established in the EU in a harmonised manner, and the evidence of implementation of licencing for the transport of radioactive materials under the BSS Directive demonstrates a significant reduction of EU/Community harmonisation and duplication of licences;
- The implementation for transport applies the same requirements to different people in different MS, providing overlaps, gaps and confusion over primary responsibilities.

Potential solution

Generally, the BSS Directive does not require harmony in implementation to function effectively, except for transport. The proposal is to use the transport directives and regulations (Directive 2008/68/EC as modified by Commission Directive 2016/2309; EU Regulations 965/2012 and 376/2014; and maritime modal regulations) as an equivalent means of applying the BSS Directive to transport.

Action plan

Following the second workshop, this solution was not taken forward at this time.

A7.3.2.4 PROPOSAL D - EPR AA12

Challenges raised

- The responses indicted that the responsibilities for emergency preparedness and response vary between MS in a manner that leaves gaps (although this is more likely a case of poor understanding by regulators leading to a poor response);
- The responsibilities for planning, exercising and response differ within certain MS;
- Some MS did not provide responses — if regulators are unable to provide information it is likely that industry will be unable to determine responsibilities;
- There are clear errors in the approach of some MS (potentially coming from applying a site based approach to transport);
- There are adequate measures in place in most MS for responding to transport accidents (with or without radioactive materials), but only a few MS appeared to be aware of them.

Potential solution

Initially, the information collected in the study needs to be made openly available to industry. In the longer run, establishing clarity over transport emergency preparedness and response and how it satisfies requirements (including the BSS Directive) is proposed in order to ensure regulators are aware that there is an existing system that leaves no gaps.

Action plan

Following the second workshop, this solution was not taken forward at this time.

A7.3.2.5 PROPOSAL E - EUROPEAN REGULATORY BODY AA28 AA37

Challenges raised

- Only a limited number of regulators have capability in all areas of compliance;
- Different MS have different areas of focus;
- There are multiple approvals in the EU for the same items against the same regulations.

Potential solution

The lack of approval and assessment expertise in the EU, along with the duplication of effort in approving the same items to the same regulations many times might suggest the setting up of a system of recognition of certificates. However, the proposal is for the establishment of a European TSO/approval body. Furthermore, the interdependency of compliance checks between MS has not been recognised by many MS, and the EU would benefit from a unified regulator checking compliance. Since this is unlikely to be realised, the next item provides an easier alternative measure.

Action plan

Following the second workshop, this was updated to "Coordination on assessment of packages":

- Communicate on assessment of packages among regulators.

A7.3.2.6 PROPOSAL F — EUROPEAN PACKAGE INFORMATION SYSTEM AND THE OPEN MARKET AA10 AA24

Challenges raised

- There are clear interdependences between MS that do not seem to be recognised;
- Several regulators were unable to identify how many package designs existed in their State, several failed to maintain a serial number list as required by legislation;
- Information sharing should be an essential part of regulatory compliance (for example, knowing that the regulator in the country of origin of a package is aware it exists);
- The IAEA provided a database previously that industry and regulators in the EU believed was useful, but it was closed over ten years ago.

Potential solution

While there would seem to be a benefit in encouraging the IAEA to re-establish its international database, there is no guarantee it would continue to function, or meet the needs of the EU. As a result ,the proposal is to establish an EU database of package designs incorporating aspects that would benefit regulatory compliance (which the IAEA and USA databases do not have).

Action plan

- Based on experience with PACKTRAM, identify useful information (and information that creates a collection burden);
- Consider whether an existing system can be adapted to the purpose;
- Determine the system specification, at a minimum including package approval information (e.g. package type, approval date, expiry date);
- Consider hosting and long-term operation (e.g. JRC);
- Create an information system and populate with existing data;
- Define a sustainable system for maintaining the database.

A7.3.2.7 PROPOSAL G - CAPACITY BUILDING AA25 AA26 AA36

Challenges raised

- Training is sporadic in the EU, and very limited in terms of regulators;
- A wide range of training providers are available and have been listed in the report;
- We believe that most regulators have not established a clear long-term resource requirement plan, based on their responses and follow up discussions;
- Evidence exists that the amount of regulatory resources is going down in comparison to needs.

Potential solution

The proposal is to adopt a capacity building strategy in the EU which initially provides good evidence of the current and future resource requirements and availability and, in the longer-term establishes a co-ordinated programme for developing adequate expertise. One option would be to host IAEA training on the condition that European regulators had free access to the training course. A particular short-term gap that needs to be filled is the cross-training between transport and radiation protection experts in the regulatory communities (see next item).

Action plan

Short term :

- Develop cross-training of transport and radiation protection experts.

Long term:

- Consider UK good practice;
- Gather information on short and long-term requirements in a coordinated manner;
- Establish a co-ordinated programme (including industry/regulator partnerships) for developing adequate competence for transport.

A7.3.2.8 PROPOSAL H — INTERFACE BETWEEN TRANSPORT, RADIOACTIVE WASTE AND RADIATION PROTECTION COMMUNITIES AA27 AA31 AA38

Challenges raised

- Clarity over the competence framework suggested for the Article 31 group or the Shipment Directive group has not been made available, nor has the actual areas of competence of the members;
- Ensuring that there is an effective interface between experts of all kinds in the development of EU/Community legislation is essential to avoid conflicts.

Potential solution

The proposal is to ensure that a means of communication between different groups be established in the development and revision of regulations (transport, radiation protection and waste experts).

Action plan

- Share MS expert contacts between the three groups (radiation protection, waste and transport) to encourage co-ordination at the national level (potentially making use of groups such as EACA);
- Establish the Commission's contact points for each group and ensure sharing of information related to expert opinion and proposals.

A7.3.2.9 PROPOSAL I - BARRIERS TO THE OPEN MARKET AA8 AA22 AA23 AA30 AA39

Challenges raised

- Some MS do not permit the carriage of certain materials on their territory;
- Some MS have enhanced approvals that make transport difficult;
- Some infrastructure is limited (e.g. the number of ports that will handle radioactive materials);
- Some problems are related to errors of consignors; however regulators may see dealing with denial as a conflict of interest.

Potential solution

The proposal is to establish EU and national bodies with a responsibility for facilitation of the transport of radioactive materials that are separate from the regulatory bodies. An initial task for this group is proposed to be a review of all ports in the EU to establish the ability to handle radioactive materials, including restrictions in terms of time and paperwork. In addition, the proposal is to carry out a legal review of the barriers currently in place.

Action plan

- Request MS to appoint a non-regulatory government body for facilitation of transport of radioactive material, and ensure that the list is made public;
- Implement activities related to DoS as required, including:
    - Review of the costs of any new regulatory proposals affecting the transport of radioactive materials;
    - Review of all ports in the EU to establish the ability to handle radioactive materials, including restrictions in terms of time and paperwork;
    - Legal review of the barriers reported as being currently in place due to diverging implementation of directives.

A7.3.2.10 PROPOSAL J — DATA GATHERING AA32

Challenges raised

- There is existing legislation apparently unknown to the MS that requires collection of data;
- Lack of data has been identified as a key area affecting the ability to ensure effective compliance.

Potential solution

Simple data collection would make a major improvement to compliance and would not require further legislation. Over-complication of the requirement could defeat the purpose, so initially the system proposed is simple and frequent reporting in line with current legislation.

Action plan

Following the second workshop, this solution was not taken forward at this time.

A7.3.2.11 PROPOSAL K — REPORT PRODUCTION AA21 AA33 AA34 AA35

Challenges raised

- There have been requests for more information by the European Parliament on a frequent basis;
- Lack of transparency was noted during the collection of information.

Potential solution

A simple annual report format has been proposed based on the data collection. The proposal is to not repeat the long complex reports produced previously by the SWG, but to limit the report to a dashboard type response, ensuring simple and low cost rapid production.

Action plan

Renamed during the second workshop as “Transparency”:

- Regulators to identify lead;
- Initially ensure the report remains simple, but:
    - Consider including consolidated incident data that should be collected at some point;
    - Consider including peer review data if produced at some point;
    - Consider including assessment of public exposure information (see BSS Directive Article 66).

A7.3.2.12 PROPOSAL L — REGULATORY INPUT AA3 AA4 AA5 AA6 AA13 AA29

Challenges raised

- Through the SWG, the EU/Community has been at the heart of the development of international transport requirements, and this no longer takes place because the SWG no longer meets;
- A small research budget managed through the SWG previously provided the basis for many of the most significant improvements in the IAEA Transport Regulations, but this was withdrawn because of insufficient budget.

Potential solution

Re-establishing the work of the SWG in leading the improvements in international regulations is proposed, with the suggestion that a research budget would provide significant leverage in ensuring that the Community maintains a leading role.

Action plan

- Reflect building on existing groups (e.g. EACA, MedNet) for considering regulatory issues;
- Establish a prioritised list of issues where significant change to regulations may be required, including:
    - Air segregation requirements;
    - Administrative requirements for former fissile-excepted material;
    - Definition of waste: Commission to decide on activity to consider whether there is systematic non-declaration as waste;
    - Consideration of ageing management of dual purpose casks prior to loading;
    - Examination of the issues related to self-approved packages, including current best practice.

A7.3.2.13 PROPOSAL M — GUIDE PRODUCTION AA11 AA16 AA17 AA18 AA19 AA40

Challenges raised

- A number of guides were identified as being beneficial:
    - Guidance documents for industry to assist compliance;
    - Guidance documents for regulators on standards for compliance.
- The European Parliament has repeatedly asked for guidance on carrier and consignor responsibilities over several decades and it has not been produced.

Potential solution

It is proposed that these guidance documents are an 'easy win'. However, to ensure they are produced, a programme for guide development needs to be established and managed. The first guide should set out carrier and consignor responsibilities, considering the ADR requirements.

Action plan

- Establish a prioritised list of guidance documents, considering:
    - Consignor and carrier responsibilities (considering the ADR);
    - Application of the graded approach in compliance assurance;
    - Assessing exposures to the public (see BSS Directive Article 66).
- Produce the documents on a prioritised basis;
- Establish a transport operational learning forum for industry for producing guidance from lessons learned.

A7.4 SPECIFIC ITEMS FROM WORKSHOP 2

Some additional items were identified as being worth noting during the second workshop:

- Important to keep regular dialogue between MS regulators at the EU level;

- There is a Convention on Dangerous goods transport liability that is not in force;
- Nuclear liability may be an issue for denial of shipment;
- The minimum level in transport regulation is above the minimum exemption level in the BSS, potentially creating a confusion;
- All regulators need to systematically assess the impact of transport on the doses to the public (see BSSD Article 66);
- Directive 2008/68/EC (cf Articles 5 and 6) sets minimum concentrations of radionuclides that may be applied in transport for safety reasons. The minimum values in the BSS Directive are lower, but MS are permitted to apply higher values. The evidence is that MS have failed to take both directives into account, leading to a lack of harmony with no significant safety benefit.

A7.5 ITEMS NOT CONSIDERED A PRIORITY

In the process of refining the work to be carried out to produce a manageable list, there were a number of items removed at the second workshop. However, a request was made that these items should not be deleted, but should be retained for future reference. These are:

- Reviewing the legal basis of Footnote 18 of the IAEA BSS, and the need for it in the BSS Directive;
- Reviewing the clearance levels (technically) and applying a fixed level for the Community;
- Re-establishing the Community research programme;
- Considering the use of freight transport licencing and dangerous goods transport licencing and training as a means for delivering notification/registration and licencing equivalent to the BSS Directive;
- Clarifying the EPR responsibilities, considering the all-hazard approach to transport accidents;
- Consideration given to removing the radioactive exemption to ADR 5.4.1.1.3 as part of this review;
- Formulating an interpretation of how to resolve this conflict caused by different definitions of the graded approach in transport;
- Developing guidance on how compliance with the EU requirements for the transport of radioactive materials provides equivalence to compliance with the BSS Directive;
- Developing guidance on how to licence an activity involving multiple processes (e.g. storage processing and transport), particularly if this made clear that it is the activity that requires licencing rather than the entities carrying it out;
- Developing guidance on how to achieve harmonised application of the BSS Directive to transport;
- Preparing a simple annual report for the EU;
- Consideration given to the need for EU impact assessments of changes to regulatory requirements (including consideration of the potential costs to transport of a lack of harmonisation in implementation);
- Gathering information important to safety using a low-impact system;
- Devising a means of speeding up assessments or slowing regulatory change.

A8 DATA RECORDING

It is important to understand the industry for a number of reasons, not least of which is the ability to ensure that adequate compliance assurance is in place and is optimised. At the same time, it is important to manage data collection in a manner which minimises the burden on industry and regulator alike.

The Italian data collection system is used as a guide for the collection of data on shipments, with a level of simplification. Generally, the EU requires statistical returns on a quarterly basis, and it is suggested to harmonise this frequency for infrastructure data, while working on an annual return for the compliance assurance records.

A8.1 INFRASTRUCTURE RECORDS

These data should be collected on a quarterly basis and are intended to guide actions related to compliance and denial of shipment. In order to ensure consistency, the data collection is aimed at gathering information from consignors, particularly since they have primary responsibility for safety. These data are provided as an initial suggestion, subject to EU discussion and agreement.

A8.1.1 DATA FROM CONSIGNORS

Number of packages consigned for multi-modal journeys count in each mode:

- Group I UN 2908; UN 2909; UN 2910; UN 2911; UN 3507; UN 2915; UN 3332.
- Group II UN 2912; UN 3321; UN 3322; UN 3324; UN 3325; UN 2913 UN 3326.
- Group III UN 3327; UN 3333; UN 2916; UN 2917; UN 3328; UN 3329; UN 3323; UN 3330; UN 2919; UN 3331; UN 2977; UN 2978.

	Road	Rail	Air	Sea	Inland Waterways
Group I					
Group II					
Group III					

Names of carriers used.

A8.1.2 BACKGROUND DATA

Number of major airports / number of airports where radioactive material is transported.

Number of major sea ports / number of sea ports where radioactive material is transported.

A8.2 COMPLIANCE ASSURANCE RECORDS

This data is collected from regulatory bodies, and annual reporting is considered appropriate.

A8.2.1 REGULATORY

Regulation in force for each mode.

A8.2.2 EPR

	Road	Rail	Air	Sea	Inland Waterways
Number of Emergency Plans Reviewed					
Number of Emergency Exercises					
Number of Emergency Exercises Witnessed					

A8.2.3 TRANSPORT OPERATIONS

	Road	Rail	Air	Sea	Inland Waterways
Consignment operations inspected					
Carrier operations inspected					

A8.2.4 ENFORCEMENT/INVESTIGATION

	Consignors	Road	Rail	Air	Sea	Inland Waterways
Number of Investigations						
Number of Enforcement Actions						

A8.2.5 MANUFACTURE

	Packages requiring CA approval	Packages not requiring CA approval
Estimated number of packages manufactured		

	Records	Packages requiring CA approval	Packages not requiring CA approval	International checks
Number of inspections of package manufacturing				

A8.2.6 TESTING

	Packages requiring CA approval	Packages not requiring CA approval
Estimated number of tests carried out		

	Records	Packages requiring CA approval	Packages not requiring CA approval	International checks
Number of inspections of package tests				

A8.2.7 MAINTENANCE/SERVICING

	Packages requiring CA approval	Packages not requiring CA approval
Estimated number of packages maintained / serviced		

	Records	Packages requiring CA approval	Packages not requiring CA approval	International checks
Number of inspections of package servicing / maintenance				

A8.2.8 ASSESSMENT

	Packages requiring CA approval	Packages not requiring CA approval
Estimated number of package assessments		

A8.2.9 MANAGEMENT SYSTEMS

	Consignor	Carrier
Number of management systems audited		
Number of RPPs reviewed		

A8.2.10 LIAISON/COOPERATION

	National	International
Number of liaison meetings		
Number of joint inspections		

A8.2.11 APPROVALS

	Country of Origin Package Approvals	EU		Non-EU	
		Multilateral Approvals by Re-certification	Multilateral approvals by Validation	Multilateral Approvals by Re-certification	Multilateral approvals by Validation
Number of approvals					

A8.2.12 TRAINING/INFORMATION

	Carriers	Consignors	Regulators	First Responders	Police	Customs