Examination of the Certification Methodology of EU States and Applicant Countries and Associate Recommendations for Allowing Joint Agreement/ Certification of Packages Related to the National and International Transport of Radioactive Materials

Final Report

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Contents

1 GENERAL INFORMATION 9

1.1 REFERENCE NO. OF THE STUDY 9

1.2 TITLE OF THE STUDY 9

1.3 SHORT DESCRIPTION OF THE PROJECT 9

1.4 DETAILED DESCRIPTION OF THE PROJECT 9

2 ACRONYMS 11

3 INTRODUCTION 13

4 SUMMARY 15

4.1 GLOBAL RECOMMENDATIONS RELATIVE TO THE ISSUE "LEGAL BASIS" 15

4.2 GLOBAL RECOMMENDATIONS RELATIVE TO THE ISSUE "APPLICATION AND REQUESTED DOCUMENTS" 18

4.3 GLOBAL RECOMMENDATIONS RELATIVE TO THE ISSUE "APPROVAL PROCEDURE" 20

4.4 GLOBAL RECOMMENDATIONS RELATIVE TO THE ISSUE "SAFETY ASSESSMENT PROCEDURE" 26

4.5 GLOBAL RECOMMENDATIONS RELATIVE TO THE ISSUE "JOINT CERTIFICATION PRACTICES" 30

5 DESCRIPTION OF THE EVALUATION METHOD 31

5.1 LITERATURE SURVEY 31

5.2 DEVELOPMENT OF THE STRUCTURE OF THE PARTICIPATING COUNTRIES METHODOLOGY 31

5.3 COUNTRY REPORTS (GERMANY, FRANCE, UK) 31

5.4 QUESTIONNAIRE TO EU MEMBER STATES AND APPLICANT COUNTRIES 31

5.5 EVALUATION OF THE RESPONSES TO THE QUESTIONNAIRE 32

5.6 APPROVAL METHODOLOGY IN GERMANY 35

5.6.1 Legal basis for the Competent Authority (CA) and technical support (TS) 35

5.6.1.1 National and international laws, regulations and guidelines for package design and shipment approvals 35

5.6.1.2 Competent authority 35

5.6.1.2.1 Name, address, nomination and responsibilities 35

5.6.1.2.2 Organization 36

5.6.2 Approval methodology 37

5.6.2.1 Application and requested documents for package design approval 37

5.6.2.1.1 Approval of new package designs 37
5.6.2.1.2 Multilateral approval/validation of foreign package designs 38
5.6.2.1.2.1 Package designs for fissile material and Type B(M) package design 38
5.6.2.1.2.2 Package designs subject to transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 39
5.6.2.2 Description of the approval procedure 39
5.6.2.2.1 Organization of the approval procedure of a new package design 39
5.6.2.2.2 Procedure in the case of modifications of the package design 40
5.6.2.2.3 Procedure for multilateral approval/validation 40
5.6.2.2.3.1 Package designs for fissile material 40
5.6.2.2.3.2 Type B(M) package design 40
5.6.2.2.3.3 Package designs subject to transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 40
5.6.2.3 Description of the safety assessment procedure 40
5.6.2.3.1 Organization of the assessment procedure 40
5.6.2.3.2 Safety assessment methods 41
5.6.2.3.3 Accepted calculation methods 41
5.6.2.3.4 Performance of package design tests 42
5.6.2.3.5 Structure of the assessment report 42
5.6.2.4 Shipment approval methodology including special arrangement 43
5.6.2.4.1 Shipment approval 43
5.6.2.4.2 Special arrangement 44
5.6.3 Description of the approval certificate 44
5.6.3.1 Structure of a approval certificate (e. g. Type B(U)/B(U)F) 44
5.6.3.2 Consideration of modifications of the package design in the approval certificate 45
5.6.3.3 Structure of a multilateral approval certificate/validation of a foreign approval certificate 46
5.6.3.4 Structure of a shipment approval certificate 46
5.6.4 Joint certification practices 46

5.7 APPROVAL METHODOLOGY IN FRANCE 47
5.7.1 Legal Basis for competent authority and technical support 47
5.7.1.1 National and international laws, regulations and guidelines for package design and shipment approvals 47
5.7.1.2 Competent authority 47
5.7.1.2.1 Name, address, nomination and responsibilities 47
5.7.1.2.2 Legal form and organization structure 47
5.7.1.3 Technical support 48
5.7.1.3.1 Name, address, nomination and responsibilities 48
5.7.1.3.2 Legal form and organization structure 48
5.7.2 Approval methodology in France 49
5.7.2.1 Description of the approval procedure 49
5.7.2.1.1 Organization of the approval procedure of a new package design 49
5.7.2.1.2 Procedure in the case of modifications of the package design 50
5.7.2.2 Description of the safety assessment procedure 50
5.7.2.2.1 Performance of package design tests 50
5.7.2.2.2 Organization of the assessment procedure 51
5.7.2.2.3 Safety assessment methods 51
5.7.2.3 Appraisal extent 53
5.7.3 Description of the approval certificate 55
5.7.3.1 Structure of a type b(u)f certificate 55
5.7.3.2 Indexation for certificates and consideration of modifications of the package design in the approval certificate of a French package design 56
5.7.3.3 Structure of a multilateral approval certificate / validation of foreign approval certificate 57
5.7.3.4 Structure of a shipment approval under special arrangement 58
5.7.4 Joint certification practices 58

5.8 APPROVAL METHODOLOGY IN THE UNITED KINGDOM 59
5.8.1 Legal basis for the Competent Authority and technical support 59
5.8.1.1 National and international laws, regulations and guidelines for package design and shipment approvals 59

5.8.1.2 Competent authority 59
5.8.1.2.1 Name, address, nomination and responsibilities 59
5.8.1.2.2 Legal form and organization structure 59
5.8.2 Approval methodology 60
5.8.2.1 Application and requested documents for package design approval 60
5.8.2.1.1 Unilateral approval of new package designs 60
5.8.2.1.2 Multilateral approval/validation of foreign package designs 61
5.8.2.1.2.1 Package designs for fissile material 61
5.8.2.1.2.2 Type B(M) package design 61
5.8.2.2 Description of the approval procedure 62
5.8.2.2.1 Organization of the approval procedure of a new package design 62
5.8.2.2.2 Procedure in the case of modifications of the package design 62
5.8.2.2.3 Procedure for multilateral approval/validation 63
5.8.2.2.3.1 Package designs for fissile material 63
5.8.2.2.3.2 Type B(M) package design 64
5.8.2.2.3.3 Package designs subject to transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 64
5.8.2.3 Description of the safety assessment procedure 64
5.8.2.3.1 Organization of the assessment procedure 64
5.8.2.3.2 Safety assessment methods 64
5.8.2.3.3 Accepted calculation methods 65
5.8.2.3.4 Performance of package design tests 65
5.8.2.3.5 Structure of the assessment report 66
5.8.2.4 Shipment approval methodology including special arrangement 66
5.8.3 Description of the approval certificate 67
5.8.3.1 Structure of a approval certificate (e. g. Type B(U)/B(U)F) 67
5.8.3.2 Consideration of modifications of the package design in the approval certificate 68
5.8.3.3 Structure of a multilateral approval certificate/validation of a foreign approval certificate 68
5.8.3.4 Structure of a shipment approval certificate 69
5.8.4 Joint certification practices 69

6 ANALYSES OF THE RESPONSES TO THE QUESTIONNAIRES 70

6.1 GENERAL FINDINGS OF EXPERIENCES IN APPROVAL AND SAFETY ASSESSMENT PRACTICES 70

6.2 DETAILED ANALYSES OF THE RESPONSES TO THE QUESTIONNAIRES IN ITEM TABLES 71
6.2.1 Legal basis and general organization 71
6.2.1.1 Item: Applicable regulations 71
6.2.1.1.1 List of practices 71
6.2.1.1.2 Categorization of different practices 79
6.2.1.1.3 Summary and Discussion 79
6.2.1.1.4 Conclusions and Recommendations 80
6.2.1.2 Item: Nomination and responsibilities of competent authority (CA) 81
6.2.1.2.1 List of practices 81
6.2.1.2.2 Categorization of different practices 89
6.2.1.2.3 Summary and Discussion 89
6.2.1.2.4 Conclusions and Recommendations 90
6.2.1.3 Item: Responsibilities for performance of regulatory tests 91
6.2.1.3.1 List of practices 91
6.2.1.3.2 Categorization of different practices 93
6.2.1.3.3 Summary and Discussion 93
6.2.1.3.4 Conclusions and Recommendations 94
6.2.1.4 Item: Nomination and responsibilities of assessment organization 95
6.2.1.4.1 List of practices 95
6.2.1.4.2 Categorization of different practices 98
6.2.1.4.3 Summary and Discussion 98
6.2.1.4.4 Conclusions and Recommendations 98
6.2.1.5 Item: Costs of certification and/or assessment 100

6.2.1.5.1 List of practices 100
6.2.1.5.2 Categorization of different practices 103
6.2.1.5.3 Summary and Discussion 103
6.2.1.5.4 Conclusions and Recommendations 103
6.2.2 Application and requested documents 104
6.2.2.1 Item: Documents requested complementary to those required by ADR (6.4.23) for unilateral approval 104
6.2.2.1.1 List of practices 104
6.2.2.1.2 Categorization of different practices 110
6.2.2.1.3 Summary and Discussion 110
6.2.2.1.4 Conclusions and Recommendations 111
6.2.2.2 Item: Application requirements referring to ADR for multilateral approval/ validation 113
6.2.2.2.1 List of practices 113
6.2.2.2.2 Categorization of different practices 117
6.2.2.2.3 Summary and Discussion 117
6.2.2.2.4 Conclusions and Recommendations 117
6.2.2.3 Item: Application requirements referring to ADR for shipment approval and shipment under special arrangement 119
6.2.2.3.1 List of practices 119
6.2.2.3.2 Categorization of different practices 122
6.2.2.3.3 Summary and Discussion 122
6.2.2.3.4 Conclusions and Recommendations 122
6.2.2.4 Item: Design Safety Report 123
6.2.2.4.1 List of practices 123
6.2.2.4.2 Categorization of different practices 128
6.2.2.4.3 Summary and Discussion 128
6.2.2.4.4 Conclusions and Recommendations 128
6.2.3 Approval procedure 130
6.2.3.1 Item: Procedure and guidelines for competent authority and technical support 130
6.2.3.1.1 List of practices 130
6.2.3.1.2 Categorization of different practices 136
6.2.3.1.3 Summary and Discussion 136
6.2.3.1.4 Conclusions and Recommendations 138
6.2.3.2 Item: Package design modification procedure for unilateral approval 140
6.2.3.2.1 List of practices 140
6.2.3.2.2 Categorization of different practices 145
6.2.3.2.3 Summary and Discussion 145
6.2.3.2.4 Conclusions and Recommendations 145
6.2.3.3 Item: Certificate renewal without change of package design 147
6.2.3.3.1 List of practices 147
6.2.3.3.2 Categorization of different practices 149
6.2.3.3.3 Summary and Discussion 149
6.2.3.3.4 Conclusions and Recommendations 149
6.2.3.4 Item: Additional practice for validation of a multilateral approval for package designs for fissile material (certificate AF, IF, B(U)F, B(M)F and CF) 150
6.2.3.4.1 List of practices 150
6.2.3.4.2 Categorization of different practices 153
6.2.3.4.3 Summary and Discussion 153
6.2.3.4.4 Conclusions and Recommendations 153
6.2.3.5 Item: Additional practice for validation of a multilateral approval for type B(M) package design 155
6.2.3.5.1 List of practices 155
6.2.3.5.2 Categorization of different practices 158
6.2.3.5.3 Summary and Discussion 158
6.2.3.5.4 Conclusions and Recommendations 158
6.2.3.6 Item: Additional practice for validation of package designs subject to transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 159
6.2.3.6.1 List of practices 159
6.2.3.6.2 Categorization of different practices 162
6.2.3.6.3 Summary and Discussion 162
6.2.3.6.4 Conclusions and Recommendations 162

6.2.3.7 Item: Additional practice for shipment approval 164
6.2.3.7.1 List of practices 164
6.2.3.7.2 Categorization of different practices 166
6.2.3.7.3 Summary and Discussion 166
6.2.3.7.4 Conclusions and Recommendations 166
6.2.3.8 Item: Additional practice for shipment approval under special arrangement 167
6.2.3.8.1 List of practices 167
6.2.3.8.2 Categorization of different practices 170
6.2.3.8.3 Summary and Discussion 170
6.2.3.8.4 Conclusions and Recommendations 170
6.2.3.9 Item: Validity of certificates 171
6.2.3.9.1 List of practices 171
6.2.3.9.2 Categorization of different practices 176
6.2.3.9.3 Summary and Discussion 176
6.2.3.9.4 Conclusions and Recommendations 176
6.2.3.10 Item: Structure of unilateral approval certificate 178
6.2.3.10.1 List of practices 178
6.2.3.10.2 Categorization of different practices 184
6.2.3.10.3 Summary and Discussion 184
6.2.3.10.4 Conclusions and Recommendations 184
6.2.3.11 Item: Structure of multilateral Approval certificates, shipment approval and shipment approval under special arrangement 186
6.2.3.11.1 List of practices 186
6.2.3.11.2 Categorization of different practices 190
6.2.3.11.3 Summary and Discussion 190
6.2.3.11.4 Conclusions and Recommendations 190
6.2.4 Safety assessment procedure 192
6.2.4.1 Item: Procedure and guidelines for competent authority, technical support and the applicants 192
6.2.4.1.1 List of practices 192
6.2.4.1.2 Categorization of different practices 195
6.2.4.1.3 Summary and Discussion 195
6.2.4.1.4 Conclusions and Recommendations 196
6.2.4.2 Item: Organization of safety assessment procedure 197
6.2.4.2.1 List of practices 197
6.2.4.2.2 Categorization of different practices 203
6.2.4.2.3 Summary and Discussion 203
6.2.4.2.4 Conclusions and Recommendations 204
6.2.4.3 Item: Accepted calculation methods for assessment 205
6.2.4.3.1 List of practices 205
6.2.4.3.2 Categorization of different practices 213
6.2.4.3.3 Summary and Discussion 213
6.2.4.3.4 Conclusions and Recommendations 214
6.2.4.4 Item: Test program for package design 215
6.2.4.4.1 List of practices for the item and issue above 215
6.2.4.4.2 Categorization of different practices 218
6.2.4.4.3 Summary and Discussion 218
6.2.4.4.4 Conclusions and Recommendations 218
6.2.4.5 Item: Performance of package design tests by the applicant and tests for special proofs 219
6.2.4.5.1 List of practices 219
6.2.4.5.2 Categorization of different practices 221
6.2.4.5.3 Summary and Discussion 221
6.2.4.5.4 Conclusions and Recommendations 221
6.2.4.6 Item: Issue of an assessment report and its structure 221
6.2.4.6.1 List of practices 222
6.2.4.6.2 Categorization of different practices 228
6.2.4.6.3 Summary and Discussion 228
6.2.4.6.4 Conclusions and Recommendations 228
6.2.4.7 Item: Assessment time according to the approval certificate type 229
6.2.4.7.1 List of practices 229
6.2.4.7.2 Summary and Discussion 232
6.2.4.7.3 Conclusions and Recommendations 232

6.2.4.8 Item: Difficulties encountered several times during assessment 233
6.2.4.8.1 List of practices 233
6.2.4.8.2 Summary and Discussion 234
6.2.4.8.3 Conclusions and Recommendations 235
6.2.5 Joint certification practices 236
6.2.5.1 List of practices 236
6.2.5.2 Categorization of different practices 237
6.2.5.3 Summary and Discussion 237
6.2.5.4 Conclusions and Recommendations 238

7 CONCLUSIONS AND RECOMMENDATIONS 239

8 REFERENCES 240

ANNEX 1 STRUCTURE OF THE EC-PROJECT 4.1020/D/02-001 247

ANNEX 2 QUESTIONNAIRE (WORD EDITION) 249

ANNEX 3 TABLE ABOUT THE CONCERNED ITEMS FROM THE QUESTIONNAIRE TO BE INVESTIGATED – ACCORDING TO THE STRUCTURE OF THE EC-PROJECT (SEE ANNEX 1) 255

ANNEX 4 MINIMUM CONTENT FOR CONSIDERATION IN THE STRUCTURE OF GUIDANCE MATERIAL FOR APPLICATION 257

ANNEX 5 STRUCTURE OF A DESIGN SAFETY REPORT (DSR) 258

ANNEX 6 TEST PROGRAM 260

ANNEX 7 RECOMMENDED STRUCTURE FOR DESIGN SAFETY REPORTS (DSR STRUCTURE OF AN ASSESSMENT REPORT OF A PACKAGE DESIGN 261

ANNEX 8 EXPERIENCE FEEDBACK IN THE APPRAISAL OF PACKAGE DESIGN SAFETY 263

ANNEX 9 MINIMUM CONTENT FOR UNILATERAL APPROVAL CERTIFICATES 270

1 GENERAL INFORMATION

1.1 REFERENCE NO. OF THE STUDY

Grant Agreement No. 4.1020/D/02-001

1.2 TITLE OF THE STUDY

Examination of the certification methodology of EU States and applicant countries and associate recommendations for allowing joint agreement/ certification of packages related to the national and international transport of radioactive materials.

1.3 SHORT DESCRIPTION OF THE PROJECT

Objectives of the project are to get a basis for recommendations towards an european harmonized approach in safety assessment and approval of packages. Therefore the certification methodology of EU states and applicant countries has to be examined and analysed. Associated recommendations for allowing joint agreement/certification of packages and shipments related to the national and international transport of radioactive material will be developed based on the situation analysed.
Participants of the project are the Bundesanstalt für Materialprüfung und –forschung (BAM) Berlin, Germany as the project coordinator and the Institut de Radioprotection et de Sûreté Nucléaire (IRSN) Fontenay aux Roses, France. . The competent authorities of these countries, BfS (Federal Institute for Radiation Protection) for Germany and DGSNR (Direction Générale de la Sûreté Nucléaire et de la Radioprotection) for France support this project.
Based upon extensive national reports from France, Germany and UK on their approval and safety assessment system a questionnaire with 51 detailed questions was developed and submitted to 28 countries in Europe. The responses were analysed and evaluated applying a categorization system to group the existing practices and procedures. This evaluation is documented and general recommendations to improve harmonization in Europe have been derived and are proposed in chapter 4.

1.4 DETAILED DESCRIPTION OF THE PROJECT

The project was divided in 13 parts:

1. Each participant reviewed and produced a synthesis of their own state certification methodologies/practice concerning safety assessment for packages including quality assurance for national transport, validation of international transport (including from ADR and non-ADR countries), administrative requirements and approval practices for package designs and shipments. They also identified national derogations and any examples of joint certification practices.

2. Each participant then reviewed and commented on the synthesis of all other participating states. To cover the UK certification methodology, BAM took contact with the UK competent authority.

3. Participants identified, from a synthesis of participating states and the UK, areas of agreement and differences.

4. Participants produced a final version of synthesis of participating states and UK certification methodologies/practices or validations.

5. Participants developed jointly the format of a questionnaire for other EU member states and applicant countries based on the above mentioned synthesis.

6. Participants submitted to identified state competent authorities a request for questionnaire completion along with a completed specimen questionnaire.

7. Participants reviewed and commented on the returned questionnaire.

8. Participants produced and agreed on a final synthesis of all returned questionnaires.

9. From the synthesis of all information identified from the above mentioned tasks, participants investigated commonalities or divergences in certification methodologies/practices and validations within EU states and applicant countries.

10. Participants to identified areas where harmonization of joint certification practices, validations and approval procedures are technically feasible within the EU states and applicant countries.

11. Participants investigated areas of disagreement in certification methodologies/practices and validations within EU states and applicant countries and identified and suggested technical and administrative solutions.

12. Participants investigated examples of other joint harmonization areas within EU states.

13. Participants produced and agreed on a final synthesis of recommendations for harmonization of practises of validations, approvals and joint certification.

2 ACRONYMS

ACT	Accident Conditions of Transport
ADR	European Agreement Concerning the International Carriage of Dangerous Goods by Road and Protocol of Signature
ADNR	European Agreement Concerning the International Carriage of Dangerous Goods on the River Rhine
APAT	Agency for the Protection of Environment and for Technical Services (Italy)
ASTM	American Society for Testing and Materials
BAM	Federal Institute for Materials Research and Testing (Germany)
BfS	Federal Office for Radiation Protection (Germany)
CA	Competent Authority
CNCAN	National Commission for Nuclear Activities Control (Romania)
COTIF	Convention on international railway transport
CSN	Consejo de Seguridad Nuclear (Spain)
DfT	UK Department for Transport
DGSNR	Direction Générale de la Sûreté et de la Radioprotection Nucléaire (France)
DGTREN	Directorate - General for Energy and Transport
DIN	Deutsche Industrie Norm
DOT	US Department of Transportation
DSR	Design Safety Report
EC	European Commission
EU	European Union
FANC	Federal Agency for Nuclear Control (Belgium)
HAEA	Hungarian Atomic Energy Authority
HAW	High Active Waste
IAEA	International Atomic Energy Agency
IATA	International Air Transport Association
ICAO-TI	International Civil Aviation Organization – Technical Instructions
IISC	Institute of Isotope and Surface Chemistry (Hungary)
IMDG	International Maritime Dangerous Goods

IRSN	Institut de Radioprotection et de Sûreté Nucléaire (France)
ISO	International Standardization Organization
LDM	Low Dispersible Radioactive Material
NCT	Normal Conditions of Transport
NIRH	National Institute of Radiation Hygiene (Denmark)
NAEA	National Atomic Energy Agency (Poland)
NRA	Nuclear Regulatory Agency (Bulgaria)
NRA	Nuclear Regulatory Authority of the Slovak Republic
NRC	US Nuclear Regulatory Commission
NRI	Nuclear Research Institute (Slovak Republic)
OHSA	Occupational Health and Safety Authority (Malta)
QA	Quality Assurance
RAM	Radioactive Material
RID	Regulation concerning the international carriage of dangerous goods by rail (RID)
RMTD	Radioactive Materials Transport Division
RTSG	Radioactive Transportation Study Group (Supra-national Group of the competent Authorities)
SKI	Swedish Nuclear Power Inspectorate
SNSA	Slovenian Nuclear Safety Administration
SONS	State Office for Nuclear Safety (Czech Republic)
SSI	Swedish Radiation Protection Authority
STUK	Radiation and Nuclear Safety Authority (Finland)
TAEA	Turkish Atomic Energy Authority
TRANSAS	Transport Safety Assessment Service
TS	Technical Support
TSCS	UK Transport Container Standardisation Committee
UK	United Kingdom

3 INTRODUCTION

This report is part of the specific European Commission programme SURE, which based on the Council Decision of 14 December 1998 adopting a multianual programme (1998 to 2002) of actions in the nuclear sector, relating to the safe transport of radioactive materials and to safeguards and industrial co-operation to promote certain aspects of the safety of nuclear installations in the countries currently participating in the TACIS programme.

The European Commission has the following objective with the SURE programme:
"Two factors which condition the acceptability of the nuclear sector are the transparency and safety of its activities. In this context it is important to create data bases recording the number and characteristics of shipments of radioactive materials and events (incidents/accidents) that could occurring during transport of RAM.
These databases should provide information about the number and type of packages transported in the EU. They would contribute to improve the safety of these shipments and facilitate the application of harmonised emergency arrangements in the event of an accident/incident occurring during these shipments.
Harmonisation of documents and of the data contained in the accompanying transport certificates is a prerequisite for the creation of these databases and is also an essential factor for the full completion of the Internal Market, especially as shipments of radioactive isotopes used in medicine, industry and research represent a large part of the sector.
A methodology to achieve simultaneous certification of packaging would facilitate the development of the Internal Market in this area. Development of a unique format and a similar structure of the Safety Report for all types of packages would go a long way in this direction.
Furthermore, development of a mechanism to achieve simultaneous validation in the other Member States of the approval issued by the competent authority of the state of origin of the shipment would facilitate the free circulation of these type of materials in the European Union." [1]

The world-wide transport of radioactive material is characterized by the acceptation and application of the recommendations of the IAEA by a lot of countries. For the area of the EU it is known that most of the countries have implemented the international regulations for the transport of dangerous goods on roads (ADR [2]) and on railways (RID [3]), based on the IAEA recommendations [4], in national legal law.
Because of the enlargement of the EU in 2004 from 15 member states to 25 member states and the plan to associate other 3 states it is important for the European Commission, Directorate - General for Energy and Transports, to know in the framework of the SURE programme the approval methodology/practice for packages and shipments related to the transport of radioactive material of all member states and applicant countries to check if there are commonality or divergences and give recommendations supporting harmonized practices for all countries.
Former studies with similar content, e. g. study from TÜV Energie Consult [5], did not consider consequently the existing practices of the competent authorities of all EU and applicant countries. However for a harmonization process it is essential to get the information about certain practices directly from the competent authority. Three countries, France, UK and Germany, with a lot of knowledge in the field of certification and safety assessment practices for radioactive material transport packages and shipments have directly participated in the preparation of the study.

The French and German contractors have the task to investigate in detail their own and the UK approval methodologies/practices including safety assessment for radioactive package designs and shipments as well as from the other member states and applicant countries by a questionnaire. The main activities are the development of this questionnaire and its evaluation. The idea of the contractors to limit the questions to a small number could not be reached because of the very extensive and special task. The questionnaire finally comprised

51 questions which were sent to the 28 competent authorities of the EU and applicant countries.
The evaluation of the responses of the questionnaire were based on the current international transport regulations. The contractors had to analyse the detailed practices of the competent authority(ies) of each country in the fields of approval and safety assessment and had to show commonalities or divergences. These results are the basis for recommendations for harmonized procedures which would have to be developed and implemented within the European Union.

4 SUMMARY

The following summary presents the conclusions from the evaluation of the response to the questionnaire to the European Competent Authorities and the recommendations deduced from these conclusions. The detailed evaluation report is given in chapter 6.
To get a basis for recommendations towards a harmonized approach in safety assessment and approval of packages for the transport of radioactive materials, the certification methodology of EU states and applicant countries has been examined and analysed. For this purpose, a questionnaire has been prepared. It has been divided in 5 parts: the first one called “Legal Basis” was relative to regulations of radioactive materials transports, the second one called “Application and Requested Documents” concerned approval methodology including the organization structure and the description of the approval procedure and approval certificate, the third one called “Approval Procedure” was relative to certification practises, the fourth one “Safety Assessment Procedure” was relative to the description of the safety assessment methodology and the last one concerned the “Joint certification”.

4.1 GLOBAL RECOMMENDATIONS RELATIVE TO THE ISSUE “LEGAL BASIS”

The issue “Legal basis” is relative to the

a) Application of modal regulations ADR [2], RID [3], IMDG-Code [6], ICAO-TI [7] based on the IAEA recommendations [4] for the transport of package designs for radioactive material, shipment and special arrangement
b) Nomination and the responsibilities of competent authority
c) Nomination and responsibilities of assessment organization (“technical support”)
d) Responsibilities for performance of regulatory tests
e) Costs of certification and/or assessment

The main conclusions derived from practices of different countries show that:

1. The modal regulations ADR, RID, IMDG-Code, ICAO-TI based on the IAEA recommendations are implemented in most of EU–member states and applicant countries. So far the regulatory framework for all competent authorities and applicants is the same. If there are limited deviations in some countries, they are not essential for the approval procedure for package designs for radioactive material, shipment and special arrangement.
2. All countries have an established legal system for the nomination and the responsibilities of the competent authority, but there exist several kinds of organization structures for assessment and certification. These organization structures are adapted to the specificity of each country. It is necessary to have an appropriate number of experienced staff of well-trained experts due to the complexity of certain approval safety assessment procedures.
3. There are two different organization models to organize the independent safety assessment within the approval process. On the one hand competent authority performs the assessment with experienced own staff on the other hand technical support is charged with the assessment. It is important for the competent authority on one hand to identify a technical support who has the assessment competence and on the other hand to have the knowledge about the workflow, performance and interpretation of results of the assessment by the technical support. If the competent authority calls upon a technical support, its nomination and its responsibilities shall be indicated in national text to ensure, in a long-term, quality assured special knowledge and experience in the assessment procedure. If the competent authority does not perform the assessment by itself, or does not have a mandatory technical support they have to establish appropriate measures for supervision of the selected experts or expert institutions. Conclusions and recommendations proposed by technical

support organizations or assessors of competent authority have not to be influenced by directives of government, applicants, management hierarchy, etc.

4. There are two different organization models for the responsibility of the performance of regulatory tests: on one side, the most common practice is that tests are performed by the applicant, and on the other side, that the tests are performed by the competent authority or nominated expert institutions. There is a problem concerning the conflict of test objectives for both responsibilities for the test performance by the applicant or by the competent authority/expert laboratory. In all cases, a guidance material for experimental testing and assessment should be developed based on existing standards or guidance material for testing and assessment.
5. The determination of the costs is a very specific national matter which depends on the finance and administration system specific in the country.

The following recommendations are deduced from the evaluation and the conclusions above:

1. **If complementary (or specific) requirements to the modal regulations exist they should be indicated in national legal texts.**

2. **No delay, between the date of official publication of the new edition regulations and the date of applicability in the EU countries, should exist (this recommendation does not include the transition period between two editions of regulations, already indicated in modal regulations).**

3. **The nomination and related responsibilities of competent authorities and the technical support organization, if needed, should be indicated in a national legal text.**

4. **The competent authority should have enough experienced experts, or should be able to call upon a suitable technical support (independent experts or expert institutions).**

5. **Independence of the competent authority and the technical support from applicant and concerned industry should be a priority.**

6. **Guidance material for the preparation and performance of tests, and for the assessment and interpretation of test results should be re-evaluated or developed on an harmonized basis in the EU.**

7. **If the applicant performs experimental testing, he should be able to demonstrate the compliance to regulatory requirements and to a QA system.**

8. **For the supervision of applicant's experimental testing by the competent authority, independent well qualified and practised staff is needed.**

9. **An organizational separation between the section which performs the tests and the section which assesses the package design type and/or issues the certificate shall be provided if the competent authority performs the tests.**

10. **All costs for certification (including assessment) should be charged directly to**

applicants or indirectly by other means of refinanziation to warrant appropriate resources for the issue of assessments and certificates.

11. **It should be clearly stated in a national legal text who has to bear the cost of assessment and certification. The fee to be paid by applicant for assessment and certification should be transparent in every EU country and known by all applicants in advance.**

4.2 GLOBAL RECOMMENDATIONS RELATIVE TO THE ISSUE “APPLICATION AND REQUESTED DOCUMENTS”

The issue “Application and requested documents” is relative to the

a) Documents requested complementary to those required by ADR (6.4.23) for unilateral approval
b) Application requirements referring to ADR for multilateral approval/ validation
c) Application requirements referring to ADR for shipment approval and special arrangement
d) Design Safety Report (DSR).

The main conclusions derived from practices of different countries show that:

1. Most of the European countries have no guidelines for application and do not require essential additional information other than those required in ADR paragraph 6.4.23 regarding documents for unilateral approval. A very comprehensive guideline for application of all package designs, special form radioactive material, low dispersible radioactive material, shipment approval and special arrangement approval is e. g. the UK "Guide to an application for UK competent authority approval of radioactive material in transport (IAEA 1996 regulations)”.
2. All countries meet the ADR paragraphs regarding the application documents for the approval of package designs containing fissile material (ADR 6.4.23.7), multilateral approval Type B(M) (ADR 6.4.23.5) and approval for transitional arrangement (ADR 1.6.6.1 and 1.6.6.2).
3. There are no essential additional requirements referring to ADR for shipment approval (ADR 6.4.23.2) and special arrangement approval (ADR 6.4.23.3) but there are requirements resulting from national nuclear safety and radiation protection law overlapping the transport law.
4. A harmonized guideline for application should be prepared to assist applicants in submitting the necessary information in a convenient form. Such guidance is also useful for the competent authority because it supports the verification of completeness and accuracy of submitted documents. This guidance, which is not a substitute for the regulations, could be only an advice for the applicant to send the necessary documents in the recommended way. It should quote the relevant paragraphs of the IAEA-Regulations (or ADR paragraphs) and explain how they are completely met by the safety proofs.
5. The applicants documentation regarding the proof of the compliance with the regulations of a package design type should be given in form of a Design Safety Report. This Design Safety Report should include the complete and up-to-date description of the packaging and its contents (and not only the modification in comparison with the last approval certificate).
6. A standardized format for the Design Safety Report could be helpful for the competent authority and the applicant because the general practice for issuing and assessment is in this case familiar for both, and can advance the application.
7. Because of the English version of IAEA-Regulations and the general spread of this language, most of the expressions in English language regarding the transport of radioactive materials are known by the majority of staff or translators, and a Design Safety Report in English should be acceptable in validation and joint certification. In dedicated cases, where the competent authority has not enough English speaking staff resources, or due to legal restrictions it may be necessary to provide the DSR or parts of it in the countries language.

The following recommendations are deduced from the evaluation and the conclusions above:

1. **Competent authorities should provide a comprehensive guidance material for each type of application on the basis of the requirements of the IAEA-Regulations (TS-R-1, TS-G-1.1). An example of such guideline is the UK "Guide to an application for UK competent authority approval of radioactive material in transport (IAEA 1996 regulations)". This guideline should include the items given in Annex 4.**
   The European Commission should organize the development of a harmonized comprehensive guidance material and should provide it to the IAEA in view of worldwide harmonization if possible.

2. **For shipment approval (ADR para 6.4.23.2) and special arrangement approval (ADR para 6.4.23.3) the Design Safety Report and emergency plans should also be part of application documents.**

3. **A harmonized guideline for the Design Safety Report preparation should be prepared. Each Design Safety Report should contain**
   a) a full definition of the design (packaging and contents),
   b) a summary,
   c) a list about the demonstration of compliance of the package design with each applicable paragraph of transport regulations,
   d) a complete set of safety analyses.
   The recommended content of the Design Safety Report is available in Annex 5.

4. **For validation of foreign approval certificates, the original approval certificates and the complete Design Safety Report (as defined above) should be provided. When the Design Safety Report is not written in the official language(s) of the country of the application, an English written Design Safety Report should be accepted. Nevertheless it always may be possible that, where the competent authority has not enough English speaking staff resources or due to legal restrictions, it may be necessary to provide the DSR or parts of it in the country language.**

5. **The applicants should systematically provide additional to the hard copy an electronic copy of the Design Safety Report.**

4.3 GLOBAL RECOMMENDATIONS RELATIVE TO THE ISSUE "APPROVAL PROCEDURE"

The issue "Approval procedure" is relative to the

a) Procedure and guidelines for competent authority and technical support
b) Package design modification procedure for unilateral approval
c) Certificate renewal without change of package design
d) Additional practice for validation of a multilateral approval for package designs for fissile material (Certificate AF, IF, B(U)F, B(M)F and CF)
e) Additional practice for validation of a multilateral approval for type B(M) package design
f) Additional practice for validation of package designs subject to transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2
g) Additional practice for shipment approval and shipment approval under special arrangement
h) Validity of certificates
i) Structure of unilateral approval certificates
j) Structure of multilateral approval certificates, shipment approval and special arrangement

The main conclusions derived from practices of different countries show that:

1. Procedure and guidelines for competent authority and technical support

1.1 It was identified that 11 countries have written internal procedures for the approval process and 9 countries have no procedures.

1.2 Only three countries have guidelines for the applicants regarding the performance of proofs and accepted criteria for assessment. A lack of information relative to preparation of a Design Safety Report and accepted calculations was identified.

1.3 The typical approval process time, after complete Design Safety Report transmittal (what requires e. g. the finalization of all tests in case of a new design), of the responding EU and applicant countries for the different package design types or shipment approvals was identified and is given in chapter 6.2.3.1.

2. Package design modification procedure for unilateral approval

2.1 All countries which have practice relative to package design modification for an unilateral approval of package design reissue a new revision of the approval certificate in the case of relevant modifications. There are different ways to classify design changes/modifications and to assign them in the unilateral approval certificate.

2.2 In all countries procedures for handling and maintenance of the package are subject to competent authority assessment/approval.

3. Certificate renewal without change of the package design

3.1 Although 12 countries require additional proofs for certificate renewal without change of package design,

a) either by considering evolutions of the applicable regulatory requirements, the feedback experiences and the last technological knowledge
b) or by requiring a confirmation of no changes on the package design and/or maintenance controls, non destructive tests or additional inspection of the manufactured packages,

there is no consistent procedure relative to certificate renewal without change of package design.

4. Additional practice for validation of a multilateral approval for package designs for fissile material (certificate AF, IF, B(U)F, B(M)F and CF)

4.1 An application of validation of approval for package designs for fissile material (certificate AF, IF, B(U)F, B(M)F and CF) has to contain (according to ADR 6.4.23.7) all details which convince the competent authority that the package design is in compliance with the requirements of ADR 6.4.11.1 and a quality assurance program according to ADR 1.7.3. Briefly ADR 6.4.11.1 requires that fissile material has to be transported in such a way that under normal and accident transport conditions sub-criticality is ensured. For these purposes, 9 countries consider that it is sufficient to assess in case of a multilateral approval/validation the criticality analysis, the parts of the Design Safety Report about the behavior of the package design under normal and accident conditions.

5. Additional practice for validation of a multilateral approval for type B(M) package design

5.1 There are differences existing in the extent of the assessment procedure of validation of multilateral approval for Type B(M) package design. 9 countries assess the parts of regulatory tests and the parts of the Design Safety Report concerning non-compliance with particular requirements, 4 countries assess the whole Design Safety Report and 4 countries assess the aspects for which the package is classified as Type B(M) and any other items when reduced safety margins are suspected.

6. Additional practice for validation of package designs subject to transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2

6.1 The assessment procedure for validation of package designs subject to transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 is different according to the countries. 6 countries assess the whole Design Safety Report, 4 countries assess the Design Safety Report parts affected by the changes in the regulations and any other items when reduced safety margins are suspected and 3 countries assess only the Design Safety Report parts affected by the changes in the regulations. 3 countries have a procedure of administrative nature or assess only the QA program or parts of it.

7. Additional practice for shipment approval and shipment approval under special arrangement

7.1 There is a nearly harmonized practice for shipment approval and shipment approval under special arrangement according to ADR 6.4.23.2 and ADR 6.4.23.3 in all countries.

8. Validity of certificates

8.1 There are two nearly commensurate groups of countries which define the validity time for certificate of approval for Type AF, Type B(U)/ B(U)F, Type B(M), Type C, Type IF, Type H(U), Special form radioactive material, Low dispersible radioactive material in maximum up to 5 years (8 countries) or in maximum 3 years (7 countries). Two countries decide to have no fixed validity time. They arrange for each particular case for which time the certificate is valid.

8.2 For shipment approval and shipment under special arrangement approval nearly all countries with experience fix a validity time which conforms to the time of the shipment and in general, validity time is not more than 1 year. Only 3 countries have validity times greater than 1 year.

9. Structure of unilateral approval certificates

9.1 The unilateral approval certificate content of all countries conforms to ADR 6.4.23.14. If the minimum content is defined, there are some differences between the countries regarding the structure and the extent of special paragraphs of the certificate, thus leading to significant variation in the certificate format.

10. Structure of multilateral approval certificates, shipment approval and special arrangement

10.1 Only 9 countries gave sufficient answers referring to multilateral certificates/ validations. The content of validations of approval certificates for package designs for fissile material, Type B(M) package designs and transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 in 2 countries consist mainly of a reference to the original certificate. Beside the reference to the original certificate 7 countries give additionally more specific and detailed information.

The following recommendations are deduced from the evaluation and the conclusions above:

1. Procedures and guidelines for competent authority and technical support

1.1 A general harmonized guideline for the approval procedure or harmonized procedures for the competent authority and the technical support should be defined. This guideline or/and procedures should comply with the ISO 9001:2000 or an equivalent standard. The contents of these guidelines should be defined. The European Commission should organize the development of these general harmonized guideline and harmonized procedures and should provide them to the IAEA in view of worldwide harmonization, if possible.

1.2 For additional instructions, circular letters or appropriate documents should be issued to applicants (instructions of the competent authority can include conclusions of international or national meetings).

1.3 A draft of the certificate should be sent to the applicant for commenting.

1.4 The applicants should transmit the complete set of safety documentation to the competent authority with due consideration of the following minimum times to allow the correct assessment of these application documents by the competent authority. Times the applicant needs for revision of documents have to be added. This time can be prolonged in case of difficulties encountered in the assessment of the safety design package.

	New design	Renewal	Extension	Special arrangement	Shipment approval	Validation
Minimum approval process time recommended after the complete DSR transmittal (months)	**12**	**6**	**4**	**6**	**2**	**6**

The information on minimum approval process time should be provided to applicants so that they apply for license in due time.

2. Package design modification procedure for unilateral approval

2.1 Package design modification that impacts the safety of package design should be subject to a revision of the design certificate.

2.2 All changes to the package design and procedures for handling and maintenance of the package should be subject to competent authority

assessment/ approval to make sure that actual design status is always known to competent authority and is in compliance with the design specifications of the certificate. Appropriate procedures (e.g. by advising this in guidance material (see chapter 6.2.3.1 and Annex 4) or by circulated letter) between competent authority and the certificate holder should be established to meet this requirement.

2.3 The unilateral approval procedure in case of package design modification should be clearly defined by any appropriate process to applicants (e. g. by advising this in guidance material (see chapter 6.2.3.1 and Annex 4) or by circulated letter).

3. Certificate renewal procedure without change of the package design

3.1 Certificate renewal procedure of the package design without change should be defined, and should consider the latest evolutions of the regulation in force, in particular the provisions for transitional arrangements and practicable experience of use of the package or general experience feedback of package design assessments (e.g. based on an experience feedback document described in chapter 6.2.4.8 and Annex 8).

4. Additional practice for validation of a multilateral approval for package designs for fissile material (Certificate AF, IF, B(U)F, B(M)F and CF)

4.1 For validation of a multilateral approval for package designs for fissile material (AF, IF, B(U)F, B(M)F and CF certificate), the competent authority should have the possibility of either performing a separate safety assessment or making use of the assessment already done by the original competent authority, thus limiting the scope and extent of their own assessment. In this case, the main Design Safety Report chapters to be assessed should be defined (see chapter 6.2.2.2). In addition, it is implied that the competent authority of the country of origin of the design should make available to other competent authorities its assessment report.

4.2 For validation of a multilateral approval for package designs for fissile material (AF, IF, B(U)F, B(M)F and CF certificate) the competent authority should have the possibility of performing a preliminary review of the Design Safety Report; if there are sufficient margins of safety (or no doubts on the safety), the extent of the detailed assessment may be limited then to criticality analysis and regulatory tests results. The competent authority should also have the possibility of performing the detailed assessment of any other items when reduced safety margins are suspected.

5. Additional practice for validation of a multilateral approval for type B(M) package design

5.1 In addition to recommendation 4.1, for validation of a multilateral approval of type B(M) package design the competent authority should have the possibility of performing a preliminary review of the Design Safety Report; if there are sufficient margins on safety (or no doubts on the safety), the extent of the detailed assessment may then be limited to items for which the package is classified as Type B(M). The competent authority should also have the

possibility of performing the detailed assessment of any other items when reduced safety margins are suspected.

6. Additional practice for validation of package designs subject to transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2

6.1 In addition to recommendation 4.1, for validation of package designs subject to transitional arrangements according to ADR paragraphs 1.6.6.1 and 1.6.6.2 the competent authority has to have the possibility of performing a preliminary review of the Design Safety Report and assessment of the Design Safety Report parts affected by the changes in the regulations if there are sufficient high margins on safety (or no doubts on the safety), and on the quality assurance program, the option of performing assessment of any other items when reduced safety margins are suspected. The package design safety shall be checked taking into account the current regulations, last knowledge/experience obtained and the provisions of transitional arrangements.

7. Additional practice for shipment approval and shipment approval under special arrangement

7.1 For shipment approval the competent authority should assess the specific measures taken for the shipment, if applicable.

7.2 From the experience of the countries participated on the study it should be recommended that:

- **Special arrangement should be treated as an exceptional case taking into account the necessity of justification of shipment deviations to the applicable transport regulations and,**
- **applicants should propose compensatory measurements**

7.3 For shipment approval under special arrangement, a complete transport safety documentation to demonstrate the compensatory measures capability to reach an equivalent level of safety should be required.

8. Validity of certificates

8.1 The validity time for certificates of approval for a package design should be defined between 3 and 5 years.

8.2 For shipment approval and shipment approval under special arrangement the validity time should be the period of operation needed, and should not exceed 1 year.

8.3 For a validation of certificate, the validity period should not exceed the validity period of the certificate of the country of origin of the design.

8.4 For certificate of approval for special form radioactive material, the validity time should not exceed 10 years.

9. Structure of unilateral approval certificates

9.1 A harmonized format for the certificate should be defined. The certificate structure should contain three essential parts:

a) Legal basis,

b) Specification of the packaging and its allowed contents (package design),

c) Other requirements to ensure compliance with regulations.

The European Commission should organize the development of a harmonized certificate structure and should provide it to the IAEA in view of worldwide harmonization, if possible.

9.2 It is recommended to consider in a harmonized structure a revision list for an overview about the history of the approval certificate. The certificate format should be complemented by a drafting guide. A list of minimum content for a certificate is given in Annex 9. Further harmonization effect could be reached by bilingual certificates giving the content in the language of the country of origin plus an English version for international transport of radioactive materials.

10. Structure of multilateral approval certificates, shipment approval and special arrangement

10.1 The European Commission should organize the development of a harmonized validation format and should provide it to the IAEA in view of worldwide harmonization, if possible. The format of the validation certificate should contain the following essential parts:

a. Legal basis,

b. Administrative matters (e.g. owner of the validation, manufacturer identification, expiry date, marking of the packaging),

c. Allowed contents,

d. Other national specifications or requirements to ensure compliance with regulation,

e. Annex – Original approval certificate in the language of the validating country or if acceptable in English.

4.4 GLOBAL RECOMMENDATIONS RELATIVE TO THE ISSUE "SAFETY ASSESSMENT PROCEDURE"

The issue "Safety assessment procedure" is relative to the

a) Procedure and guidelines for competent authority, technical support and the applicants
b) Organization of safety assessment procedure
c) Accepted calculation methods for assessment
d) Test program for package design
e) Performance of package design tests by the applicant and tests for special proofs
f) Issue of an assessment report and its structure
g) Assessment time according to the approval certificate type
h) Difficulties encountered several times during assessment

The main conclusions derived from practices of different countries show that:

1) Most of the competent authorities have no internal procedures and no Quality Assurance system concerning the assessment of the Design Safety Report.
2) Only three countries have guidelines for the applicants regarding the performance of proofs and accepted criteria for assessment. Then, a lack of information relative to preparation of a Design Safety Report and accepted calculations was identified.
3) Existing national and international guidelines or standards for different technical items in the package Design Safety Report are given in chapter 6.2.4.1.3.
4) The assessment is based in general on two steps: a "preliminary review" and a detailed assessment.
5) The preliminary review is an important assessment step which should take into account the feedback experience of assessment. For that, an experience feedback document listing all encountered difficulties should be developed.
6. In general all calculations are accepted by the competent authorities if justified and if used codes are verified. The applicant has to give the evidence for the applicability of the method and the verification of the calculated results.
7. A detailed recalculation by the competent authority or its technical support is not necessary in any case; independent calculations should be performed when there are insufficient safety margins, or according to the results of the experience with the assessments of similar package designs, or when there are doubts on the applied calculation methods or on validity of extrapolation of the results of tested scale model.
8. In the case of assessment of the criticality safety, in nine countries, the competent authority or independent assessors check the criticality safety by full checking or recalculation with other calculation methods.
9. For computer based numerical calculations like FEM analysis requirements should be defined regarding the completeness, modelling, the extent of data, the demonstration of data and the justification of the results (e. g. like in the German guideline BAM-GGR 008).
10. Most of competent authorities require a test program which it has to approve before testing.
11. In case where applicants perform the tests, the competent authorities control the test performance by independent witnessing.
12. An assessment report is written to identify and record the verifications performed during independent assessment and the reasons of the conclusion of the assessment. The assessment report is sometimes sent to applicants.
13. A time for the assessment can only be a guidance level for the applicant. The real time depends mainly on the type of package design and the quality and completeness of demonstration of the safety proofs of the package design by the applicant in the Design Safety Report.

14. The competent authorities identified mainly problems regarding the assessment work with the structure of the Design Safety Report and the demonstration of safety proofs.
15. To consider the evaluation experience from the past a national French document called 'Feedback experience document' (see Annex 8) lists difficulties most frequently encountered in Design Safety Reports assessments. This document is periodically up-dated (every year or two years) to take into account the most recent evolutions of the regulations and new difficulties recorded since the last issue.

The following recommendations are deduced from the evaluation and the conclusions above:

1. **The competent authority should have a QA management system for the assessment of the package design which includes the description of organization of assessment work. These procedures should comply with the ISO 9000:2000 or equivalent standard.**

2. **The competent authority should define a harmonized guideline for assessing the Design Safety Report including general recommendations and details about accepted calculations or accepted demonstrations. Based on existing guidelines a harmonized guideline should be developed to be used in the EU. The European Commission should organize the development of this harmonized guideline and should provide it to the IAEA in view of worldwide harmonization, if possible.**

3. **The competent authority should issue a harmonized guideline for preparing the Design Safety Report (as defined in Annex 5) to the applicants, including general recommendations and details about accepted calculations and test methods, acceptance criteria, and other detailed assessment requirements that should be addressed. Based on existing guidelines a harmonized guideline should be developed to be used in European Countries. The European Commission should organize the development of a harmonized comprehensive guidance material and should provide it to the IAEA in view of worldwide harmonization if possible.**

4. **An internal procedure should describe the organization of work for assessment.**

5. **The organization of the assessment work should include at least the following actions:**
    - **i. determination of the persons (for the applicant, the competent authority and its technical support) involved in the assessment process,**
    - **ii. planning of the assessment work,**
    - **iii. checking of contents of the application**
    - **iv. work practices for assessment (indicate if the organizational unit or the assessor deals with one subject for all applications/kinds of package design, or if there is an organizational unit or assessor which covers all necessary functions and responsibilities for identified groups of applications and package designs, or if it is a combination of both),**
    - **v. The assessment should be started with a preliminary review supported, e.g. by a feedback experience document (see also chapter 6.2.4.8 in order to identify the missing elements)**
    - **vi. Determine the exchange with applicants**

vii. **If needed, determine the exchange with competent authority**
viii. **Determine the possibilty to call upon external experts, safety committees …**
ix. **Drafting of the assessment report**

6. **Any appropriate calculation method for safety proof should be allowed subject to justification of the method validity.**

7. **The competent authority should ensure that proper codes and models have been used, that they have been adequately verified by appropriate experiments and that all input data have been defined conservatively or correctly. For supporting this item a harmonized procedure for the use of computer based numerical analysis like FEM for calculation proof should be developed.**

8. **For experimental testing a test program should be required and approved by the competent authority. The test program should include the items given in Annex 6.**

9. **Before acceptance of the test program, a functional report of the package safety (description of intended containment system, confinement system, heat dissipation system, shielding system, expected performances in accident conditions, and criticality safety) and justifications for the test series, package orientations and other relevant test conditions should be required. This may include calculations and pre-test results.**

10. **Before starting the tests a QA documentation of the fabricated test object and a documentation demonstrating the compliance of the test equipment with the regulations should be given to and accepted by the competent authority or technical support.**

11. **Before starting the tests by the applicant the competent authority should inspect the testing arrangement, the target and the measuring system.**

12. **A Quality Assurance procedure should be established to track the test program, and changes during the tests, and of the test object.**

13. **A witness of package design tests by independent experts who confirm the completeness and reliability should be possible in any case by the competent authority.**

14. **Necessary tests or investigations in case of new scientific and technical developments or in case of practical uncertainties in the field of package design assessment should be actively accompanied by the competent authority to use the results for increasing its assessment competence.**

15. **An assessment report should be written for each appraisal. This assessment report should be sent to applicants, and in case of assessment service to competent authority. The format of the assessment report should be harmonized in all EU countries. This report should contain at least the information given in Annex 7.**

16. **To avoid incomplete Design Safety Reports with insufficient safety proofs beside the recommended guidelines in this report a European feedback experience document should be developed which lists the most frequently**

encountered difficulties in package design safety. This document has to be periodically updated. The period should be determined under review by the DGTREN standing working group.

4.5 GLOBAL RECOMMENDATIONS RELATIVE TO THE ISSUE "JOINT CERTIFICATION PRACTICES"

The main conclusions derived from practices of different countries show that:

1) There is a European joint certification practice regarding the certification of H(U)/H(M) UF_6-package designs.
2) The number of joint certifications is very low while a validation is necessary by each country through or into which the consignment is to be transported. In the case of international transport needing a validation, the encountered difficulties in the assessment of the Design Safety Report should be discussed between the competent authority of the original country of the design or shipment and all competent authorities involved in the transport.

In the case where some competent authorities decide to perform a joint certification, the recommendations, deduced from the evaluation and the conclusions above are the following:

1. **At any time, the competent authorities should have the same documentation available (same Design Safety Report…).**
2. **Reciprocal information meetings should be organized by the competent authorities and their technical supports, if needed.**
3. **Questions to applicants and answers should be circulated among the relevant competent authorities.**
4. **Assessment reports should be exchanged.**

5 DESCRIPTION OF THE EVALUATION METHOD

5.1 LITERATURE SURVEY

At first the contractors carried out an extensive study of literature on the subject of the project. Some publications were found about the regulatory framework concerning the transport of radioactive material [8], [9], [10], [11] as well as regulations and procedures regarding the approval methodology in different countries [12], [13], [14], [15], [16], [17], [18], [19], [20], [21], [22], [23]. Furthermore, there was an investigation by TÜV Energie Consult for the European Commission about the harmonization of methods for the safety evaluation of packages and of the competent authority approval of practices for package design [5]. Another activity in this field has been discussed in the "Standing Working Group on Safe Transportation of Radioactive Materials (SWG)". A FORATOM final report "Harmonization of Transport Documents for the Shipment of B(U) and B(U)F Packages" has been presented to the Commission. These documents gave a good first overview about the subject.

5.2 DEVELOPMENT OF THE STRUCTURE OF THE PARTICIPATING COUNTRIES METHODOLOGY

Before starting with the completion of their own approval and safety assessment methodology, BAM, supported by the German competent authority BfS, and IRSN in contact with the French competent authority, DGSNR, worked together on the structure of the study. When the first version of the structure (see final version in Annex 1) was established the work on the participant country reports started. During the issuing of the reports, a permanent discussion between the institutes connected with improvements of the structure was performed.

5.3 COUNTRY REPORTS (GERMANY, FRANCE, UK)

IRSN worked together with the French competent authority, DGSNR, and BAM together with BfS on their country reports. IRSN provided the English version of report on the French methodology including the preliminary review of the Design Safety Report for a package design, the appraisal of the Design Safety Report for radioactive material transport package designs, the experience feedback in the appraisal of Design Safety Reports for packages and the index procedures. BAM also prepared the draft report about the approval and safety assessment methodology in the UK. Basis for this report were the UK Applicants Guide [24], the publications [21] and [23] and the IAEA-appraisal for the UK [25]. There was an exchange of the national reports between the participating countries.
To get more internal information about the UK approval and safety assessment system it was decided to have a meeting with the representative of the UK competent authority (RMTD). This meeting was hosted by the Belgium competent authority what gave the chance to explain in detail also the Belgium system. The UK report (see chapter 5.8) was finished by BAM and sent to RMTD for comment.

5.4 QUESTIONNAIRE TO EU MEMBER STATES AND APPLICANT COUNTRIES

Parallel to the completion of the country reports the questions, and the format of the questionnaire for the EU and applicant countries were elaborated. Because of the own experience of BAM, BfS, IRSN and DGSNR in approval and safety assessment procedures, and the synthesis of their own state certification methodologies, important items and problems were identified (for instance, we can quote the existence of systematic preliminary reviews for assessment, the possibility for the competent authority to assess any part of the DSR for a validation…). The questions of the questionnaire were therefore concentrated to

these topics beside the administrative and organizational items of the approval procedure. Basis for the questions were the current international regulations for the transport of radioactive material, especially ADR [2] and IAEA-Recommendations [4].

The questionnaire (see Annex 2) was divided into 5 issues:

1.	Legal Basis	(5 questions)
2.	Approval methodology	
2.1	Organization	*(4 questions)*
2.2	Description of the approval procedure and approval certificate structure of an unilateral approval	*(12 questions)*
2.3	Description of the multilateral approval procedure/ validation of foreign approval certificate	*(6 questions)*
3.	Shipment approval and special arrangement	*(2 questions)*
4.	Joint certification practices	*(1 question)*
5.	Description of the safety assessment methodology in the approval process	*(21 questions)*

In total 51 questions were elaborated and transferred in two electronic versions - an Microsoft-Excel-file and a Microsoft-Word file. The two electronic versions were sent to competent authorities by mail on a floppy disk together with the Excel-file as paper document to allow handwritten answers, as well as by e-mail.
The questionnaire was sent by BAM to the competent authorities of following countries:

Austria, **Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Hungary, Ireland, Latvia, Lithuania, Malta, Poland, Romania, Slovak Republic, Slovenia, Sweden, Turkey and United Kingdom**.

IRSN sent the questionnaire to the competent authorities of

Belgium, Greece, **Italy, Luxembourg, Netherlands**, Portugal, **Spain**.

The above-named countries in bold face letters gave a response to the questionnaire. Three countries did not answer.

5.5 EVALUATION OF THE RESPONSES TO THE QUESTIONNAIRE

For the evaluation of the responses of the questionnaire BAM and IRSN divided the questions into 5 issues and 28 items (see Annex 3) derived from the structure (see Annex 1) which was given for the synthesis of the participating state certification methodologies/practice and from the structure of the questionnaire (see Annex 2). The issues explained which most important aspects they should cover are:

1. Legal Basis

This issue had to show which international transport regulations are implemented in national law, which deviations exist, who is nominated as competent authority, for which package designs and shipments the competent authority is responsible, if there is an expert institution for safety assessment or testing and who pays the costs for the application.

2. Application and Requested Documents

Under this issue , the purpose was to analyse which documents are requested for different submitted package designs and shipments and if there is a standardized format for the Design Safety Report.

3. Approval Procedure

This issue deals with possible existence of internal procedures and guidelines used for certification, for approval in case of package design modification, for certificate renewal without change of package design and for validation for package designs for fissile material, for Type B(M) package design, for package designs subject to transitional arrangements and for shipments. The interest of this issue was also the structure and the validity time of unilateral and multilateral approval certificates.

4. Safety Assessment Procedure

This issue had to demonstrate the possible existence of procedures and guidelines used for assessment of the DSR and had to give a description of the assessment procedures and accepted calculation methods for assessment. One important item was also the requirements relative to test programs and the points which are to consider in case of experimental test by the applicant. Another item was the necessity of an assessment report of the competent authority or the assessment organization and how should be the structure of this report. The assessment time was investigated as well as difficulties during the assessment.

5. Joint Certification Practices

This issue had to show the existence, of past joint certification practices between EU member states or applicant countries and to propose recommendations to implement this practise.

Especially the items in the issues “Application and Requested Documents” and “Approval Procedure” based on the current requirements of the transport regulations in the EU, as representative the ADR [2] legal basis was chosen.

There were discussions between BAM and IRSN about the evaluation method of the results of the questionnaire.
The first approach was to issue reports about the approval and safety assessment methodology for each country on the basis of the questionnaire and according to the reporting structure given in Annex 1 and evaluate them.
a. A second approach was to create lists with the global issues, fill in the practices resulting from the responses of the country and evaluate them with defined terms, as good practice, usual practice and special practice. Basis for these definitions were the current international regulations. The list was improved by adding specific items for the global issues. These first two evaluation approaches had the disadvantage that no direct comparison of practices/procedures of the countries, and not clear conclusions and recommendations could be derived. Furthermore the distinction between usual and special practices was not easy.

Therefore it was decided to retain the original developed structure but to find a more effective and objective evaluation method which is described below.

In general the original responses of each country to a specific item were completely listed in tables which are given in chapter 6. Sometimes it was necessary to modify the responses without changing their content by the contractors themselves for better understanding in this study.
From these responses BAM and IRSN developed different categories to the item in a separate list and the response of each country was classified. The categorization was orientated on significant practices or methods in the country specific responses. Because of the different amount of answers the categorization was difficult in some cases. In such a

case a request was carried out by the contractors. Sometimes the contractors themselves could evaluate the responses considering the whole approval or safety assessment procedure. E.g. they could consider if there are an unilateral approval practice or only validation of foreign certificates in a country or if there exists a safety assessment procedure with experiences of different types of radioactive material transport casks.
After the classification of each country's response to an item the number of responses belonging to the categories was counted, and a summary including a discussion of the different practices or methods was performed. The discussion should explain more detailed the significant practices, or methods, or additions to the regulations, and show objective possible merits and disadvantages. The summary and discussion are the basis for the item specific conclusion and recommendation for a harmonized procedure in all EU and applicant countries. The conclusions identify if a harmonized practice in the EU and applicant countries is already existing, or if there are disagreements in approval practices, and show the necessity to recommend a certain harmonized practice or method. The recommendations demonstrate the project partners' suggestions of possible technically and administratively means resolving disagreement and giving significant improvement of the joint certification practices.
The final recommendations are based on

- the consideration that a harmonized methodology/practice has to be in line with the current transport regulations (comparison of methodology/practice in conformity with the current transport regulations in the EU)
- the experience of the participating countries given in the synthesis of the participating state certification methodologies/practice (see chapter 5.6, 5.7 and 5.8),
- the experience of the participating countries resulting from the work in international meetings, working groups and committees,
- the consideration that a harmonized methodology/practice has to be independent from influence of government and industry, technically feasible and quality assured,
- the consideration that national specific conditions, or deviations have to be taken into account.

All item specific conclusions and recommendations of the issues 1 to 5 were summarized in see chapter 4.

5.6 APPROVAL METHODOLOGY IN GERMANY

5.6.1 LEGAL BASIS FOR THE COMPETENT AUTHORITY (CA) AND TECHNICAL SUPPORT (TS)

5.6.1.1 NATIONAL AND INTERNATIONAL LAWS, REGULATIONS AND GUIDELINES FOR PACKAGE DESIGN AND SHIPMENT APPROVALS

The transport of radioactive materials in Germany [22] is regulated by two parts of the law

(1) The part of the dangerous goods transport law [26] and the dangerous goods transport regulations [27], [28], [29], [30] for which the Federal Ministry of Transport, Building and Housing (BMVBW) is responsible;
(2) and the Atomic Energy Act [31] with the Radiation Protection Ordinance [32] for which the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) has the responsibility.

Transport of radioactive material has to be performed in Germany within this legal framework. That means that for a specific transport the requirements of the dangerous goods transport regulations of class 7 have to be met as well as the requirements of the Atomic Energy Act and the Radiation Protection Ordinance. There is a link between these two areas in so far as the Atomic Energy Act and the Radiation Protection Ordinance contain the requirement that the transport must comply with the dangerous goods transport regulations.

The IAEA Regulations TS-R-1 [4] are applied in Germany through the implementation of the dangerous goods transport regulations for class 7 of the International Modal Organizations.

The international modal regulations for dangerous goods transport of class 7 ADR [2], RID [3], IMDG-Code [6], ADNR [33] and ICAO-TI [7] are implemented nationally by the German regulations GGVSE (Road and Rail) [27], GGVSee (Sea) [28], GGVBinsch (Inland waterway) [29] and Luftverkehrs-Zulassungs-Ordnung (Air) [30].

Basis for the package approval procedure is the German guideline R003 [34] issued by the Federal Ministry of Transport, Building and Housing (BMVBW).

5.6.1.2 COMPETENT AUTHORITY

5.6.1.2.1 NAME, ADDRESS, NOMINATION AND RESPONSIBILITIES

There are two governmental organizations with responsibilities as competent authority.

(1) Federal Office for Radiation Protection (BfS), Willy-Brandt-Straße 5, 38226 Salzgitter and
(2) Federal Institute for Materials Research and Testing (BAM), Unter den Eichen 87, 12205 Berlin.

Their responsibilities are defined by the German regulations (see chapter 5.6.1.1) and additional information are given in the German guideline R003 – “Directives concerning the type approval procedure for shipping containers to carry radioactive substances” [34].
In the German dangerous goods transport regulation for road and rail - GGVSE [27] are the responsibilities defined under paragraph 6:

> *“...(2) The Bundesanstalt für Materialforschung und –prüfung is for the enforcement of this regulation responsible for …*

13. *the assessment and approval of special form radioactive material according to 5.1.5.3.1 in connection with subsection 6.4.22.5 sentence 1 and the confirmation according to subsection 6.4.22.6 letter a and the approval of package design types containing non-fissile or fissile excepted uranium hexaflouride according to 5.1.5.3.1 in connection with subsection 6.4.22.1 and the confirmation according to subsection 6.4.22.6 paragraph a;*
14. *the assessment and approval of design types for low dispersible radioactive materials according to 5.1.5.3.1 in connection with subsection 6.4.22.5 sentence 2 and the confirmation according to subsection 6.4.22.6 paragraph a in agreement with the Bundesamt für Strahlenschutz;…*
18. *the design type test of packages for radioactive materials which need an approval according to chapter 6.4;*
19. *the supervision of quality assurance measurements regarding the construction, manufacture, testing, documentation and inspection of packages for radioactive materials which have to be approved according to chapter 6.4 in connection with section 1.7.3;*
20. *the recognition and supervision of quality assurance programs regarding the design, manufacture, testing, documentation, use, maintenance and inspection of packages for radioactive materials which have the obligation to be tested according to chapter 6.4 in connection with section 1.7.3;…*

(2) The Bundesamt für Strahlenschutz is for the enforcement of this regulation responsible for …

2. *the approval of shipments of radioactive materials according to 5.1.5.2.2;*
3. *the approval of shipments under special arrangement for the transport of radioactive materials according to 5.1.5.2.3 and*
4. *the approval of package design types for radioactive material according to 5.1.5.3.1 in connection with subsection 6.4.22.2 up to 6.4.22.4 and the confirmation according to subsection 6.4.22.6 paragraph a."*

BfS is the competent authority for the approval of Type B(U), Type B(M), Type C packages and all packages containing fissile material as well as for all shipments approvals and special arrangements and performs own assessments of criticality and shielding safety analysis. BfS is also the competent authority for all shipment licences for fissile material and large sources according to the German Atomic Energy Act.

BAM is the competent authority for approvals for special form and low dispersible radioactive material (LDM) and H(U)/H(M) packages for UF6 and the responsible authority for the assessment of the mechanical and thermal behaviour of the package, the leakage rate and the quality assurance program. BAM is also responsible for the quality monitoring of the packages, manufacture and re-inspection.

5.6.1.2.2 ORGANIZATION

BfS and BAM are governmental organizations. They are absolute independent from private industry.

In BAM the section III.32 "Transport Packagings for Radioactive Materials" deals with the assessment of cask for radioactive materials. This section as well as the test laboratory III.31 "Testing of Containers" responsible for all experimental investigations belong to the Division III.3 "Safety of Transport and Storage Containers" which is part of the Department III "Containment Systems for Dangerous Goods". The Department III has 3 divisions. Division III.3 consist of 3 sections.
The head of the department and the head of the division bear the professional, organizational and personal responsibility for the organization unit which they manage and for the representation and further development of this specific field.

At the moment 10 employees are working in the section BAM-III.32. All of them have a university degree or a university of applied sciences degree. The specific fields of these degrees are mechanical engineering, physics and material science. There is a specialisation for the assessment of the Design Safety Report in the fields of mechanical (2 employees), thermal (1 employee), material (1 employee), leakage (1 employee) and quality assurance (1 employee) assessment. This specific qualification adopted the employees during their work by themselves, by other long expierienced colleagues or by specific further education.
The BAM test laboratory III.31 has 7 employees permanent staff of similar qualification (2 scientists, 3 engineers, 1 technician, 1 worker).
Because of the task to perform design type tests BAM has the facility to test casks up to 100 tons in required drop tests, casks with dimension of 8,5 m x 5 m in thermal test and for leak tightness test [35]. A drop test facility on the test site Horstwalde (south of Berlin) for casks up to a mass of 160 tons is under construction.

The Federal Office for Radiation Protection-BfS belongs to the scope of the Federal Ministry of Environment, Nature Conservation and Nuclear Safety (BMU). BfS deals with all questions of radiation protection including non-ionizing radiation.
The transport section (SE 1.6) of BfS belongs to the licensing division for transport and interim storage (SE1) which is part of the department for nuclear safety (SE).
It consists at the moment of 9 employees-mainly physicists and engineers with university degree. The transport section is responsible for

- all approvals and licenses for packages and shipments including packages for transport and storage (see 5.6.1.2.1),
- the assessment work for shielding and criticality safety by applying various computer codes ranging from simple one-dimensional codes to complex three-dimensional Monte Carlo Codes, and
- all radiation protection questions related to transport of radioactive material as expert authority to support the Ministry of Transport, Building and Housing (BMVBW) and the BMU.

5.6.2 APPROVAL METHODOLOGY

5.6.2.1 APPLICATION AND REQUESTED DOCUMENTS FOR PACKAGE DESIGN APPROVAL

5.6.2.1.1 APPROVAL OF NEW PACKAGE DESIGNS

With the application for an approval of a new package design a documentation is required which contains at least the applicable information according to chapter 6.4.23.4 to 6.4.23.7.of ADR/RID. The evidences that all applicable requirements are met must be in form of a safety analysis report. This report must contain in particular:

- the transport modes, that should be covered by the package design approval
- a detailed description of the proposed radioactive contents, in detail
  - nuclide(s)/nuclide composition
  - activity, mass
  - physical and chemical state, geometry, arrangement, irradiation data, material
  - nature of the radiation emitted
  - heat generation
  - mass of fissile contents
- a reproducible illustration (max. 21 cm x 30 cm) showing the make-up of the package with maximum dimensions and package mass (empty and loaded)
- a detailed description of the design and design components by complete engineering drawings, parts list, material specifications, and descriptions of:
  - package concept
  - package inserts

  - containment system incl. accessory components
  - necessary components for radiation shielding
  - confinement system incl. accessory components
  - transport concept incl. components necessary for safe handling, transfer operations and securing on the conveyance
  - corrosion protection
  - contamination protection
  - shock absorbing components
- safety evidences that show that all applicable requirements are met with the following main topics:
  - evidence for mechanical resistance under normal and accident conditions of transport for:
    - components of the containment system
    - components of the radiation shielding
    - components of the confinement system
    - lifting attachments
  - evidence for thermal resistance for normal and accident conditions of transport for:
    - components of the containment system
    - components of the radiation shielding
    - components of the confinement system
  - evidence that the release of radioactive material under normal and accident conditions of transport are within required limits
  - evidence that the dose rates under normal and accident conditions of transport are within required limits
  - evidence of sub-criticality for fissile material under normal and accident conditions of transport
- quality assurance programme and all necessary instructions for use, re-testing etc.
- in the case of an applications for a type B(M) or type B(M)F package design additional information are required:
  - a list of the requirements specified for type B(U) or type B(U)F with which the package does not conform
  - any proposed supplementary operational controls during transport which are necessary to ensure safety of the package or to compensate for the deficiencies
  - a statement relative to any restrictions on the mode of transport and to any special loading, carriage, unloading or handling procedures
  - the range of ambient conditions (temperature, solar radiation) which are expected to be encountered during transport and which have been taken into account in the design

5.6.2.1.2 MULTILATERAL APPROVAL/VALIDATION OF FOREIGN PACKAGE DESIGNS

5.6.2.1.2.1 PACKAGE DESIGNS FOR FISSILE MATERIAL AND TYPE B(M) PACKAGE DESIGN

With the application for the multilateral approval (validation) of foreign package design approvals it is required to send at least the following documents:

- the original certificate of the package design
- a German translation of this certificate
- all instructions for the use of the package (in original language)
- a German translation of these instructions
- the appropriate quality assurance programme (in original language)
- for type B(M) package designs or if the contents is fissile material, the complete Design Safety Report (in original language) is required.

See also chapter 5.6.2.2.3.1 and 5.6.2.2.3.2.

5.6.2.1.2.2 PACKAGE DESIGNS SUBJECT TO TRANSITIONAL ARRANGEMENTS ACCORDING TO ADR 1.6.6.1 AND 1.6.6.2

The same documentation as written in 5.6.2.1.2.1 is required for package designs which are subjected to the transitional arrangements. Also the complete Design Safety Report is requested for information purposes in original language.

5.6.2.2 DESCRIPTION OF THE APPROVAL PROCEDURE

5.6.2.2.1 ORGANIZATION OF THE APPROVAL PROCEDURE OF A NEW PACKAGE DESIGN

BfS is responsible for the whole package design approval procedure. An approval procedure can be described briefly as follows:

- submission of the application to BfS and BAM
- sending an acknowledgment of receipt to the applicant
- checking the completeness of required documentation, see 5.6.2.1.1 (if not, the missing documentation is requested)
- checking if there are statements to all applicable requirements (if not, this is requested)
- detailed examination and assessment of all statements according to the responsibilities of BfS and BAM, see 5.6.1.2.1
- sending all questions and remarks to the applicant for comments and, if necessary, for revision of the appropriate reports
- drawing up the BAM assessment report, internal coordination and signing within BAM
- sending the BAM assessment report to BfS and applicant
- comparison of the applicant assumptions for mechanical and thermal behaviour which effect the shielding and criticality analysis with the results of the BAM assessment by BfS
- drawing up the internal BfS assessment reports for shielding and criticality analysis
- draft of the package design approval certificate (if appropriate, with additional provisions due to BAM and BfS assessment)
- internal BfS coordination and clearing by section head and legal section of the draft of the certificate
- sending the draft to the applicant due to “Verwaltungsverfahrensgesetz” [36] (hearing of persons concerned)
- receipt of comments due to internal BfS coordination and hearing
- inclusion of comments into the draft (if necessary, new coordination and hearing)
- signing the package design approval certificate by the main responsible person, making the fee declaration
- sending the certificate and fee declaration to the applicant (copies of the certificate are sent also to BAM and BMVBW)

The time period for an approval procedure ranges from some month to some years. Generally it depends from:

- quality and completeness of the application
- number of applications to be assessed by BfS and BAM
- Have new materials or design principles been used for the applied design?
- Are there any earlier already approved package designs similar to the applied design?
- Have impact or thermal tests to be performed?
- extent of modelling efforts of complicated designs for own re-calculation

5.6.2.2.2 PROCEDURE IN THE CASE OF MODIFICATIONS OF THE PACKAGE DESIGN

Changes of the contents of an approved package design and any other change with effect on the Design Safety Report lead to a revision of the approval certificate.
With the application the applicant has to provide all necessary documents to show that the requirements of the regulations are met. The documents must cover all required information according to chapter 5.6.2.1.1 due to the change.
For other changes other procedures are implemented with no need to change the approval certificate (see chapter 5.6.3.2).

5.6.2.2.3 PROCEDURE FOR MULTILATERAL APPROVAL/VALIDATION

5.6.2.2.3.1 PACKAGE DESIGNS FOR FISSILE MATERIAL

In the case of fissile contents BfS first checks the criticality safety analysis and formulates when necessary questions to BAM for the assumptions of geometry and if applicable of water leakage of the package design. BAM evaluates the assumptions of the geometrical changes after the mechanical and thermal tests and compares these with the geometrical basic assumptions of the applicants criticality calculation.
BAM also checks the proof of the mechanical and thermal tests about differences, like a high leakage rate, a missing slap down drop test, the behaviour of lid screws after drop test or a crack in a weld.
Furthermore it is requested by BfS that BAM checks the quality assurance aspects in particular the specifications for use, maintenance and inspection of the package design too.
BAM sends to BfS a short evaluation report.
When the BAM evaluation results are positive BfS examines the criticality analysis of the applicant by own calculations and checks the basic assumptions of the dose rate assessment.
Finally the validation certificate is granted by BfS based on positive BfS/BAM evaluation results.

5.6.2.2.3.2 TYPE B(M) PACKAGE DESIGN

The validation of a type B(M) package design approval is similar to the validation process of package designs for fissile material. In addition, any difference to a type B(U) package design allowed by the regulations will be checked in detail.

5.6.2.2.3.3 PACKAGE DESIGNS SUBJECT TO TRANSITIONAL ARRANGEMENTS ACCORDING TO ADR 1.6.6.1 AND 1.6.6.2

For package design approval applications the complete Design Safety Report is requested and the extent of the assessment work depends on the specific design.
For a validation of a type B(U) package BAM is involved with the evaluation of the instructions for the use of the package and the quality assurance programme and if necessary for specific design aspects regarding mechanical and thermal stability.
For the validation of package designs containing fissile material see chapter 5.6.2.2.3.1.

5.6.2.3 DESCRIPTION OF THE SAFETY ASSESSMENT PROCEDURE

5.6.2.3.1 ORGANIZATION OF THE ASSESSMENT PROCEDURE

In the BfS the application for a package design approval is handled in project-oriented way according to German guide R003 [34]. That means that the main responsible person has to coordinate all the necessary work within the section SE 1.6 where all evaluations regarding criticality and shielding are made. He has also the contact to BAM and the applicant if necessary. He is responsible for the internal BfS assessment reports, which are created according to internal guidelines, checklists and sample reports.

Section BAM-III.32 assess a design type in a composition of object-orientated and functional process. One assessor is responsible for the contact to the applicant, the progress of the assessment and for the final assessment report. This assessor checks at first the documentation regarding completeness and consistency (preliminary review) and he notice specific problems, like decontamination problems, high stresses or temperatures or a high leakage rate. Then the assessment of mechanical, thermal and leakage proofs of the applicant will be checked by a specialist in this field. He writes a statement which the assessor use for the assessment report. Is there the necessity of further investigations the assessor organise the contact to intern or extern specialists. The assessor must demonstrate in the assessment report point by point if and how the relevant regulatory requirements are fulfilled for the design type by the applicant's safety case. The assessment report may contain proposals for conditions in the approval design certificate.

5.6.2.3.2 SAFETY ASSESSMENT METHODS

BfS and predecessor organizations have many years of experience in evaluating criticality and dose rate assessments within the package design approval procedures.
BfS is using modern three-dimensional Monte Carlo computer codes, i.e. the SCALE code system, for the evaluation of criticality and shielding analysis of the applicant. If appropriate and applicable in some cases also simpler, one-dimensional codes like MICROSHIELD are used.
In addition to that BfS performs also radiation field measurements on spent fuel casks, casks with HAW and other Type B packages to validate computer programs.

BAM deals with assessment questions of transport packagings for radioactive materials since more than 30 years. During this time BAM assess and tests a lot of packaging design types especially the CASTOR casks [37], [38], [39] [40], [41].
Special equipment for the assessment of computer based mechanical and thermal calculations are known finite-elements-software ANSYS, LS-DYNA, FLOATRAN, PATRAN and ABAQUS. Additionally BAM programs and uses its own software for special problems. These programs are mostly written in FORTRAN. Calculations will performed with the software MATHEMATICA.
At the first step the Design Safety Report is checked by the person in charge regarding plausibility. Then he check the components of the cask which are responsible for the integrity and leaktightness and the geometry of the components responsible for subcriticality. In general these components are spot checked but the person in charge choose the critical cask areas or implausible proofs and recalculate or reassess these with own calculations or investigations if possible with a different (calculation) method.
For specific investigations, like corrosion, non-destructive material tests, tests on plastics or ease of decontamination, section BAM-III.32 can cooperate with the experts of the whole BAM and other institutions.

5.6.2.3.3 ACCEPTED CALCULATION METHODS

For criticality and dose rate assessments BfS accepts all standards, codes and computer software provided the applicant can give evidence for the applicability of the standard, code and computer software and the correctness of the calculated results (validated and quality assured codes and computer software).

BAM accepts every appropriate standard or code, but the applicant has to demonstrate compliance between the problem to be investigated and the limits of the code used. For specific cases BAM develops own guidelines for applicants, e.g.

- A guideline for the use of ductile cast iron for Type B packages [42], [43],
- A guideline for numerical safety analyses (of mechanical and thermal calculation) [44],
- A (draft) guideline for the assessment of the activity release from spent fuel transport casks,
- A guideline for design criteria of lid bolts and trunnion bolts is currently under preparation.

All appropriate calculation for mechanical and thermal problems are accepted. BAM has actually issued a “Guideline for numerical safety analyses in design assessment of transport and storage containers for radioactive materials” [44]. This guideline describes BAM’s acceptance criteria for numerical mechanical and thermal calculations, mainly the finite-element-method and is the basis for the quality assurance during compilation, checking and assessment of these calculations. The use of this guideline ensure the traceability of the calculation steps, of the requirements and the assumptions which form the basis of the calculations.

5.6.2.3.4 PERFORMANCE OF PACKAGE DESIGN TESTS

Necessary mechanical and thermal design tests must be performed in Germany by BAM as the competent testing authority according to German guideline R003 [34]. The BAM-laboratory III.31 “Testing of Containers” [35] performs the required mechanical and thermal tests on components, original or scale model packagings. The tests are carried out following a test program that is signed by BAM and the applicant before the test. For all tests of a design type the BAM laboratory issues a test report, which is one basis for the assessment of the design type safety case.

5.6.2.3.5 STRUCTURE OF THE ASSESSMENT REPORT

The results of the BfS assessment are summarised in internal assessment reports which contain mainly:

- reference to the applicable documents
- description of the calculation model
- results of the calculation and comparison to BfS calculation results and applicable limits and requirements of the transport regulations
- criteria, parameters and conditions to be specified in the package design certificate

These BfS assessments reports follow internal guidelines, checklists and sample reports which are subject to continuous review. They are signed by the assessors and cleared by the transport section head. They are also part of the final clearing procedure of the certificate which includes also legal experts.

The BAM Assessment Report for a Type B(U) package has in general the following gross structure:

- ***Content of the application / Evaluation task of BAM***

- ***Description of the packaging design type***
- Package body
- Closures

- Basket
- Containment design
- Shielding design
- Lifting devices
- Shock absorbers
- Ease of Decontamination
- Corrosion protection

- ***Description of content***

- ***Requirements on the package***

- ***Tests and safety proof***
- Mechanical tests
- Thermal tests
- Water immersion test

- ***Safety proofs***
- General requirements for all packagings and packages
- Requirements for Type A packages
- Requirements for Type B(U) packages

- ***Quality assurance***
- Quality management system of the applicant
- Measures of package specific quality assurance

- ***Conditions for approval***

- ***Summary***

The assessment report will be signed by the head of the division, the head of the section and the assessor.

5.6.2.4 SHIPMENT APPROVAL METHODOLOGY INCLUDING SPECIAL ARRANGEMENT

5.6.2.4.1 SHIPMENT APPROVAL

An application for shipment approval must include the information according to the requirements of ADR, 6.4.23.2. In practice a more detailed list of required information within this framework is given to the applicant by BfS on request. The shipment approval certificate of BfS takes into account the requirements of ADR, 6.4.23.13 and contains the following information:

- Identification number of the approval certificate (competent authority identification mark)
- Legal basis for issuing the certificate
- Applicant and date of application
- Carrier (for the different transport modes)
- Specification of the permissible radioactive material (activity, nuclides, mass, form, enrichment,...)
- Permissible number of shipments
- Consignor, transport route including different modes, consignee
- Conveyance

- Package (type, identification mark, package design approval certificate, validation certificate if applicable)
- Transport index (TI), criticality safety index (CSI)
- Expiry date of the certificate
- Additional specific provisions including any restrictions
- Fee declaration
- Legal instruction
- Date, signature, seal

In case of shipment approval / transport licenses according to the Atomic Energy Act and the Radiation Protection Ordinance for nuclear material and large sources (see 5.6.1.2.1) the following additional information are included in the certificate:

- Authorized companies for transport including transhipment
- Nuclear liability insurance
- Physical protection measures
- Specific emergency arrangements (for large sources)

The shipment approval process in BfS is handled in a project-oriented way by a responsible person. This person gets also support from package design experts in the transport section if needed. The whole procedure is supported by internal guidelines, checklists and sample certificates. The responsible person drafts the certificate and finally signs it after the clearing process by section head and by a responsible person from the legal section.

5.6.2.4.2 SPECIAL ARRANGEMENT

The use of special arrangement is handled very restrictive by BfS. It is considered to be the exceptional case. A special arrangement certificate is issued by BfS only if the applicant is able to demonstrate the justification for it and the equivalent level of safety (equivalent to an approved package design or to a package design in full compliance with the applicable requirements).
An application for special arrangement must contain the information according to the requirements of ADR, 6.4.23.3.
If needed BAM is charged by BfS to provide their expertise on package design safety issues (mechanical and thermal aspects, leaktightness, quality assurance). Based on this and BfS assessment the special arrangement certificate is issued according to the same procedure as outlined under 5.6.2.4.1. The certificate itself contains the same kind of information as given under 5.6.2.4.1 with the addition of the reason for the special arrangement. The special arrangement certificate of BfS takes into account all the information given under ADR, 6.4.23.12.

5.6.3 DESCRIPTION OF THE APPROVAL CERTIFICATE

5.6.3.1 STRUCTURE OF A APPROVAL CERTIFICATE (E. G. TYPE B(U)/B(U)F)

The structure and the content of a package design approval in form of a approval certificate correspond to following scheme:

- Competent authority identification mark of the certificate
- Legal basis for issuing the certificate (type of the package design, applicant, application, name of the package design, allowed transport modes, applicable regulations)
- Certification holder
- Documents (Design Safety Report and other necessary documents) including the reference to the documentation that demonstrates the criticality safety of the contents

- Name of the package
- Identification mark of the package design
- Expiry date of the approval certificate
- Permissible content
- Criticality Safety index (CSI) for package designs with fissile material
- Design type of the packaging including the reference to the BAM Assessment Report
- Description of the packaging
- Additional provisions and restrictions
  (e.g. additional instructions including the reference to instructions for the use of the package and re-inspection, specific provisions regarding some implementation aspects of the certificate requirements,...)
- Fee declaration
- Legal instructions
- Date, signature, seal
- Appendices
  - List of revisions of the approval certificate
  - Drawing of the packaging
  - (other necessary information, i.e. tables, figures)
  - Design type list

5.6.3.2 CONSIDERATION OF MODIFICATIONS OF THE PACKAGE DESIGN IN THE APPROVAL CERTIFICATE

BfS decided to introduce a “design type list” into the design approval certificate which includes the actual and all previous (if needed) revisions of the main parts list.
A benefit of the introduction of the design type list was that changes and improvements that are non-safety relevant or where the safety is equivalent to the examined one as laid down in the Design Safety Report can be handled in an easy way. Because of signing the design type list separately it can be replaced without making a revision of the whole certificate.

In some cases the change of a drawing or a sub parts list can lead also to many changes in other related drawings and parts list, which would result in a very intensive work to create a new design type list. In addition to that it is not possible to change the parts list of manufactured casks if design improvements are desirable. Another procedure to handle changes and improvements was therefore developed in such a way that the applicant provides a “certificate of modification” with a detailed description of the change itself and the justification why it is non-safety relevant.

Both the revised parts list as well as the certificate of modification will be examined by BAM as the competent authority for the evaluation of mechanical, thermal and leaktightness properties as well as for the quality assurance programmes of a cask and by BfS for the evaluation of sufficient shielding and sub-criticality. If the evaluation has appositive result either

- an extended design type list will be issued by BfS and becomes part of the approval certificate if a revision of the parts list had been made, or
- an agreement will be given by BfS if the applicant applies for the accepting of a certificate of modification.
  Both the agreement and the certificate of modification becomes part of the cask documentation. If some more casks shall be built all modifications have to be included into the constructional documentation when the applicant will apply for the next revision of the certificate approval.

In the case that an approved instruction which is part of the approval certificate has to be modified due to practical experiences either a statement is included in the main instruction or

an additional provision is included in the approval certificate how to handle these cases without the need of changing the approval certificate. At least the clearance by BAM, for instructions concerning e.g. the testing of contamination or shielding in cooperation with BfS, is required sometimes in addition an endorsement by BfS is needed.

Since the implementation of these procedures it can be stated that on the one hand the descriptions/provisions are detailed enough to comply with the applicable requirements of the Regulations and on the other hand they provide a certain degree of flexibility to cover practical needs [45].

5.6.3.3 STRUCTURE OF A MULTILATERAL APPROVAL CERTIFICATE/VALIDATION OF A FOREIGN APPROVAL CERTIFICATE

A validation consist of the following parts:

- Competent authority identification mark of the certificate
- Legal basis for issuing the certificate (reference to the original package design approval certificate, applicant, application, name of the package design, allowed transport modes, applicable regulations, reference to the BAM Assessment Report)
- Certification holder
- Name of the package
- Identification mark of the package design
- Expiry date of the approval certificate
- Permissible content (i.e. by referencing of chapter of original certificate)
- Criticality Safety index (CSI) for package designs with fissile material
- Additional provisions and restrictions
  (e.g. additional instructions including the reference to instructions for the use of the package and re-inspection by reference of the applicable chapters of the original certificate)
- Fee declaration
- Legal instructions
- Date, signature, seal
- Appendix (translation of the original certificate)

5.6.3.4 STRUCTURE OF A SHIPMENT APPROVAL CERTIFICATE

See chapter 5.6.2.4.1.

5.6.4 JOINT CERTIFICATION PRACTICES

Joint certification practice between France and Germany is currently performed for the NCS-45 package design (for irradiated fuel rods and fuel pellets) and the TN 81 package design (for high level vitrified radioactive waste).

5.7 APPROVAL METHODOLOGY IN FRANCE

5.7.1 LEGAL BASIS FOR COMPETENT AUTHORITY AND TECHNICAL SUPPORT

5.7.1.1 NATIONAL AND INTERNATIONAL LAWS, REGULATIONS AND GUIDELINES FOR PACKAGE DESIGN AND SHIPMENT APPROVALS

The applicable regulations used by DGSNR and IRSN for assessments are:

- Regulations for the Safe transport of radioactive Material, TS-R-1, IAEA
- ADR +Decree 01/06/2001 for dangerous goods transports by road, modified
- RID + Decree 05/06/2001 for dangerous goods transports by rail, modified
- IMDG + Decree 23/11/1987 for dangerous goods transports by sea, modified
- Technical Instructions of ICAO + Decree 12/05/1997 for dangerous goods transports by road, modified
- ADNR + Decree 05/12/2002 for dangerous goods transports by Inland waterways
- Additional decrees for transport of radioactive materials through road tunnels

These decrees contain some deviations with the international regulations concerning for instance gamma radiography devices

5.7.1.2 COMPETENT AUTHORITY

5.7.1.2.1 NAME, ADDRESS, NOMINATION AND RESPONSIBILITIES

The French competent authority for transport of radioactive material for civil use is the “Directeur Général de la Sûreté Nucléaire et de la Radioprotection (DGSNR director)”; as the representative of the Ministry in charge of Industry and the Ministry in charge of Environment. The competent authority is responsible for the development of the regulations, the approval of packages, shipments and materials and the control of implementation of the regulations.

The DGSNR address is:

Direction Générale de la Sûreté et de la Radioprotection
6 Place du Colonel Bourgoin
F-75572 PARIS CEDEX 12

5.7.1.2.2 LEGAL FORM AND ORGANIZATION STRUCTURE

The DGSNR organization includes 7 engineers including a coordinator, the sub-manager and his assistant for preparing decisions. The coordinator supervises the files according to the difficulties, deals with the regulation and with the feedback experience document [.

The competence fields are divided according to four items:

1. Irradiated and unirradiated fuels,
2. Fissile powders, vitrified wastes,
3. Sources, other wastes,
4. uranium hexafluoride, uranium nitrate and other materials

5.7.1.3 TECHNICAL SUPPORT

5.7.1.3.1 NAME, ADDRESS, NOMINATION AND RESPONSIBILITIES

In France, the technical support is provided by the “Institut de Radioprotection et de Sûreté Nucléaire (IRSN)”. IRSN is completely independent from private industry.

The address of IRSN is:

Institut de Radioprotection et de Sûreté Nucléaire

Direction de la Sûreté des Usines, des laboratoires, des transports et des déchets (DSU)

Service de Sûreté des Transports et des installations du Cycle (SSTC)

B.P. 17

F – 92262 FONTENAY-AUX-ROSES Cedex

IRSN performs the complete assessment of the Design Safety Report. The concerned role of the IRSN is defined in article 36 of French ADR “decree”(or in article 28 of French RID “decree”, article 15 of ADNR decree, article 411-4.04 of Division 411 appendix of IMDG decree) in the following way:

“Article 36 – Packaging for the radioactive materials. –

The minister in charge of industry and the minister in charge of the environment jointly deliver the approvals envisaged in para. 5.1.5.3.1 and 2.2.7.7.2.2 for:

- *radioactive materials in special form;*
- *low dispersible radioactive materials;*
- *all packages containing fissile materials;*
- *packages containing 0,1 kg or more uranium hexafluoride;*
- *packages of the type B(U), type B(M), and type C;*
- *special arrangements;*
- *the shipment specified in para 5.1.5.2.2;*
- *the calculation of A1 and A2 values, which do not appear in the table 2.2.7.7.2.1.*

The institute of radiation protection and nuclear safety (IRSN) brings its support to the general direction of nuclear safety and radioprotection (DGSNR) on this activity.”

According to article 42 of French ADR “decree” or article 33 of French RID “decree”, payment of expenses relative to the delivery of the certificates or the realization of the tests and checks envisaged by this decree are the responsibility of the applicant. The costs of the technical assessments are defined by IRSN according to type of approval (new approval, special arrangement, multilateral approval, special form material approval…) [46]. There is no additional payment required for the delivery of the certificates.

5.7.1.3.2 LEGAL FORM AND ORGANIZATION STRUCTURE

IRSN performs the complete assessment of the Design Safety Report. In IRSN, the section called « Bureau d’Expertise de la Sûreté des Transports » (BEST, Transport Safety Assessment Unit) which is a unit of « Service de Sûreté des Transports et des installations du Cycle du combustible » (SSTC, Transports and Fuel Cycle Facilities Safety Section) which is a part of « Direction de la Sûreté des Usines, des laboratoires, des transports et des déchets » (DSU, Plants, Laboratories, Transports and Wastes Safety Division”), deals with the assessment of package designs for radioactive materials transport.

In the BEST unit, there are 13 experts including a manager for checking assessment reports, drafts of approval certificate and recommendation letters.

IRSN organization involved in package certification implements its own procedures to assure proper qualification of its staff.

Each IRSN expert is in charge of the whole Design Safety Report and may request additional support by identified experts in particular in the field of criticality safety and of dynamic mechanics and brittle fracture.

IRSN experts may use the following softwares to appraise the Design Safety Reports or subcontract the verification of calculations:

(NAME)	(Field of use)
- POSEIDON	Evaluation of radionuclides maritime dispersion
- LUSEC	evaluation of activity release
- CALLIOPE	Data base on radionuclides
- MICROSHIELD	Dose rates calculations
- THERMX + PROTEE	Thermal calculation, code adapted to package configurations
- ANSYS 5.4	Mechanical + Thermal calculations
- CASTEM2000	Mechanical + Thermal calculations
- APOLLO, MORET, CRISTAL	Criticality calculations

5.7.2 APPROVAL METHODOLOGY IN FRANCE

The following description of the French approval system was taken from references [47], [48], [49], [50], [51], [52], [53].

5.7.2.1 DESCRIPTION OF THE APPROVAL PROCEDURE

5.7.2.1.1 ORGANIZATION OF THE APPROVAL PROCEDURE OF A NEW PACKAGE DESIGN

Any approval procedure with regard to a package design can only be initiated via the transmission of an application in writing to DGSNR, by an individual or a legal entity called "the applicant". This application usually is supported by four hard copies of the Design Safety Reports which justify the package compliance to the regulation (one Design Safety Report is studied by the technical support of the French competent authority, the second one by the DGSNR and the last two are archived to be used in case of emergency).

Recently electronic copies have been requested to optimize the archiving constraints.

A copy of the application with enclosure is transmitted by the applicant to the technical support of the French competent authority. Upon receipt of the application documents, the DGSNR appoints an individual in charge of investigating this file. If the application is considered as admissible, he may request a technical support with regard to the compliance of the package model to the regulation for radioactive material transports. The recommendation request results in the transmission to the technical support (IRSN) of an assessment order, drafted and signed by the DGSNR manager.

After appraisal of Design Safety Report the technical support, transmits a recommendation letter and an appraisal report to the DGSNR. If the recommendation is positive or partially positive, a draft approval certificate meeting all or part of the applicant’s request supports it. A certificate validity period may be proposed by the technical support in its recommendation.

The DGSNR manager continues his analysis, based on these documents, on the application file transmitted by the applicant, and on the necessary exchanges with the technical support and the applicant, which may result in the transmission of a new draft certificate, on his request. If the DGSNR manager agrees for delivering the certificate, he defines the expiry date on the certificate. The DGSNR secretariat assigns a registration number to be stamped on all copies of the draft certificate. It specifies the identification mark of the certificate concerned, and checks that it was not already been assigned in the past days. The "n" draft certificates are communicated for signature to the DGSNR director.

When the "n" certificates are signed, the DGSNR secretariat:

- Dates the approval certificates and records the date in the specific day-to-day register,
- Transmits an original certificate to each applicant,
- Makes a copy of original certificate for transmission to the technical support,
- Transmits the last original copy for archiving.

In general, there are 5 cases for the validity period of an approval certificate:

a) If all points are correct, the validity period is about five years for certificates of approval for a package design,
b) If additional justifications are needed, the validity period is limited (it depends on the impact of the safety, but the maximum validity period is five years),
c) For a validation certificate, the validity period does not exceed the validity period of the certificate of the country of origin of the design,
d) For shipment approval and shipment approval under special arrangement certificate, the validity period is generally one year or less,
e) For certificate of approval for special form radioactive material, the validity time should not exceed 10 years.

5.7.2.1.2 PROCEDURE IN THE CASE OF MODIFICATIONS OF THE PACKAGE DESIGN

DGSNR considers that design changes can be classified under three different categories:

- CATEGORY A: Major change which impacts the safety of the package design. In this case, the change will be assessed and a new certificate will be issued.
- CATEGORY B: A minor change is the situation where the applicant may be able to demonstrate that the design change will not affect the safety, by using the same demonstration process and by providing the same order of magnitude for safety margin than in the original Design Safety Report. For such changes, it is expected that the applicant informs systematically DGSNRand accordingly, gives the demonstration that the safety is not altered. The concerned foreign competent authorities should be informed. The competent authority validates the modification two months after receipt; the modification will be fully described in the next renewal application.

- CATEGORY C: changes with no impact on safety; these minor changes shall be documented according to quality assurance provisions. The competent authority may subsequently inspect the quality assurance program and the related documentation. Applicants have to keep a database of these modifications and have to transmit their list at each renewal application.

5.7.2.2 DESCRIPTION OF THE SAFETY ASSESSMENT PROCEDURE

5.7.2.2.1 PERFORMANCE OF PACKAGE DESIGN TESTS

Package testing, where required, is carried out by the applicant, but witnessed by DGSNR or its technical support to ensure that they are satisfied that the tests meet the regulatory requirements.
A test program is required and approved by the competent authority. Before acceptance of the test program, a functional report of the package safety is required. The regulations require tests to be carry out in the most damaging attitude, and if there is any ambiguity in this, the assessor may require the conduct of further tests to cover all possibilities.

5.7.2.2.2 ORGANIZATION OF THE ASSESSMENT PROCEDURE

The appraisal of the whole Design Safety Report is performed by the IRSN unit specialized in transport safety, the BEST.

5.7.2.2.3 SAFETY ASSESSMENT METHODS

The IRSN assessments are based on two steps, the preliminary assessment of completeness (approximately 1 month) and the detailed appraisal. The pre-review and the appraisal are structured by a combination of functional analysis and object-oriented specialization.

The preliminary review and the appraisal are structured by a functional analysis that identifies the significant components for the safety and the requirements of performances under the different transport conditions specified in the regulation.

The basic safety functions that should be ensured for a radioactive material package include:

- containment,
- radiation protection,
- subcriticality,
- heat dissipation.

Each transport condition (routine, normal, or accidental) is modelled by a number of tests, defined in the applicable regulations, and associated to performance criteria, which depend on the type of package. A Design Safety Report should provide the essential information and justifications sufficient to ensure the package safety in any situation specified in the regulations (routine, normal and accident conditions of transport) and to guarantee the associated safety functions. The safety functions are provided if the behavior of the components providing them meet the performance criteria applicable in the situations concerned. A Design Safety Report that does not include all these justifications will most probably not be considered sufficient to allow the competent authority to confirm the package conformity.

The IRSN preliminary review and final appraisal are also based on Experience-feedback. An “Experience-feedback document” in the form of a list of difficulties encountered in safety reports assessments is periodically updated and mailed to applicants.

IRSN issues for almost each application a preliminary list of complementary justifications to be provided by the applicant.

Based on the technical justifications described in the safety report, the purpose of the appraisal is to check whether the package design performances comply with international and national regulations applicable to radioactive material transport. For this purpose, considering the available experience feedback, the expert analyses the file contents, estimates the pertinence and acceptability of assumptions and analysis methods applied, assesses the uncertainty associated with these methods, and checks the performance compliance with the regulatory requirements of the package safety-related components. In case of doubt with regard to the validity of the justifications described in the safety report, the

expert should extend his appraisal and may contact the applicant to obtain additional information and, if applicable, request for support from an external body to complete his appraisal.

The expert appraisal is based on:

- the safety report,
- the experience feedback document,
- the preliminary review of the safety report,
- his own experience,
- the additional justifications provided by the applicant.

The appraisal more specially focuses on the following technical areas:

- resistance of materials, in order to quantify the distortions, displacements, or risk for sub-assembly break-up, including brittle fracture hazard,
- dynamic mechanics, in order to assess the risks due to impacts, considering the amplification, instability, dampening, crushing, break-up phenomena, etc.,
- thermal, in order to assess the temperatures of sensitive components, whether in steady state (due to the thermal power released by certain contents), or in transient conditions (due to a fire enveloping the package),
- thermodynamics, in order to assess the radioactive releases outside the package containment,
- radiation protection, for calculating the dose rates outside the package. In general the shielding calculation is not checked in detail by IRSN, because the dose rates must be measured and checked before shipment as specified in every approval certificate which raised no difficulties in the past.
- safety-criticality, in order to demonstrate maintenance of a subcritical condition, in routine situation and upon completion of the mechanical and thermal regulatory tests. For criticality analysis IRSN systematically checks by independent calculation the most reactive arrangement. The appraisal of reactivity calculations is delegated by the expert to another IRSN specialized unit (“Service d’Etudes de Criticité”, SEC); however, the expert checks the consistency of calculation hypotheses with other results of the safety report.

Any appropriate calculation method for safety proof is allowed subject to justification of the method validity; same thing for the computer software. For criticality analysis, systematic checks by independent calculation of the most reactive arrangement. For mechanical, thermal and leaktightness analyses, an independent calculation may be performed when analysis validity is doubtful.

The appraisal only covers the design of the package model such as described in the safety report; it does not concern the appraisal of the conformity of the actual packaging to the packaging design defined in the safety report. Checking the packaging and the package contents conformity follows another procedure.

There are 3 cases for the evaluation report:

a) All points are correct.
b) Limited uncertainties can be accepted, if they are removed in a certain time.
c) Deviations or too large uncertainties are not acceptable and the application must be declined.

In any case, IRSN returns a technical advice to DGSNR comprising a recommendation letter and the appraisal report. The recommendation letter shows in summary the main conclusions of the appraisal report and recommends which kind of decision should be taken by the competent authority. With the support of these documents, DGSNR takes the decision to deliver the requested certificate or not. DGSNR also decides

whether uncertainties should be removed in limited time. Justifications of removal of uncertainties, when available, are further assessed by IRSN that returns a new technical advice to DGSNR.

The time necessary to complete the assessment is in average:

- one year for new designs,
- six months for validations, shipment under special arrangement and renewals and four months for extensions and shipment approval..

These times however depend on the capacity of the applicant to provide the additional justifications requested by the technical support.

As an example, an appraisal for a new package model contains:

1. An introduction, in order to describe the application and its background and, if necessary, to make a file history;
2. References to documents used for the assessment;
3. Description of packaging model
4. Description of the allowed contents
5. Evaluation of safety of packaging
   a) A material resistance paragraph, more specially covering brittle fracture, as the package models should be designed for an ambient temperature ranging from -40°C to +38°C;
   b) A mechanics paragraph, with discrimination between normal and accidental transport conditions. This paragraph describes the appraisal of all the mechanical aspects of the appraisal of the safety analysis of the package model design and, for example, the mechanical resistance of components ensuring maintenance of the package model safety functions with regard to regulatory tests, the fatigue analysis;
   c) A thermal paragraph, with discrimination between normal and accidental transport conditions. This paragraph describes the appraisal of all the thermal analyses of the various components of the package design either in steady state or transient (fire) conditions;
   d) An activity release paragraph covering the package design leak tightness under normal and accident transport conditions, in order to meet the regulatory limits for environmental release;
   e) A radiation protection paragraph, in order to appraise the calculation of dose rates outside the package model. These dose rates in CNT and in CAT should meet the regulatory limits;
   f) A radiolysis paragraph, for cases when the radioactive materials are transported in presence of hydrogenous materials;
   g) A criticality paragraph;
6. Methods of manufacturing and checking, methods of testing and examination
7. Utilization procedures and maintenance program
8. Quality assurance program
9. A conclusion in which the IRSN expert gives his opinion with regard to the package model safety, based on his appraisal of the Design Safety Report. He reminds deviations, uncertainties and missing justifications.

5.7.2.3 APPRAISAL EXTENT

- New approval:

The appraisal of a new approval file covers the whole safety appraisal report.

- Renewal:

During the appraisal of a renewal file, IRSN incorporates the experience feedback highlighted in the appraisal feedback experience document. He also checks whether

previous requests for additional justifications issued by the Authority were satisfied. He relies on the conclusions of previous appraisals.

- Extension

If the extension is justified only by a formal modification to the approval certificate, the expert does not perform any new technical appraisal.

If the extension involves a significant change to the package design, IRSN appraises the impact on the safety of the design. If the safety-criticality parameters have changed, whether for the contents or the package, a criticality appraisal is required systematically involving experts from the SEC unit.

- Validation

In the case of a multilateral (type B(M), or fissile material package) or non-ADR approval, a complete appraisal of the Design Safety Report is desirable.

If the complete Design Safety Report is not available, and if the Authority accepts it, the appraisal may be restricted to the areas justifying the multilateral aspect. These areas include:

- for fissile material packages: all regulatory performances associated with the fissile character. The appraisal of the criticality safety analysis systematically includes the checking of the geometrical assumptions and water leakage after the mechanical and thermal tests.
- for B(M) packages: all performances required from type B(U) packages that are not met;
- for packages approved under a previous issue of the IAEA regulations: all feedback experience document items and regulatory changes;
- For packages approved by a non-ADR country: a complete appraisal of the Design Safety Report may be done.

However, any doubt with regard to the compliance of a non-appraised function should be expressed in the appraisal report and, depending on its importance, in the advice to the competent authority.

The DGSNR assessment order to IRSN points out the required extent of assessment when it is restricted. The IRSN assessment is focussed on this defined extent but the whole Design Safety Report is quickly checked if available using at least the preliminary review procedure. Information relative to any uncertainty detected by IRSN even outside this extent is transmitted to DGSNR.

- Special arrangement

IRSN performs a complete appraisal of the Design Safety Report of the package model concerned, and checks that the compensating measures provide the transport with a safety level equivalent to a package fully compliant with the regulation.

- Shipment approval

The appraisal may be restricted to the areas justifying the application of specific measures for the consignment and, if applicable, may rely on the results of already existing appraisals of the package model Design Safety Report.

- Special form material approval

Special form materials may be subject to an approval, a renewal, an extension, or a validation.

The appraisal of a safety report for a new special form material should be complete, except in case of validation when only the feedback experience main areas should be reviewed.

5.7.3 DESCRIPTION OF THE APPROVAL CERTIFICATE

5.7.3.1 STRUCTURE OF A TYPE B(U)F CERTIFICATE

The approval consists of three parts: administrative part, packaging part N°0 and content part N° i (i ≥ 1). Every part can be revised, whereas certain dependencies on the revision index are taken into account between these parts.

1) The first administrative part is the first page of a certificate which contains:
   (a) Type of certificate.
   (b) The competent authority identification mark
   (c) The reference to safety appraisal report
   (d) The reference to letter of applicant
   (e) The issue date and an expiry date.
   (f) List of applicable national and international regulations for the allowed modes of transport, including the edition of the IAEA Regulations for the Safe Transport of Radioactive Material under which the design is approved.
   (g) The following statement: "This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported."
   (h) A reference number for the decision delivered by DGSNR
   (i) the signature of the ministries

2) The second part is the appendix N°0 relative to the packaging and contains:
   (a) Definition of the packaging
   (b) The mass of packaging with and without content or basket
   (c) A summary of overall dimensions of packaging (length, diameter…)
   (d) Packaging is designed, manufactured and tested in conformity with:
   - The Design Safety Report (reference and date of the file of safety),
   - The design drawings
   (f) Instruction for use
   (g) Program of maintenance
   (h) Verifications to be performed before shipment

Example:
- To check the conformity of the contents to the certificate of approval.
- To control the general state of packaging, -
- To control the good condition of the screws and bolts
- To check the tightening torques
- To check the setting in depression of the cavity to the pressure of… absolute bar.
- If necessary, control of drying of the cavity + acceptance criteria for leak tightness rates
- To check the leakage rates
- To control contaminations of external surfaces of packaging in conformity with the regulatory limits
- To control the radiation levels around the package
- To measure the temperatures of accessible surfaces - the criteria are:

If	50°C <TC≤ 85°C	Transport under exclusive use,
If	85°C < TC	Transport under exclusive use with barriers or screens intended to give protection to people

- List of special provisions in the case of stowage, transport …
   (i) Marking on the package
   (j) Notification requirements
   (k) Quality assurance
   (l) Sketch of the packaging

(m) Additional sketch of the internal arrangements

3) The last part contains the appendices relative to the allowed contents (an appendix by content). Each appendix contains a detailed definition of the allowed contents:

(a) A definition of its nature
(b) The allowed maximum activity
(c) The physical form
(d) The description of the basket (mass, dimensions, concept drawings, schema…) when it is not included in the packaging definition in the second part
(e) The reference to Design Safety Report that justifies the safety of the package loaded with the concerned content
(f) The hypotheses taken into account in the criticality safety analysis
(g) The criticality safety index
(h) Special provisions during loading, transport…
(i) Mention of necessity of multilateral approval in case of use of para 565b) of SS6 regulation.

5.7.3.2 INDEXATION FOR CERTIFICATES AND CONSIDERATION OF MODIFICATIONS OF THE PACKAGE DESIGN IN THE APPROVAL CERTIFICATE OF A FRENCH PACKAGE DESIGN

The references of the approval certificate parts are in the **F/xyz/Type (Lm)** form with:

1) - F : Code for France
2) - xyz : 3-digit or more chronological number
3)- Type : In compliance with the definitions of the types of packages (ex: B(U) or AF). Moreover, “Type” includes the following symbols: “-85” or “-96” depending on the pertinent edition of the applicable IAEA recommendations; “ (nothing) if the model is in compliance with a former edition of the IAEA recommendations (1967, 1973, 1973 (amended version)).
4) an alphanumeric index "Lm", <u>between brackets only for the first administrative part of the certificate</u> (ex: (Aa) or 1b)

✦ With “L”:

- either a capital letter “L” in the administrative part only, characterizing the number of renewals since the origin of the approval, starting with A at first issue.

- or a digit “α” characterizing the appendix N°
  α = 0 : for the appendix defining the packaging
  α = i: for the appendix N°i defining the allowed contents N°i ($i \geq 1$)

✦ With “m”: small letter corresponding to the revision index of the administrative part or other parts.

- begins with an "a" for the first approval of the package model
- incrementation from "a" to "z", then if necessary "aa", "ab"..., for the administrative part, each time the approval certificate is re-issued
- any modified appendix will take the new index "m" of the administrative part of the approval certificate, the other unchanged appendices will keep their former indexing.

5) Pages are numbered in each appendix independently.

<u>Example</u>:

Purpose of the issue	Main appendix	Packa-ging appendix	Content N° 1 appendix	Content N° 2 appendix	Content N° 3 appendix
Initial approval	***(Aa)***	***0a***	***1a***	*	***3a***
Extension to the modified packaging	***(Ab)***	***0b***	***1a***	*	***3a***
Extension to the modified content No 1	***(Ac)***	***0b***	***1c***	*	
Extension to the content No 2	***(Ad)***	***0b***		***2d***	
Renewal	***(Be)***	***0b***	***1c***	***2d***	***3a***
Renewal + extension to the modified content N°3 and N°1	***(Cf)***	***0b***	***1f***	***2d***	***3f***
Renewal + suppression of content N°1	***(Dg)***	***0b***	**	***2d***	***3f***

* Reserved: in case the concerned content is not yet sufficiently justified.
** A content definition can be withdrawn when the content is no longer transported.

Remarks:

A. Certificates Aa, Ab, Ac, Ad are to have the same expiry date and may be therefore simultaneously valid for same periods.
B. Certificate Be supersedes all previous issues.

5.7.3.3 STRUCTURE OF A MULTILATERAL APPROVAL CERTIFICATE / VALIDATION OF FOREIGN APPROVAL CERTIFICATE

The structure of a multilateral approval certificate / validation of foreign approval certificate is the same as in 5.7.3.1.

Concerning the indexation, the references of the validation certificate parts are in the same form but with the following differences:

✦ For L:

- Either (blank) in the administrative part only: As revisions of the foreign certificates, which correspond to extensions of contents, are often issued with validity renewal although the former certificate has not reached the maturity date, the capital letter, characterizing the number of 3-year renewals, does not have any meaning for the foreign certificates. That is why the capital letter of the main appendix was left.

- Or a digit "α" = 0, 1 or 2 for the following appendix:

The French translation of the original approval certificate (a translation in English or the original approval in English may be exceptionally tolerated)
The original approval certificate
The restrictions of contents and additional specifications required for sub-criticality or other safety functions.

- Or the small letter “t” for the appendix concerning consignment modalities, in case of shipment approval

✦ For "m": a small letter corresponding to the revision index of the parts of the certificate, starting with “a” at first issue, incremented then from "a" to "z, then if necessary “aa”, “ab”… All modified appendices will take the new index “m” of the approval certificate.

A foreign certificate may be validated for successive parts of the set of contents. In this case, the index “m” is incremented each time a new French certificate of partial validation is issued.

Example:

Purpose of the release	Main appendix	Appendix N°0: French or English translation	Appendix N°1: Original approval certificate	Appendix N°2: Additional specifications (or restrictions)
1st validation: Validation of the Rev. 1	**(a)**	**0a**	**1a**	**2a**
2nd validation: Partial validation of the Rev. 5	**(b)**	**0b**	**1b**	**2b**
3rd validation: Additional validation of the Rev. 5	**(c)**	**0b**	**1b**	**2c**

5.7.3.4 STRUCTURE OF A SHIPMENT APPROVAL UNDER SPECIAL ARRANGEMENT

The structure of a shipment approval under special arrangement is the same as in 5.7.3.1.
Concerning the indexation, the references of the approval certificates of shipment under special arrangement are in the same **F/xyz/X** form, but without revision index.

5.7.4 JOINT CERTIFICATION PRACTICES

Examples for joint certification practices are appraisal co-operations for a few applications: validation process of the H(M) package approval for 48Y cylinders, Fuel Integrity Project (F.I.P), NCS 45 and TN 81 packages.

5.8 APPROVAL METHODOLOGY IN THE UNITED KINGDOM

The following description of the UK approval system was taken from references [21] and [24], and prepared under kind assistance of Mr. Jim Stewart, UK DfT/RMTD.

5.8.1 LEGAL BASIS FOR THE COMPETENT AUTHORITY AND TECHNICAL SUPPORT

5.8.1.1 NATIONAL AND INTERNATIONAL LAWS, REGULATIONS AND GUIDELINES FOR PACKAGE DESIGN AND SHIPMENT APPROVALS

The international transport regulations ICAO-TI [7] and IMDG-Code [6] for class 7 are directly implemented in national law. ADR [2] and RID [3] are not fully implemented, there are some exceptions concerning items of container and radiography equipment (e. g. smoke detectors, limited quantities or orange placards for private drivers), but no deviations concerning the approval process of package designs, shipments and radioactive materials.
The RMTD "Guide To An Application For UK Competent Authority Approval Of Radioactive Material in Transport" [24] ensure consistent presentation of all the information relevant to each application as required by the Competent Authority to enable it to carry out the assessment. This guide is a recommendation for creation of the application by the applicant. Additional guidance material exists for freight containers, to be used as IP-2 and IP-3 packages.

5.8.1.2 COMPETENT AUTHORITY

5.8.1.2.1 NAME, ADDRESS, NOMINATION AND RESPONSIBILITIES

The Competent Authority for the UK is the Secretary of State for Transport (DfT) nominated for instance in [54, 55]. The Secretary of State delegates that responsibility in [54, 55] at his or her discretion to the appropriate body. The delegated body for the transport of radioactive material is

Radioactive Materials Transport Division (RMTD)
DfT
Great Minster House
76 Marsham street
London SW1P 4DR

of the DfT. Each mode of transport is regulated by a different legal body, and each issues its own set of regulatory documents. RMTD is nominated in these regulatory documents for all modes of transport (except post) for the package design approval, based on engineering assessment, criticality assessment and quality assurance assessment. Packages subject to RMTD includes Types B(U), B(M) and C packages, packages containing fissile packages and packages containing uranium hexaflouride. Other responsibilities include approvals of special form radioactive material, special arrangements and shipments.

5.8.1.2.2 LEGAL FORM AND ORGANIZATION STRUCTURE

RMTD is a government body. It is absolute independent from private industry. The specialist technical expertise used principally in the assessment of package design determines the structure of the Division. There are three branches as follows:

a) Engineering – which examines all aspects of package construction, including mechanical integrity, containment and radiation shielding, thermal performance and the response to the regulatory performance tests.

b) Criticality - which examines criticality safety cases for fissile material shipments, and ensures generally that the requirements for radiation protection are fulfilled.

c) Quality Assurance - which examines the applicants' quality assurance arrangements for package design, manufacture and maintenance, conducts audits of organizations involved in transport of radioactive materials, and manages the enforcement responsibilities of the Division.

An administration is responsible for the provision of information, for the distribution of assignments within the Division, and for the production and issue of certificates of approval supports the three branches.

The processing of application is in the UK for the applicant cost-free.

4 employees together with a branch leader deal with Engineering, 4 plus a branch leader with Quality Assurance and 2 plus a branch leader with Criticality.
Special equipment of RMTD for calculation and safety assessment are the following computer software:

- Criticality code MONK
- DYNA 3D for impact calculation
- ANSYS for thermal calculation
- NUCLEAR for burn up credit calculation.

5.8.2 APPROVAL METHODOLOGY

5.8.2.1 APPLICATION AND REQUESTED DOCUMENTS FOR PACKAGE DESIGN APPROVAL

5.8.2.1.1 UNILATERAL APPROVAL OF NEW PACKAGE DESIGNS

All relevant information regarding the application is written in the Applicants Guide [24]. All questions are to be answered and referenced in accordance with this Guide. Any question that appears to be either irrelevant, or not applicable, should be answered by stating the reason why it is regarded as such. If preferred applicants may present the safety case in the form a Design Safety Report (DSR). The DSR document is defined as all supporting information and documentation necessary to demonstrate compliance with regulations. The answers to all the questions in the Guide may form part of the DSR.
The following information or documents are to submitted to RMTD for all kinds of design approval:

a) Administrative information (applicant, designer, manufacturer, Type of packaging, modes of transport, Identification Mark, QAP, Serial numbers, required date of approval, date of application)

b) Specification of radioactive contents (e. g. general nature of contents, radionuclides, physical state, chemical composition or state, quantity and enrichment, maximum total/specific activity, maximum rating at end of life, maximum irradiation, minimum cooling time, initial enrichment, minimum irradiation, maximum heat load, further dangerous properties)

c) Specification of packaging (e. g. description of materials, finishes, treatments, condition of use, maintenance, tests, inspections, drawings)

d) Transport operations (e. g. Handling, Tie-down (or retention) system, stowage provisions, action by consignor before each shipment, action required during shipment, emergency instructions, exclusive use conditions)

e) Testing (regulatory compliance testing of package design, performance tests before first shipment)

f) Design (structural evaluation, radiation shielding, containment system, leak-tightness, thermal considerations, pressure considerations, impact evaluation)

g) Quality assurance (quality control in manufacture and construction, maintenance, control of use and care of packages).

5.8.2.1.2 MULTILATERAL APPROVAL/VALIDATION OF FOREIGN PACKAGE DESIGNS

5.8.2.1.2.1 PACKAGE DESIGNS FOR FISSILE MATERIAL

Additional design information is required for fissile material:

a) Irradiation history
b) Neutron poisons
c) Assessment of arrays of packages under normal conditions
d) Assessment of arrays of damaged packages
e) Criticality safety index for nuclear criticality control
f) Assessment of the single package in isolation
g) Validation of calculations
h) Special arrangement transport operations
i) Nuclear matter transport certificates.

5.8.2.1.2.2 TYPE B(M) PACKAGE DESIGN

For Type B(M) packages the applicant has to submit to RMTD the following information:

a) Prescriptions of IAEA [4] 637, 653, 654 and 657 to 664 with which the package design does not conform (IAEA [4] 810a).
b) The reasons for non-compliance.
c) The operational controls to compensate for non compliance (IAEA [4] 810b).
d) State whether or not the package is intended to be vented intermittently during transport and, if so, provide full details of the operational controls proposed, including details of any ancillary equipment required during operation (IAEA [4] 666)
e) Where transport is restricted to the UK, an ambient temperature range of –10°C to 26°C and half the insolation data values of IAEA [4] tale XI may be assumed. Such a package must be classified a Type B(M). It will not be subject to Shipment Approval solely on this account (for UK movements) but will require Shipment and Design Multilateral Approval for other movements.

The DSR, which must be submitted for validation to the Competent Authority must include:

a) All drawings.
b) Summary test results, or details of alternative demonstrations of compliance.
c) Material specifications, if not given on the drawings.
d) References to Quality Assurance programmes applicable within the jurisdiction of UK Competent Authority.

e) References to the emergency response procedures applicable whilst the package or consignment is in the UK.
f) For package designs and shipments involving fissile materials, appropriate safety information on the means of establishing compliance with the regulatory criticality safety provisions.

g) For approvals under special arrangements, detail the reasons for special arrangement and compensatory safety measures that demonstrate regulatory standards of safety are attained.

h) For Type B(M) packages, details of operational controls, specific to transport in the UK.

5.8.2.2 DESCRIPTION OF THE APPROVAL PROCEDURE

5.8.2.2.1 ORGANIZATION OF THE APPROVAL PROCEDURE OF A NEW PACKAGE DESIGN

The Administration unit of RMTD is responsible for the production and issue of certificates of approval. There are no specific work instructions for this procedure.
The approval certificate will be signed and issued by the Head of the division, the Transport Radiological Adviser.
For the assessment procedure of a package design see chapter 5.8.2.3.1.

5.8.2.2.2 PROCEDURE IN THE CASE OF MODIFICATIONS OF THE PACKAGE DESIGN

Modifications to existing designs may be approved without a full reappraisal of the safety case, and are categorised according to their effect on the safety of the package. Applicants must provide details of modification on a sheet specified in the Applicants Guide [24], and state, with justification, the modification category. The categories are defined as follows:

Category A
Major change to the package and/or the package design application directly affecting the assessed package safety, i. e. structural integrity, containment, shielding, heat transfer and criticality.

The request for modification approval must be accompanied by all supporting documentation. If approval is granted, a revised certificate of approval will be issued before the modification can be put into effect.

Category B
Significant change to the package and/or the package design application not primarily affecting the assessed package safety.

If the approval is granted, the modification sheet will be endorsed and returned to the applicant to be attached to the current certificate of approval. Applicant's documentation will be updated:
a) within a six month period, or
b) prior to the next renewal of the certificate, whichever is the shortest period, unless otherwise specified by the Competent Authority.

Category C
Minor change to the package and/or the package design application not primarily affecting the assessed package safety.

If the approval is granted, the modification sheet will be endorsed and returned to the applicant to be attached to the current certificate of approval. Applicant's documentation will be updated:

a) within a one year period, or
b) prior to the next renewal of the certificate, whichever is the shortest period, unless otherwise specified by the Competent Authority.

Amendments

Minor changes to documentation having no design or safety significance to the applicants existing approval. An amendment does not entail the amendment of a DSR other then in iii) below. The following example s fall within this category.

i) Changes in reference document numbering system (provided they do not change the scope of reference).
ii) Changes in drawing numbers resulting from the applicants own internal organizational requirements (provided they do not change the detail of the pre-existing drawing(s))
iii) A correction to a drawing or safety document which is required amendment is obvious from the error. Applicant's documentation will be updated:
    a) within a one year period, or
    b) prior to the next renewal of the certificate, whichever is the shortest period, unless otherwise specified by the Competent Authority.

Concessions

A concession is the authorisation to use a package which deviates from drawing or specification, in some respect which does not affect its integrity or safety and which it is not intended to introduce systematically to all package designs. The requirement for a concession may be recognised during manufacture, maintenance or in service. A concession does not entail the amendment of a DSR. Applicant's documentation will be updated:

a) within a one year period, or
b) prior to the next renewal of the certificate, whichever is the shortest period, unless otherwise specified by the Competent Authority.

5.8.2.2.3 PROCEDURE FOR MULTILATERAL APPROVAL/VALIDATION

According to ADR the Competent Authority can require a full approval for validation of foreign package approval certificates. But in general RMTD practise is the acceptance of approved certificates from ADR countries. RMTD accepts the approval procedure of other ADR competent authorities. In the case of problems at first the other Competent Authority will be contacted and then the applicant.

Foreign package approvals which were already validated by an other ADR country, for example during a transport through several countries, will accepted by the UK Competent Authority without further checking. The point of view of the UK Competent Authority is that it is sufficient if the first concerned ADR country validates the package approval certificate.

5.8.2.2.3.1 PACKAGE DESIGNS FOR FISSILE MATERIAL

For validation of package designs for fissile material RMTD assess the criticality safety case and any other multilateral aspects of the design. A review is performed to any parts of the tests which affect criticality safety.

5.8.2.2.3.2 TYPE B(M) PACKAGE DESIGN

For validation of Type B(M) package design RMTD apply the regulatory standard. However it is permitted to challenge any aspect of the package design. Generally it is the variations from the B(U) that are assessed. RMTD retain the right to look at the full design if there are not sufficient high safety margins or any other doubts on the safety of the package design.

5.8.2.2.3.3 PACKAGE DESIGNS SUBJECT TO TRANSITIONAL ARRANGEMENTS ACCORDING TO ADR 1.6.6.1 AND 1.6.6.2

RMTD apply the standard regulatory requirements. The same aspects are examined as for a "non-transitional" package - except RMTD compare to the old regulations for most aspects, and to the new regulations for those aspects specifically mentioned in 1.6.6.1 and 1.6.6.2.

5.8.2.3 DESCRIPTION OF THE SAFETY ASSESSMENT PROCEDURE

5.8.2.3.1 ORGANIZATION OF THE ASSESSMENT PROCEDURE

Design assessments are managed on a project basis and when an application is received, an assessor is assigned from each of the three technical branches - Engineering, Criticality, Quality Assurance, one of whom is the project officer, who manages and progresses the assessment and becomes the main point of contact with the applicant. The application and all supporting documentation are fully examined by the assessor for completeness and consistency, and to ensure compliance with all relevant regulatory requirements.
RMTD has a Quality Management according to ISO 9001. There are written internal procedures for each branch which regulate the organization of work and the cooperation of the employees, but not technical assessment details. The interfaces between the different branches will regulated in overall documents. A job control sheet is used to coordinate the review among the three groups. Once a month a meeting takes place with all members involved in the approval procedure of transport packagings.
RMTD accepts all suitable standard for the assessment of the DSR. The applicants use often the standards from Industry, especially from TSCS (Technical Committee of Standardisation of Containers).
RMTD can use external experts for the assessment of the DSR whenever and whoever they want, so they use e. g. external experts for the assessment of old waste material packagings.

5.8.2.3.2 SAFETY ASSESSMENT METHODS

The assessment of calculation proofs of different parts of the Design Safety Report are performed in the way given in the table below:

	Full checking and recalculation with other calculation methods	***Full recalculation with the same method***	***Comparison of the results with the maximum allowable values***	***Other Method***
Mechanical stability	Yes	Yes	Where there are large safety margins	
Thermal stability	Yes	Yes		
Leakage rate		Yes		

Shielding		Where the accident conditions vary from the normal conditions w.r.t. shielding	Normal conditions of transport	
Criticality safety	Yes - the most appropriate method is used.	Yes	Yes - normally for very low content packages	Yes

RMTD performs his own calculations in appropriate cases.

5.8.2.3.3 ACCEPTED CALCULATION METHODS

Applicants choosing to demonstrate compliance by analysis have a wide range of calculational options to choose from, ranging from hand calculations to computer analysis. The analysis choice should be appropriate to the design feature requiring demonstration.
Hand calculations should be accompanied by sufficient discussion, sketches and references to allow the method and results to be independently verified.
Use of computer analysis is in general acceptable under the Regulations and therefore is acceptable to the Competent Authority where such calculation procedures and parameters are agreed to be reliable or conservative.
When using any computer code for such analysis, the applicant shall have available for review:

a) Evidence of validation of the code and operating platform (QA aspects of the validation, management and use of the code).
b) Discussion of benchmark studies between code and tests, where appropriate.
c) Evidence of the suitability of the particular application of the code.
d) A review of the analysis technique and its appropriateness to the analysis in hand (including any shortcomings and how they are addressed).
e) An analysis of potential errors and how these errors translate to safety related aspects of the design.
f) Evidence to demonstrate the appropriate level of competence, by training record, experience, or academic background, of the staff engaged on any safety related analysis.

The input/output data should be available on request. When requested this data should be supplied in an agreed format and media with sufficient discussion to allow independent verification/assessment to be undertaken.

In addition the applicant should provide the following to support a particular computer analysis:

a) Dimensional sketches of the geometric models used in the assessment.
b) Identify and discuss differences between the geometric models and the package specification. Show that these differences are conservative or justify the use of any non-conservative assumptions.
c) Provide the results of scooping and sensitivity studies, where appropriate.
d) Describe the basic calculation method, referencing any appropriate documentation.

For all analysis, discuss and justify that the results of the analysis meet the overall performance requirements and design criteria of the evaluation.

5.8.2.3.4 PERFORMANCE OF PACKAGE DESIGN TESTS

Package testing, where required, is carried out by the applicant, but witnessed by RMTD assessors to ensure that they are satisfied that the tests meet the regulatory requirements.

Prior to physical package tests, the applicant must notify RMTD that such test are to be carried out. Sufficient notice shall be given of the intended tests for RMTD to arrange to witness such tests, at their discretion. The notification of such tests must be accompanied by detailed test procedures and Quality assurance documentation to allow RMTD to review fully such documents, prior testing. A test Quality Plan should be submitted, identifying responsible persons/organizations for each element of the proposed test.
The regulations require tests to be carry out in the most damaging attitude, and if there is any ambiguity in this, the assessor may require the conduct of further tests to cover all possibilities.

5.8.2.3.5 STRUCTURE OF THE ASSESSMENT REPORT

RMTD create three internal independent assessment reports – for Criticality, Engineering and Quality Assurance. This reports are not sent to the applicant and not published. The Applicants Guide is the check list for the applicable paragraphs for each package design (see 5.6.2.15.8.2.1) and consequently for the structure of the internal assessment reports.

5.8.2.4 SHIPMENT APPROVAL METHODOLOGY INCLUDING SPECIAL ARRANGEMENT

For shipment approval according to ADR 6.4.23.2 RMTD do not request routeing, but examine emergency arrangements in more detail.

For shipment approval RMTD require the following information for the application:

a) Applicant
b) Consignor
c) Originator of shipment
d) Consignee
e) Actual radioactive contents
f) Expected modes of transport
g) Type of conveyance
h) Probable or proposed route (IAEA 822(b)).
i) Special precautions, operational controls and how these controls are to be put into effect (IAEA 822(c)).
j) In the case of Exclusive Use give details of any special vehicle or fright container that will be used to comply with IAEA [4] 572.
k) Where Shipment Approval is needed because the Criticality Safety Index for the consignment exceeds 50, state the arrangements and controls required for the continued segregation of the consignment during loading, transport and unloading.
l) Competent Authority Identification Mark
m) Quality Assurance arrangements or programmes that will apply
n) Emergency arrangements
o) Number of packages per load, number of loads per consignment
p) For each transit store specify place, nature of the storage place, expected duration, person who will be responsible for custody.
q) Date(s) of intended shipment(s)
r) For what period is shipment required (IAEA [4] 822(a))
s) Date of application.

For shipment approval under special arrangement RMTD consider that special arrangements need to be justified and equivalent safety levels established against relevant requirements of TS-R-1.

The application for a special arrangement approval should be contain the following information:

a) Applicant
b) Designer (if other than applicant)
c) Manufacturer
d) Consignor
e) Originator of shipment
f) Consignee
g) Actual radioactive contents
h) Mode of transport
i) Type of conveyance
j) Probable or proposed route (IAEA 822(b)).
k) Any restrictions on the modes of transport, types of conveyance or freight container to be used (IAEA 831(e)).
l) Number of packages per conveyance
m) Number of conveyances per consignment
n) Competent Authority Identification Mark
o) Reasons why the consignment cannot be made in full accordance with the applicable requirements of the regulations.
p) Compensatory safety measures , or controls, are proposed to compensate for failure to meet the requirements of the regulations. Demonstrate how the appropriate regulatory standard of safety will be achieved and how these will be put into effect (IAEA 825(b)).
q) Quality Assurance arrangements or programmes that apply and will be referenced on the Certificate
r) Emergency arrangements
s) For each transit store specify place, nature of the storage place, expected duration, person who will be responsible for custody.
t) Date(s) of intended shipment(s)
u) Date of application.

5.8.3 DESCRIPTION OF THE APPROVAL CERTIFICATE

5.8.3.1 STRUCTURE OF A APPROVAL CERTIFICATE (E. G. TYPE B(U)/B(U)F)

The Type B(U) approval certificate consist of the following parts

- A cover sheet with the confirmation that the Secretary of State of Transport is the Competent Authority of UK, the Type of the cask, the Transport modes, the Packaging identification, the Expiry date, the Competent Authority identification mark and the Signature and Stamp of the Competent Authority.
- A sheet with international and national regulations and codes of practise governing the transport of radioactive materials.
- Package design specification with the most important information about the specification of design, the authorised contents, the fissile material restrictions and the package dimensions and weights.
- Use of package with the most important information about the use of packaging, actions prior to shipment, emergency arrangements and the ambient temperature range for package design.
- Quality assurance
- Administrative information about other related certificates (alternative radioactive contents), additional technical data/information, shipment approval, non-fissile or fissile excepted and renewal of certificates.

- Package illustration

Design approval certificates are normally issued for a period of three years, and renewed on application subject to further assessment if appropriate.

5.8.3.2 CONSIDERATION OF MODIFICATIONS OF THE PACKAGE DESIGN IN THE APPROVAL CERTIFICATE

Where significant modifications are made during the life of the certificate, that certificate is reissued, and the new issue supersedes and invalidates the earlier issue. It is clear that for complex designs that are subject to frequent change and used with different internal details, this could result in unacceptable delays and an excessive administrative burden. RMTD has devised a number of ways to minimise the complexity of certificates and the need for modifications and to cope with the possible delays associated with revalidation. A summary of these is given below:

a) Each variant of a design type is assigned what is known as a 'make-up letter'. This gives a distinct design reference and an independent certificate to each assembly of an outer container, internal components and contents. Thus, for example, a hypothetical certificate number GB/7034A/B(U)-85 would refer to the outer container design number 7034 with a particular array of inner components plus contents. This certificate stands alone and may be renewed under the same design number, subject to Competent Authority scrutiny. If the applicant needs to use design 7034 with a different internal arrangement, then a separate application is made for design 7034B, without affecting the status of 7034A.

b) If a change or addition of contents is required without any alteration to the internal structure of the packaging, then the certificate is normally adjusted and reissued to accommodate the change. Where foreign validation procedures present a problem, then the Competent Authority can (and does) issue a separate certificate designated for example GB/7034A(1)/B(U)-85, with the same expiry date as the original 7034A certificate. This is a temporary designation which allows the continued use of the GB/7034A/B(U)-85 certificate alongside the new certificate. Upon expiry, the specification is updated to include the new or changed contents within the 7034A certificate, and the temporary 7034A(1) designation is discontinued.

c) The modification procedure described under 5.6.2.2.2 takes account of the scale of the modification. Although a major modification affecting safety necessitates a reissue of the certificate and hence validation where appropriate, with lesser modifications, reissue of the certificate may be deferred.

d) Where a revised certificate is issued as a replacement for an earlier issue, the revised certificate may include an effective date in the future from which earlier issues cease to be valid and the new issue becomes effective. This allows time for the new issue to be validated by other competent authorities as necessary before the original issue lapses.

5.8.3.3 STRUCTURE OF A MULTILATERAL APPROVAL CERTIFICATE/VALIDATION OF A FOREIGN APPROVAL CERTIFICATE

The content of validation of foreign approval certificates for fissile package designs, Type B(M) and transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 conforms to ADR 6.4.23.16.

5.8.3.4 STRUCTURE OF A SHIPMENT APPROVAL CERTIFICATE

The content of approval certificates for shipment approval and shipment approval under special arrangement conforms to ADR 6.4.23.13 and 6.4.23.12.

5.8.4 JOINT CERTIFICATION PRACTICES

Examples for joint certification practices are TN-Gemini and H(U)/H(M) package designs.

6 ANALYSES OF THE RESPONSES TO THE QUESTIONNAIRES

6.1 GENERAL FINDINGS OF EXPERIENCES IN APPROVAL AND SAFETY ASSESSMENT PRACTICES

A general evaluation of the responses to the questionnaire showed that the approval procedures and the practices, regarding unilateral approval of all package designs, validations of fissile material package designs and detailed experience/practice in the safety assessment of package designs, are very different according to the EU and applicant countries and according to needs.

From the answers to our questionnaire it is noticed that the quantity and specific experience of the safety assessment depends on the capacity of the competent authority of a country issuing unilateral approval certificates.

It could be seen from the responses that countries which have a complete and extensive nuclear fuel cycle like Belgium, Czech Republic, France, Germany, Spain, and UK have a full developed approval and safety assessment methodology. Also Hungary, Italy, the Netherlands and Sweden have such developed approval system.

Poland, Romania, Latvia and Slovak Republic have also a developed approval methodology but from the answers to the questionnaire we could not clearly identify if there exist practice or experience regarding unilateral approval of package designs or validation of fissile material package designs.

Denmark, Finland and Slovenia have no practice regarding unilateral approval of package designs. The responses show that their practice is up to now restricted to validations of foreign approvals.

There is no experienced approval methodology in Cyprus, Lithuania, Luxembourg, Malta, Ireland, Estonia, Turkey and Bulgaria. There is no necessity for the development because there are no important transports of radioactive material (Cyprus, Luxembourg, Malta, Ireland, Turkey) and no package manufacturers or the development of the methodology is under way (Bulgaria, Lithuania).

6.2 DETAILED ANALYSES OF THE RESPONSES TO THE QUESTIONNAIRES IN ITEM TABLES

6.2.1 LEGAL BASIS AND GENERAL ORGANIZATION

6.2.1.1 ITEM: APPLICABLE REGULATIONS

This item contains the implementation of IAEA recommendations, international and national regulations and guidelines according to different modes of transport and used for approval procedure.

6.2.1.1.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**E**
Belgium	IAEA, ADNR, IMDG, IT-ICAO with an application law and without deviations ADR and RID with an application law and with deviations (limitation of exposure at the drivers location, marking of vehicles carrying only excepted packages, alarm on closure of loading space (ADR only)) General regulations concerning the protection of the public, the workers and the environment against ionising radiation	**C**
Bulgaria	• "European Agreement concerning the International Carriage of Dangerous Goods by Road" (ADR) ratified by law (promulgated in O.J. No. 28 of 1995), Agreement promulgated in O.J. No.73 of 1995 without annexes A and B; The annexes published as a separate books in 2002; • International Regulation Concerning the Carriage of dangerous Goods by Rail (RID). Of the Central Office for the International Transport by Rail (OCTI) – this regulation is annex to the Convention on international railway transport (COTIF), promulgated in O.J. No. 46, 1982; • International Maritime Dangerous Goods Code (IMDG Code by IMO) implemented into Bulgarian legislation on 02. 02, 1984 • Technical Instruction for the Safe Transport of Dangerous Goods by Air. (ICAO – Technical Instructions) – enforced on the territory of Bulgaria by Regulation No. 18 on Safe Transport of Dangerous Goods by Air, issued by the Minister of	**B**

Transport (promulgated in O.J. No.25, 1999;

The Bulgarian constitution Art. 5 §4 gives clear priority to legislation which arises as a consequence of international agreements adopted by Bulgaria. A further development of legislation with regard to the safe transport of RAM is in progress, especially to meet also the relevant regulations of the European Union.

A new regulation for safe RAM transport is in preparation and it includes the requirements of the IAEA regulations (1996 Edition (Revised), TS-R-1).

Licences and permits shall be granted, amended, renewed, suspended, revoked and controlled according to a procedure established by a new regulation, which is in preparation, too.

The principal regulations for the safe transport of radioactive material in the Bulgarian republic are:

- Act on the Safe Use of Nuclear Energy (ASUNE) (promulgated in O.J.No.63 of 2002);
- Regulation No. 5 "On the Issue of Licenses for the Use of Atomic Energy", of the CUAEPP (promulgated in O.J.No.13 of 1989 and O.J.No.37 of 1993);
- Regulation No. 46 "Transportation of Radioactive Substances" (promulgated in O.J. No.53 of 1976); based on IAEA Safety Series No.6 of 1973 (Regulations for the Safe Transport of Radioactive Material);
- Regulation No.7 "Collection, Storage, Processing, Keeping, Transport and Disposal of Radioactive Waste on the Territory of the republic of Bulgaria" (promulgated in O.J. No. 8 of 1992);
- "European Agreement concerning the International Carriage of Dangerous Goods by Road" (ADR) ratified by law (promulgated in O.J. No. 28 of 1995), Agreement promulgated in O.J. No.73 of 1995 without annexes A and B; The annexes published as a separate books in 2002;
- Technical Instruction for the Safe Transport of Dangerous Goods by Air. (ICAO – Technical Instructions) – enforced on the territory of Bulgaria by Regulation No. 18 on Safe Transport of Dangerous Goods by Air, issued by the Minister of Transport (promulgated in O.J. No.25, 1999;
- International Maritime Dangerous Goods Code (IMDG Code by IMO) implemented into Bulgarian legislation on 02. 02, 1984
- International Regulation Concerning the Carriage of dangerous Goods by Rail (RID). Of the Central Office for the International Transport by Rail (OCTI) – this regulation is annex to the Convention on international railway transport (COTIF), promulgated in O.J. No. 46, 1982;
- Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (promulgated O.J. No. 63, 2001);
- VIENNA CONVENTION on civil liability for nuclear damage (promulgated O.J. No. 64, 1994);
- CONVENTION on physical protection of nuclear material (promulgated O.J. No. 44, 1987);
- CONVENTION on operational notification in case of nuclear accident (promulgated O.J. No. 12, 1988);

	• CONVENTION on assistance in case of nuclear accident or radiological emergency situation, (promulgated O.J. No. 13, 1988) • AGREEMENT between the Government of the Republic of Bulgaria, Government of the Republic of Moldova, Government of the Ukraine and Government of the Russian Federation on the transportation of nuclear materials (promulgated O.J. No. 52, 2003); • Act on the Ministry of Interior (promulgated O.J. No. 122, 1997, many amendments); • Rules of Procedure of the Nuclear Regulatory Agency (promulgated O.J. No. 86, 2002); • Regulation for Basic Standards for Radiation Protection-2000, adopted by the Council of Ministers (promulgated O.J. No. 5, 2001); • Regulation No.2 concerning the cases and procedures for notification of the Committee on the Use of Atomic Energy for Peaceful Purposes about operational changes, events and accidents related to nuclear and radiation safety (promulgated O.J. No. 26, 1988); • Regulation on Accounting, Storage and Transportation of Nuclear Material and Application of the Safeguards under the Treaty for non-proliferation of Nuclear Weapons (promulgated O.J. No. 66, 1988, amended O.J. No. 83, 1993 and No. 33, 2001); • Regulation No. 8 of CUAEPP and Ministry of Interior on Physical Protection of Nuclear Facilities and Nuclear Material (promulgated O.J. No. 83, 1993); Issues related to: - Quality assurance - Radiation protection programme - Physical Protection - Liability - Import/Export - Training - Emergency preparedness are either in the responsibility of NRA as determined by ASUNE or are a prerequisite where a relevant certificate has to be presented to NRA for giving licenses or a permits for transport of RAM.	
Cyprus	IAEA, ADR, IMDG-Code, ICAO-TI are implemented in their original form. There are no other national regulation or guideline to be considered in the approval of package designs for radioactive materials and shipments.	**A**

Czech Republic	The international modal regulations for dangerous goods transport of class 7 ADR and RID are fully implemented. IAEA is also implemented but with the following administrative deviations: Approval from the State Office for Nuclear Safety is required also for a) all shipment of nuclear materials, except uranium depleted of 235U isotope, provided it forms shielding of packagings, b) shipment of special form radioactive material with activity greater than 3.10E3 of A1 and radioactive substances other than in special form with activity greater than 3.10E3 of A2 or radioactive substance with activity higher than 1000 TBq, depending on which level is lower. IMDG-Code is not implemented because Czech Republic is a landlocked country. IMDG-Code will be implemented within national legislation and will come into force from the date of the association of the Czech Republic. ADNR is not implemented because Czech Republic is not the signatory state. ICAO-TI will be implemented within national legislation and will come into force from the date of the association of the Czech Republic. An additional national regulation to be considered in the approval of package designs for radioactive materials and shipments is the Regulation of the competent authority - SONS No. 317/2002 Coll. on Design Approval of Packaging for Shipment Storage or Disposal of Nuclear Materials and Assigned Radioactive Substances, on Design Approval of Ionizing Radiation Sources and on Transportation of Nuclear Materials and Assigned Radioactive Substances (Design Approval and Transport Regulation).	**C**
Denmark	IAEA, ADR, RID, IMDG-Code, ICAO-TI are implemented in their original form. ADNR is not relevant. A survey of legislation on transport material of radioactive material may be found at www.sis.dk. This covers all pertinent requirements for all modes of transport. The legislation is available only in Danish.	**B**
Estonia	The IAEA regulations (1996 Edition (Revised), TS-R-1) and the international transport regulations ADR, RID, IMDG-Code, ICAO-TI for materials of class 7 are implemented in their original form. There are no other national regulation or guideline to be considered in the approval of package designs for radioactive materials and shipments.	**A**
Finland	ADR, IMDG-Code, ICAO-TI are implemented in their original form. IAEA are adopted via modal regulations. ADNR is not	

	implemented. Other national regulations or guidelines to be considered in the approval of package designs for radioactive materials and shipments are: • Governmental Decree on Transportation of Dangerous Goods by Road (194/2002) • Governmental Decree on Transportation of Dangerous Goods by Rail (195/2002) • Governmental Decree on Transportation of Dangerous Goods in Packaged Form by Sea (666/1997) • Governmental Decree on Transportation of Dangerous Goods by Air (210/1997) • Decree by the Ministry of Transport and Communications on Transport of Dangerous Goods by Road (277/2002) • Decree by the Ministry of Transport and Communications on Transport of Dangerous Goods by Rail (277/2002)	**B**
France	IAEA, ADR, RID, ADNR, IMDG, IT-ICAO with application orders and with deviations Orders concerning the protection of the public, the workers and the environment against ionising radiation	**C**
Germany	ADR, RID, IMDG-Code, ADNR, ICAO-TI are implemented in their original form. IAEA regulation is adopted via modal regulations. For licensing of shipments additional provisions of the Atomic Energy Act and the Radiation Protection Ordinance must be considered. Guidances: Richtlinien für das Verfahren der Bauart-Zulassung von Versandstücken zur Beförderung radioaktiver Stoffe vom 20.02.1991 –R003–; VkBl. Heft 4, 1991, S. 231 (Guideline for the application and approval procedure) (new edition in print, publication expected in 2004) Technische Richtlinie über Maßnahmen zur Qualitätssicherung (QM) und -überwachung (QÜ) für Verpackungen zur Beförderung radioaktiver Stoffe vom 20.02.1991 –TRV006–; VkBl. Heft 4, 1991, S. 233 (Guideline for QA)	**B**
Greece	No response	**E**
Hungary	ADR, RID, IMDG-Code, ICAO-TI are implemented. ADNR is not implemented. The provisions of the TS-R-1 are implemented by the international modal transport regulations. This approach results in some deviations (e. g. TS-R-1 para. 619 and the corresponding provision in ICAO-TI). Other national regulations to be considered in the approval of package designs are: • Decree No.14/1997(IX.3.) KHVM on the 'Transport and Packaging of Radioactive Materials'	**B**

	Decree No.13/1997(IX.3.) KHVM on the 'Regulation Concerning the Safe Transport of Spent Nuclear Fuel by Rail'.	
Ireland	IAEA, ADR, RID, IMDG-Code, ICAO-TI are implemented in their original form. ADNR is not relevant. There are no other national regulation or guideline to be considered in the approval of package designs. Package designs for the transport of radioactive material are not approved by our Institute. The RPII accept the certificates provided by other competent authorities.	**A**
Italy	IAEA, ADR, RID, IMDG, IT-ICAO with application orders and without deviations ADNR not implemented No additional regulations concerning transport of radioactive materials	**A**
Latvia	IAEA, ADR, IMDG-Code, ICAO-TI are implemented in their original form. RID is implemented with relevant deviations. ADNR is not implemented. The Cabinet of Ministers Regulations on Protection against Ionising Radiation during the Transport of Radioactive Materials has small deviation from the IAEA regulation due to implication in Latvian legislation. A National regulation to be considered in the approval of package designs is the Cabinet of Ministers Regulations on Protection against Ionising Radiation during the Transport of Radioactive Materials, issued on 3 July 2001, which fully based on the IAEA Regulations for the Safe Transport of Radioactive Material (TS-R-1 and TS-R-2).	**C**
Lithuania	IAEA, ADR, RID, IMDG-Code, ICAO-TI are implemented in their original form. ADNR is not implemented. They do not have the national competent authorities approval certificates for package design, special form material and shipment of radioactive material, but we guide IAEA - TECDOC - 1302.	**A**
Luxem-bourg	IAEA, ADR, ADNR, RID, IMDG, IT-ICAO with application orders and with deviations indicated in the large-ducal regulation of the 14th of December 2000 concerning the protection of the population against the dangers resulting from the ionising radiations General regulations concerning the protection of the public, the workers and the environment against ionising radiation Luxembourg has not the means of appraising and certifying package designs and materials. Nevertheless, for each transport or transit of radioactive sources, it is requested copies of approval of special form radioactive material and package design. Luxembourg does not authorize the transport and the transit of fissile materials since Luxembourg does not sign Conventions of Paris and Brussels.	**C**
Malta	IAEA - Followed in principle, will be implemented soon by the Rad. Pot. Brd.	

	ADR - Is awaiting publication by the Malta Transport Authority. RID - Not applicable as Malta does not have a rail system. IMDG-Code - Implemented by the Malta Maritime Authority. ADNR – Not relevant. ICAO-TI - Implemented by the Department of Civil Aviation. There are no other national regulations or guidelines because no packages are designed in Malta.	**A**
The Nether-lands	IAEA, ADR, RID, ADNR, IMDG, IT-ICAO with application orders and without deviations No additional regulations concerning transport of radioactive materials	**A**
Poland	IAEA, ADR, RID, IMDG-Code and ICAO-TI are implemented. ADNR is not implemented. There are no any other national regulations or guidelines.	**A**
Portugal	No response	**E**
Romania	ADR, RID, IMDG-Code and ICAO-TI are implemented. IAEA is implemented with relevant deviations. ADNR is not implemented. The Romanian Fundamental Norms for the Safe Transport of Radioactive Materials are transposing TS-R-1 requirements with the following deviations: a) Art. 207 (supplementary; defining the Romanian competent authority); b) Section IX (Final disposition) is supplementary; c) Schedules of requirements for the transport of specified types of radioactive material consignments are not included in Romanian Regulation); d) Annex I (Summary of approval and prior notification requirements is not applicable on Romanian territory; e) the authorization requirements are described in a separate regulation on authorization procedures). • The Fundamental norms for the safe transport of radioactive materials, approved by order of the CNCAN president no. 373/2001 and published in Official Bulletin of Romania no.137 bis/2002, • Norms for the international shipments of radioactive materials involving the Romanian territory, approved by order of the CNCAN president no. 374/2001 and published in Official Bulletin of Romania no.127 bis/2002, • Norms for the international shipments of radioactive waste involving the Romanian territory, approved by order of the CNCAN president no. 183/2002 and published in Official Bulletin of Romania no.913 bis/2002, Norms for transport of radioactive materials - Authorization Procedures, approved by order of the CNCAN president no. 222/2002 and published in Official Bulletin of Romania no.9/2003	**C**
Slovak	IAEA, ADR, RID are implemented.	

Republic	Atomic Act No. 130/1998 Coll., Regulation on transport of nuclear materials, radioactive wastes and spent nuclear fuel No. 284/1999 Coll.	**B**
Slovenia	The IAEA regulations (1996 Edition (Revised), TS-R-1) and the international transport regulations ADR, RID, IMDG-Code, ADNR and ICAO-TI for materials of class 7 are implemented in original form. There are no any other national regulations or guidelines.	**A**
Spain	IAEA, ADR, RID, IMDG-Code and ICAO-TI are implemented. ADNR is not applicable. Real Decreto 2115/1998 sobre transporte de mercancias peligrosas por carretera (published in “Boletin Oficial del Estado” of 16/October/1998. These regulations refer to comply with the ADR and include some particularities in subjects on licenses for Spanish drivers, traffic rules, authorization and periodical inspections of vehicles, containers and packages manufactured in Spain, actions to be taken in case of emergency and enforcement. These requirements are not opposite to those included in ADR and they actually complement them for carrying out the activity in Spain.	**A**
Sweden	ADR, RID and the IMDG-code are translated and implemented into Swedish regulations without any important deviations for class 7. ICAO-TI is implemented as it is without translation. ADNR is not applicable in Sweden. No additional regulation, but for transport of nuclear material and of waste from nuclear activities (nuclear waste), the Nuclear Activities Act and the Nuclear Activities Ordinance have to be complied with. For transport of all radioactive material also the Radiation Protection Act and the Radiation Protection Ordinance and applicable regulations issued by SSI have to be complied with.	**A**
Turkey	RID and ICAO-TI are implemented. Turkey has applied the general principles of the IMDG-Code, but not the detailed requirement. Turkish version of IAEA Regulations (1996 Edition, TS-R-1) is currently underway and expected to be in effect in 2004. ADR is not implemented.	**D**
United Kingdom	IMDG-Code and ICAO-TI are implemented. IAEA, ADR, RID are implemented with deviations. There are some additional requirements related to emergency arrangements (from EURATOM BSS etc) implemented for road - in accordance with TS-R-1 para 308. There are various derogations in place for road and rail, in accordance with EC directive procedures (e.g. limited exemption from use of orange plate for some consignments). ADNR is not implemented. Guide to an application for UK competent authority approval of radioactive material in transport (IAEA 1996 regulations) - this is an advisory guide.	**C**

6.2.1.1.2 Categorization of different practices

Cate-gory	Country specific practice	Number of practices
A	- IAEA, ADR, RID, ADNR*, IMDG, IT-ICAO with application orders and **without complementary requirements** - **No additional regulations** concerning transport of radioactive materials	**11**
B	- IAEA, ADR, RID, ADNR*, IMDG, IT-ICAO with application orders and **without complementary requirements** - **Additional regulations** concerning transport of radioactive materials	**6**
C	- IAEA, ADR, RID, ADNR*, IMDG, IT-ICAO with application orders and **with complementary requirements** - **Additional regulations** concerning transport of radioactive materials	**7**
D	Only RID and ICAO-TI are implemented	**1**
E	No response	**3**

* only for countries relevant

6.2.1.1.3 SUMMARY AND DISCUSSION

In general, the IAEA, ADR, RID, IMDG and IT-ICAO regulations are applicable in all EU – and applicant countries. ADNR is applicable in the relevant countries. IMDG-Code is not implemented in Slovak Republic and in Czech Republic. Most of them have implemented the regulations without complementary requirements (category A, B – 17 countries).
Most of complementary requirements (category C) concern only one or two modal regulations because of country specific conditions (e.g. Belgium, Czech Republic, Latvia, Romania, UK).
Additional regulations concerning transport of radioactive materials are existing mainly in those countries which have nuclear energy (Belgium, Bulgaria, Czech Republic, Finland, France, Germany, Hungary, Romania, Slovak Republic, UK). Probably in these countries the administrative effort regarding the transport of radioactive material is more extensive because of fissile materials transport than in the countries without nuclear energy.
Luxembourg does not deliver approval certificates and does not authorize the transport and the transit of fissile materials since Luxembourg does not sign Conventions of Paris and Brussels. For each international transport or transit of radioactive sources, copies of approval of special form radioactive material and package design are requested and in addition, an insurance certificate, attesting that radiological risks in case of an accident are covered, has to be presented.
At present Turkey has only implemented RID and ICAO-TI and followed the general principles of the IMDG-Code. The Turkish version of the IAEA-Regulations (1996 Edition, TS-R-1) is expected to be in effect in 2004.

According to the directives 94/55/CE and 96/49/CE respectively relative to the approximation of the laws of the Member States concerning the transport of dangerous goods by road and

by rail, European requirements are established to ensure a satisfying degree of harmonization which facilitates the freedom of movement of the dangerous goods and the services, and to guarantee a high level of safety in the international transport operations. If a European country signed these European agreements, this country cannot require more severe provisions under penalty of decreasing international exchanges. However, in the case of international transports, a EU country can apply additional requirements (not included in modal regulations) on its territory provided that those provisions do not conflict with modal regulations and not be more restrictive from those required by European regulations. For national transports, each country can apply specific requirements which are different from those required by European regulations. In all cases, the complementary requirements have to be indicated in legal texts.

6.2.1.1.4 CONCLUSIONS AND RECOMMENDATIONS

The modal regulations ADR, RID, IMDG-Code, ICAO-TI based on the IAEA recommendations are implemented in all EU–member states and applicant countries. So far the regulatory framework for all competent authorities and applicants is the same. There are some limited complementary requirements in 7 countries (category C) which are not essential for the approval procedure for package designs for radioactive material, shipment and special arrangement.
The following recommendations for applicable regulations for the transport of package designs for radioactive material, shipment and special arrangement can be given:

- The complementary (or specific) requirements to the modal regulations should be indicated in national legal texts.
- No delay, between the date of official publication of the new edition regulations and the date of applicability in the EU countries, should exist (this recommendation does not include the transition period between two editions of regulations, already indicated in modal regulations).

6.2.1.2 ITEM: NOMINATION AND RESPONSIBILITIES OF COMPETENT AUTHORITY (CA)

This item contains law and regulation nominating the CA and identification of the responsibilities in issuing approval certificates and assessing Design Safety Reports (DSR).

6.2.1.2.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Cate-gory of practice
Austria	No response	**G**
Belgium	- Nomination and responsibilities of the competent authority in national legal text (Law of 15th April 1994 relative to the protection of the population and the environment against the danger from ionizing radiations and relative to the Federal Agency for Nuclear Control.) - The competent authority issues all approval certificates - The assessment of DSR is issued by the competent authority	**A**
Bulgaria	The Act for the Safe Use of Nuclear Energy (ASUNE) (promulgated in O.J.No.63 of 2002) assigns certain responsibilities connected to the safe transport of RAM to Nuclear Regulatory Agency (NRA). The obligation of co-operation with other governmental bodies is given in ASUNE Art. 5. §7 in general and Art. 26. §4 specifically with the Minister of Transport and Telecommunication. The authorisation to issue licences or permits for transports are assigned to NRA in ASUNE Art.15 §3.5; §4.12 and §4.16. Up to now only foreign approved packages have been used, where approvals are required. These packages were transported with Bulgarian shipment approvals, issued by NRA. RAM with high activity are imported.	**F**
Cyprus	The Protection from Ionizing Radiation Law of 2002 (N.115(I)/2002, Official Gazette No. 3621, 12/7/2002). The competent authority issues the approval certificates for following types: Type AF, Type B(U)/B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/H(M), Special form radioactive material, Low dispersible radioactive material, Shipment, Special arrangement. The assessment of the Design Safety Report is performed by the competent authority itself.	**A**
Czech Republic	Act No. 18/1997 Coll. of 24 January 1997 on Peaceful Utilisation of Nuclear Energy and Ionising Radiation (the Atomic Act) and on Amendments and Additions to Related Acts, as Amended. The competent authority issues the approval certificates for following types: Type AF, Type B(U)/B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/H(M), Special form radioactive material, Low	**B**

	dispersible radioactive material, Shipment, Special arrangement. Competent authority SONS uses technical support for the assessment of the Design Safety Report.	
Denmark	• Law No. 94 of 31 May 1953 on the Use etc. of Radioactive Material • National Board of Health Order No. 993 of 5 December 2001 on the Transport of Radioactive Material (The competent authority National Institute of Radiation Hygiene (NIRH) is a part of the National Board of Health) NIRH issues the approval certificates for following types as the competent authority: Type AF, Type B(U)/B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/H(M), Special form radioactive material, Low dispersible radioactive material. Competent authorities for shipment approval certificates are: NIRH (road and rail), or CAA (air), or DMA (sea). Competent authorities for special arrangements are: NIRH (road and rail), or CAA , or DMA. The assessment of the Design Safety Report is performed by the Competent authority itself.	**D**
Estonia	The Radiation Act (1997, as amended). The competent authority in the field of radiation protection is the Radiation Protection Centre and for the international transport regulations the Ministry of Transport and Communications. There are no packages, which need the approval, used in Estonia and the procedures have not been established.	**F**
Finland	• The Finnish Act on Transportation of Dangerous Goods (719/1994) • Nuclear Energy Act (990/1987) • Radiation Act (592/91) The competent authority STUK issues the approval certificates for following types: Type AF, Type B(U)/B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/H(M), Special form radioactive material, Low dispersible radioactive material, Shipment, Special arrangement. STUK has no regular supporter, if needed, technical support (from a domestic or foreign designed organization) is supported by special contract. The "final" assessment is performed by STUK.	**B**
France	- Nomination and responsibilities of the competent authority (articles 3 and 36 of ADR order, articles 3 and 28 of RID order, article 411-4.04 of Division 411 appendix of IMDG decree, article 15 of ADNR order and DGSNR/DGAC protocol for air transport) The competent authority issues all approval certificates - The assessment of DSR is issued by the technical support of the competent authority	**C**

Germany	The legal basis for the nomination of the competent authority in Germany are: - Verordnung über die innerstaatliche und grenzüberschreitende Beförderung gefährlicher Güter auf der Straße und mit Eisenbahnen (Gefahrgutverordnung Straße und Eisenbahn - GGVSE) vom 11. Dezember 2001 (BGBl. I S. 3529) in der Fassung der Bekanntmachung vom 10. September 2003 (BGBl. I S. 1913), zuletzt geändert durch die Verordnung über die Beförderung gefährlicher Güter mit Seeschiffen (Gefahrgutverordnung See – GGVSee) vom 4. November 2003 (BGBl. I S. 2286 - Verordnung über die Beförderung gefährlicher Güter mit Seeschiffen (Gefahrgutverordnung See – GGVSee) vom 4. November 2003 (BGBl. I S. 2286) - Verordnung über die Beförderung gefährlicher Güter auf Binnengewässern (Gefahrgutverordnung Binnenschifffahrt - GGVBinSch) vom 21. Dezember 1994 (BGBl. I S. 3971), zuletzt geändert durch die 5. Binnenschifffahrts-Gefahrgut-änderungsverordnung vom 27. März 2002 (BGBl. I S. 1246) und 4. Verordnung zur Inkraftsetzung der Änderungen der Anlagen A, B1 und B2 zur Verordnung über die Beförderung gefährlicher Güter auf dem Rhein (ADNR) und der Änderungen der Anlagen A, B1 und B2 zur Verordnung über die Beförderung gefährlicher Güter auf der Mosel vom 22. Dezember 1998 (BGBl. II S. 3000) - Luftverkehrs-Zulassungs-Ordnung in der Fassung der Bekanntmachung vom 27. März 1999 (BGBl. I S. 610), zuletzt geändert durch Verordnung vom 10. Februar 2003 (BGBl. I S. 182) in Verbindung mit den ICAO-Gefahrgutvorschriften (ICAO Technical Instructions). BfS is the competent authority for issuing the approval certificates for following types: Type AF, Type B(U)/B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Shipment, Special arrangement. BAM is the competent authority for issuing the approval certificates for Type H(U)/H(M), Special form radioactive material, Low dispersible radioactive material. BAM is responsible for mechanical and thermal design assessment and approval of quality assurance measures of packages requiring competent authority approval, and BfS is responsible for shielding and criticality assessment. The assessment of the Design Safety Report is performed by the competent authorities themselves.	**D**
Greece	No response	**G**
Hungary	The legal basis for the nomination of the competent authority in Hungary is the Government Decree No. 87/1997 (V.28) on Duties and Scope of Authority of the Hungarian Atomic Energy Committee and on the Scope of Duty and Authority, and Jurisdiction for Imposing Penalties, of the Hungarian Atomic Energy Authority. The competent authority, Hungarian Atomic Energy Authority (HAEA), issues the approval certificates for following types: Type AF, Type B(U)/B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/H(M), Special form radioactive material, Low dispersible	**B**

	radioactive material, Shipment, Special arrangement. Competent authority uses technical support for the assessment of the Design Safety Report .	
Ireland	• The Radiological Protection Act, 1991 (Number 9 of 1991), The Stationery Office, Dublin. • The Radiological Protection (Amendment) Act, 2002 (Number 3 of 2002), The Stationery Office Dublin, • The Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000 (S.I. No. 125 of 2000), The Stationery Office Dublin. • The Carriage of Dangerous Goods by Road Act, 1998 and The Carriage of Dangerous Goods by Road Regulations,2001 (S.I. No. 492 of 2001)[implements the ADR]. • The European Communities (Transport of Dangerous Goods by Rail) Regulations S.I. No. 500 of 2001 implements the RID. There are no approval certificates of any type because of package approval is not undertaken in Ireland.	**F**
Italy	- Nomination and responsibilities of the competent authority in national legal text [1) Circular of Ministry of Transport and Navigation D.G. n. 162 of 16.12.1996 (for transport by road); 2) Decree of Ministry of Transport and Navigation of 27.02.2002 - Annex E (for transport by rail); 3) Circular of Ministry of Transport n. 334096/30 of 03.12.1992 (for transport by air); 4) Decree of President of Republic n. 1008 of 09.05.1968 (for transport by sea)] - The competent authority issues all approval certificates - The assessment of DSR is issued by the competent authority	**A**
Latvia	The 2000 Act on Radiation Safety and Nuclear Safety; The Cabinet of Ministers Regulations on Radiation Safety Centre Statute (22.05.2001). The competent authority issues the approval certificates for following types: Type AF, Type B(U)/B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/H(M), Special form radioactive material, Low dispersible radioactive material, Shipment, Special arrangement. The assessment of the Design Safety Report is performed by the Competent authority itself.	**A**
Lithuania	• Law on Nuclear Energy of the Republic of Lithuania • Law on Radiation Protection of the Republic of Lithuania • Law on Management of Radioactive Waste of the Republic of Lithuania • Law on Environment Protection of the Republic of Lithuania • Order No 397 On the Import, Export, Transit and Internal Transportation of Radioactive Substances and Radioactive • Waste and Returning of Spent Sealed Sources, adopted on 13 December 1999 by the Ministry of Environment	**F**
Luxem-	Nomination and responsibilities of the competent authority in	

bourg	national legal text *Luxembourg has not the means of appraising and certifying package designs and materials. Nevertheless, for each transport or transit of radioactive sources, it is requested copies of approval of special form radioactive material and package design. Luxembourg does not authorize the transport and the transit of fissile materials since Luxembourg does not sign Conventions of Paris and Brussels.*	**F**
Malta	Legal Notice 44 (2003). The issue of a shipment approval certificate is performed by the Occupational Health & Safety Authority. This will be taken over by the Radiation Protection Board when set up. The issue of Type AF, Type B(U)/B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/H(M), Special form radioactive material, Low dispersible radioactive material, or Special arrangement approval certificates is not applicable. The performance of the assessment of the Design Safety Report by the competent authority or technical support is not applicable.	**F**
The Nether-lands	- Nomination and responsibilities of the competent authority in national legal text (Kernenergiewet (Dutch Nuclear Energy Act), Besluit vervoer splijtstoffen, ertsen en radioactieve stoffen (Transport of fissile materials, ores and radioactive materials decree)) - The competent authority issues all approval certificates - The assessment of DSR is issued by the competent authority	**A**
Poland	• Act of Parliament of 29 November 2000 Atomic Law (Dz.U. z 2001 r. Nr 3 poz. 18, Nr 100, poz. 1085, Nr 154, poz. 1800; • Dz.U. z 2002 r. Nr 47, poz. 676, Nr 135, poz. 1145). Act of Parliament of 28 October 2002 on the transport of dangerous goods by road (Dz.U. z 2002 Nr 199 poz. 1671). The competent authority (NAEA) issues the approval certificates for following types: Type AF, Type B(U)/B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/H(M), Special form radioactive material, Low dispersible radioactive material, Shipment, Special arrangement. The assessment of the Design Safety Report is performed by the competent authority itself.	**A**
Portugal	No response	**G**
Romania	The Law no.111/1996 on the safe deployment of nuclear activities, with the subsequent completions and modifications. The competent authority (NAEA) issues the approval certificates for following types: Type AF, Type B(U)/B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/H(M), Special form radioactive material, Low dispersible radioactive material, Shipment, Special arrangement.	**A**

	The assessment of the Design Safety Report is performed by the competent authority itself.	
Slovak Republic	"Zakon o organizacii cinnosti vlady a organizacii ustrednej statnej spravy" Law No. 575/2001 Coll. Slovak Republic has several competent authorities. Nuclear Regulatory Authority of the Slovak Republic (NRA) and its technical support issue approval certificates for Type AF,Type B(U)/B(U)F, Type B(M)/B(M)F, Type C. The assessment of the Design Safety Report is not performed by the competent authority itself.	**E**
Slovenia	Act on Transport of Dangerous Goods (Off. Gaz., RS, No. 79/99, 96/2002) and Act on Ionising Radiation Protection and Nuclear Safety (Off. Gaz., RS, No. 50/2003). For issuing the approval certificates according to ADR 6.4.22 is responsible Ministry of Environment, Spatial Planning and Energy – Slovenian Nuclear Safety Administration. For issuing the approvals for shipment and special arrangements in the case of nuclear materials and radioactive goods is responsible Ministry of Environment, Spatial Planning and Energy – Slovenian Nuclear Safety Administration in agreement with the minister responsible for health, while a permit for transportation of radio-pharmaceuticals shall be issued by the minister for health. The assessment of the Design Safety Report is also performed by the competent authority.	**A**
Spain	- Nomination and responsibilities of the competent authority in national legal text Real Decreto 1836/1999. Reglamento sobre instalaciones nucleares y radiactivas, published in “Boletín Oficial del Estado” nº 313 of 31-December-1999. It defines the Ministry of Economy (Dirección General de Política Energética y Minas) as the competent authority for package and shipment approvals in base to technical reports submitted by the Consejo de Seguridad Nuclear (CSN). Ley 15/1980 de creación del Consejo de Seguridad Nuclear., published in “Boletín Oficial del Estado” nº 100 of 25/April/1980. It defines the CSN as the competent authority on radiological protection and nuclear safety. Real Decreto 1952/1995 . Published in “Boletín Oficial del Estado” of 10/Febreuary/1996. It defines the different competent authorities in the field of the transport of dangerous goods. This Decree names the Comisión para la Coordinación del Transporte de Mercancías Peligrosas (included in the Ministry of Transport) for the co-ordination of regulatory activities in that field. - The competent authority issues all approval certificates - The assessment of DSR is issued by the technical support of the competent authority	**C**

Sweden	• Förordning (1982:923) om transport av farligt gods. (Ordinance (1982:923) on the transport of dangerous goods. • SKI or SSI issues the types of approval depending on the type of approval. The split between SKI and SSI is between fissile and non-fissile material. So a certificate with an F is issued by SKI, a certificate with no F is issued by SSI if non-fissile content. I.e. that a special arrangement certificate can be issued either by SKI or SSI depending on the content. The rule is: If the package has to be approved for its fissile content, then and only then, SKI is the competent authority. There is no competence at SSI on neutron chain reactions, therefore this split. • The assessment of the Design Safety Report is performed by the Competent Authority itself. But for criticality assessments SKI is supported by a selected independent company. This may also sometimes happen for other kind of assessments, both for SKI and SSI. We can also note that there is collaboration between SKI and SSI during the assessment procedure of packages with nuclear material and nuclear waste, varying with the type of approval to be issued.	**D**
Turkey	• The Turkish Atomic Energy Authority Act, Act 2690, 13 July 1982 • The Radiation Safety Decree, published 7 September 1985 • The Radiation Safety Decree, published 24 March 2000 • The draft revision of Turkish Transport Regulation based on TS-R-1 (to published in 2003 or late in first half of 2004) Turkey currently has no radioactive material packaging or special form material production. The need to carry out a package design or special form design assessment is therefore not required. The review and assessment process is confined to checking the applicability of paperwork and that the package and special form certificates are applicable and valid. No mechanical assessment work is carried out for packages currently requiring multilateral approval. The Turkish Atomic Energy Authority is responsible to issue such certificates. The assessment of the Design Safety Report is not performed by the competent authority itself.	**F**
United Kingdom	There are many regulations, identifying different competent authorities (for different purposes). For package design approval there are agreements in place such that the duties of the CA are carried out by the Radioactive Material Transport Division. This issue was examined by the IAEA TRANSAS mission in 2002 (TranSAS-3), and documents 3, 4, 5, 8 and 9 are particularly applicable from Table II. The competent authority is the Secretary of State (SOS) for Transport: in practice the Radioactive Material Transport Division caries out duties on behalf of the SOS. The competent authority issues the approval certificates for following types: Type AF, Type B(U)/B(U)F, Type B(M)/B(M)F, Type C, Type IF, Type H(U)/H(M),	**A**

	Special form radioactive material, Low dispersible radioactive material, Shipment, Special arrangement. The assessment of the Design Safety Report is performed by the competent authority itself.	

6.2.1.2.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	- Nomination and responsibilities of the competent authority in national legal text - **One** competent authority issues all approval certificates - The assessment of DSR is issued by the **competent authority itself**	**9**
B	- Nomination and responsibilities of the competent authority in national legal text - **One** competent authority issues all approval certificates - The assessment of DSR is issued by the **competent authority and a technical support**	**3**
C	- Nomination and responsibilities of the competent authority in national legal text - **One** competent authority issues all approval certificates - The assessment of DSR is issued by the **technical support of the competent authority**	**2**
D	- Nomination and responsibilities of the competent authorities in national legal text - **Several** competent authority issues different approval certificates or the same approval certificate for a special transport mode - The assessment of DSR is issued by the **competent authority itself**	**3**
E	- Nomination and responsibilities of the competent authorities in national legal text - **Several** competent authority issues different approval certificates or the same approval certificate for a special transport mode - The assessment of DSR is issued by the **competent authority and a technical support**	**1**
F	- Nomination and responsibilities of the competent authority in national legal text - Approval procedure not established	**7**
G	No response	**3**

6.2.1.2.3 SUMMARY AND DISCUSSION

All countries have an established legal system for the nomination and the responsibilities of the competent authority. Germany has a technical support nominated as the responsible Federal institution.

14 countries have only one competent authority for issuing all approval certificates (categories A, B, C), solely 4 countries (categories D, E) share the responsibilities regarding the issue of approval certificates to different competent authorities due to splitted competences for different transport modes (Denmark) or design aspects (Germany, Sweden).

The competent authorities of the majority of the countries perform the assessment of the DSR by itself or by participation of an expert institution (categories A, B). In France and Spain only the nominated technical support perform the assessment of the DSR (category C).

In 7 countries (Bulgaria, Estonia, Ireland, Lithuania, Luxembourg, Malta, Turkey – category F) where the manufacture of transport packages for radioactive material is not existent, an approval procedure for Type AF, Type B(U)/B(U)F, Type B(M)/B(M)F, Type C, Type IF, Type H(U)/H(M), Special form radioactive material, Low dispersible radioactive material is not established.

6.2.1.2.4 CONCLUSIONS AND RECOMMENDATIONS

Due to the nomination of one ore more competent authorit(y)ies, several structures for organizing the issue of approval certificates and the assessment of DSR have been established in the countries. All organization structures (categories A, B, C, D) are adapted to the specificity of each country, but they have to be orientated on the effort and on the complexity of approval procedures. With more complexity of the approval procedure it is necessary (recommendable) to have an appropriate number of experienced staff of well-trained experts. If the competent authority works together with a technical support a nomination in a national legal text of this support should be foreseen due to have a clear designation of responsibilities and to ensure a long-term, quality assured special knowledge and experience in the assessment procedure.

The following recommendations for the nomination and responsibilities of competent authority can be given:

- The nomination of competent authorities should be indicated in a national legal text.
- The responsibilities of competent authorities should be indicated in a national legal text.

6.2.1.3 ITEM: RESPONSIBILITIES FOR PERFORMANCE OF REGULATORY TESTS

6.2.1.3.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**E**
Belgium	The applicant carries out the experimental tests.	**A**
Bulgaria	No experimental tests, because up to now only foreign approved packages have been used, where approvals are required.	**D**
Cyprus	No response	**E**
Czech Republic	The applicant carries out experimental tests.	**A**
Denmark	Technical support: Danish Technological Institute (possible)	**C**
Estonia	Not relevant.	**D**
Finland	The applicant self or designed organization upon agreement with the applicant carries out experimental tests.	**A**
France	The applicant carries out the experimental tests.	**A**
Germany	The competent authority BAM or applicants carry out experimental tests.	**A/B**
Greece	No response	**E**
Hungary	The applicant carries out experimental tests.	**A**
Ireland	Not relevant.	**D**
Italy	The applicant carries out the experimental tests.	**A**
Latvia	The competent authority hasn't such possibilities to do the tests yet. Applicant shall do by himself or arrange tests at specialised facilities outside of country.	**A**
Lithuania	Not relevant.	**D**
Luxem-bourg	*Luxembourg has not the means of appraising and certifying package designs and materials.*	**D**
Malta	Not relevant.	**D**
The Nether-lands	The applicant carries out the experimental tests.	**A**
Poland	The applicant carries out experimental tests.	**A**
Portugal	No response	**E**

Romania	The experimental tests are carried out at an approved test facility.	**C**
Slovak Republic	No response	**E**
Slovenia	Experimental tests with packages or models, such as drop or thermal tests would be carried out by expert institutions.	**C**
Spain	The applicant carries out the experimental tests.	**A**
Sweden	The applicant select on his own who to perform the tests. He may do the tests himself. This is usually discussed before the tests are performed to allow the competent authority to witness the tests.	**A**
Turkey	Not relevant.	**D**
United Kingdom	The applicant may sub-contract testing.	**A**

6.2.1.3.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	Experimental tests carried out by the applicant	**13**
B	Experimental tests carried out by the competent authority	**1**
C	Experimental tests carried out by a nominated expert institution of the CA	**3**
D	No practical experience.	**7**
E	No response	**5**

6.2.1.3.3 SUMMARY AND DISCUSSION

There are two groups for the responsibility of the performance of regulatory tests: on one side, the most common practice is that tests be performed by the applicant (category A) and on the other side, that the tests be performed by the competent authority or nominated expert institutions (categories B, C) besides those countries where no experiences in experimental testing exist (category D).

There is a potential conflict of test objectives for both responsibilities for the test performance by the applicant or by the competent authority/expert laboratory.

One has to consider that the qualified testing and interpretation of measurements (decelerations, strains, deformations, temperatures, pressures, leakage rates etc.) is as complicated as the performance and interpretations of calculations.
The demonstration of compliance with the regulations should be in the responsibility of applicants, on the other hand test details and problems with the design could be “covered” by the applicant in a test report. The competent authority should be able to supervise the tests by the applicant and has to be involved in the whole test process from preparation up to interpretation of the test results. So the staff of the competent authority has to be confident and experienced in this field.

If the authority or expert institution performs tests, errors can potentially affect the design and can give co-responsibility to the authority, but there is a higher grade of guarantee that the test methods required by the regulations will be performed in conformity with these, and the test results are completely known by the competent authority.
The preparation, performance and especially the assessment of experimental tests need staff with high qualification and test experience as well as modern test equipment. A competent authority or a nominated expert institution, which performs tests, can deal intensively with the preparation, performance, assessment and interpretation. There are for example complications in the interpretation of scale model testing regarding the scaling of shock absorbers and seals because of their non linear force-deflection-curve which warrants additional complex assessment. The applicants who perform tests by themselves and the competent authorities that supervise the test performance need also this know-how. Performing tests by a mandatory expert institution leads to an accumulation of know-how, what gives higher confidence in those tests. Best in this case the applicant itself has to supervise carefully those tests with experienced staff to transfer the full knowledge to the designer. To minimize the test activities of state laboratories and to develop the design appropriate every applicant has to have test capabilities and know-how.

6.2.1.3.4 CONCLUSIONS AND RECOMMENDATIONS

A guidance material for experimental testing and assessment should be developed. At the moment you can refer to the following standards or guidance material for testing and assessment:

- Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material [56],
- DIN EN 1779, 10/1999 “Leakage testing – Criteria for the selection of Leakage test methods and –procedures”,
- DIN EN 13185, 07/2001, “Leakage testing – test gas procedures”,
- (ANSI) N14.5-1997, "Leakage Tests on Packages for Shipment of Radioactive Materials",
- TCSC 1068 (UK Industry Code), Leakage tests on Packages for Transport of RAM,
- ISO 12807, 1996 “ Safe Transport of Radioactive Materials - Leakage Testing on Packages”,
- ASTM International, Designation: E 2230-02, “Standard Practice for Thermal Qualification of Type B Packages for Radioactive Material”,
- TSCS- 1086 - Testing Radioactive Materials Transport Packagings,
- Ove Arup & Partners International Ltd and Gesellschaft für Nuklear-Behälter GmbH, Evaluation of Codes for Analysing the Drop Test Performance of Radioactive Materials Transport Container [57].

The “Advisory Material” in the present state does not cover all aspects of experimental testing. An update should be recommended considering open questions or new guidance materials.

The following recommendations for the responsibilities in performing regulatory tests can be given:

- Guidance material for the preparation and performance of experimental tests, and for the assessment and interpretation of test results should be re-evaluated or developed on an harmonized basis in the EU.
- When the applicant performs testing, he should be able to demonstrate the compliance to regulatory requirements and to a Quality Assurance system.
- For the supervision of applicant’s testing by the competent authority independent well qualified and practised staff is needed.
- An organizational separation between the section which performs the tests and the section which assesses the package design type and/or issues the certificate shall be provided if the CA performs the tests.

6.2.1.4 ITEM: NOMINATION AND RESPONSIBILITIES OF ASSESSMENT ORGANIZATION

This item contains in which way does occur the choice of the assessment organization and is there an independence from concerned industry.

6.2.1.4.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**G**
Belgium	If deemed necessary, the advice of external experts or institutions can be asked. The assessment institutions can be independent or not from industry.	**A/E**
Bulgaria	No assessment procedure	**F**
Cyprus	No assessment service.	**A**
Czech Republic	The choice of the expert institutions goes such a way: 1. Applicant proposes two or three institutions for the assessment 2. SONS refuses this institutions which are connected with design or with designer, and other accepted 3. Applicant chooses one institution from accepted ones and makes contract with it 4. Applicant pays for the assessment to contracted institution and submits one copy to SONS as a part of the safety report The main condition is that the expert institution has to be independent from the concerned industry.	**D**
Denmark	Not applicable.	**A**
Estonia	Not relevant.	**F**
Finland	Normally outsider organizations are not used in safety report assessments. If special expertise from outside of STUK is needed, it is done by a contract. The expert institution has to be independent from the concerned industry.	**A**
France	The assessment organization is IRSN. IRSN is occasionally supported by external experts chosen among university, industries, CEA, or by external contractors (engineering companies not directly concerned by transport of radioactive materials). Nomination and responsibilities of IRSN (article 36 of ADR order and 28 of RID order, article 15 of ADNR order, article 411-4.04 of Division 411 appendix of IMDG decree and DGSNR/DGAC	**B**

	protocol for air transport)	
Germany	Not applicable.	**C**
Greece	No response	**G**
Hungary	According to the Decree No. 14/1997(IX. 3.) KHVM on the 'Transport and Packaging of Radioactive Materials' the IISC provides expert opinion to the HAEA for special forms of radioactive material design, transportation under special arrangement, and when approval of the package design and/or transport of radioactive material is required by international transportation mode specific regulations. The independence from concerned industry is a basic requirement.	**B**
Ireland	Not relevant.	**F**
Italy	No call upon other expert institutions.	**A**
Latvia	Authority can invite legally recognised expert(s) if needed for additional assessment, or can initiated this recognition of the competence for experts and then used them for assessments. Experts shall be independent, institution (TSO) should be, but due to limited number of such competence centres it could be case where institution (TSO) has some relations with concerned industry.	**A/E**
Lithuania	Not relevant.	**F**
Luxem-bourg	*No assessment procedure*	**F**
Malta	No expert Institution used.	**A**
The Nether-lands	Two expert institutions: Nuclear Research and consultancy Group (NRG) (NRG is established as a partnership firm through the merger of ECN's and KEMA's business activities in the nuclear fields - NRG is independent from the industry but is by itself part of the industry. NRG works for business and governments.) and TNO, Institute of applied physics (statutory organization (established by law). TNO is independent. TNO works for businesses and governments.	**B**
Poland	No expert Institution used.	**A**
Portugal	No response	**G**
Romania	No assessment service.	**A**
Slovak Republic	The assessment work is procured by tender. A contract between the CA and the assessment service about the assessment tasks is placed. But we do not have many institutions available to provide	**D**

	support for NRA. Therefore the choice is very simple. The technical support of the competent authority is Nuclear Research Institute (NRI). The expert institution has to be independent from the concerned industry.	
Slovenia	The assessment institutions are chosen by invitation for tender and in accordance with the regulations. In general, the assessment institution is independent from the concerned industry.	**D**
Spain	No call upon other expert institutions than the nominated technical support.	**B**
Sweden	The assessment institutions are chosen by special contract. The assessment institution has to be independent from the concerned industry.	**D**
Turkey	No response	**G**
United Kingdom	Not applicable.	**A**

6.2.1.4.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	Normally no technical support of the competent authority, only in special cases support by independent institutions or experts	**10**
B	Only mandatory technical support	**4**
C	Technical support nominated as responsible Federal institution	**1**
D	Choice of technical support no nominated in national legal texts (independent from concerning industries)	**4**
E	Choice of technical support no nominated in national legal texts (not independent from concerning industries)	**2**
F	No assessment procedure	**5**
G	No response	**4**

6.2.1.4.3 SUMMARY AND DISCUSSION

There are different kinds for the choice of technical support independent from concerned industry by the competent authority (see also chapter 6.2.1.2).

- Most of the competent authorities perform the assessment of the DSR itself or call upon a technical support only in cases for specialized competence in a field, to reduce high work load or unavailable hardware or software (category A).
- A by-law-nominated technical support (category B) is established in France, Hungary, The Netherlands and Spain.
- In Germany a technical support is nominated as the responsible Federal institution (category C).
- The choice of an independent technical support which is possible in 4 countries (Czech Republic, Slovak Republic, Slovenia, Sweden) (category D) whereas in Czech Republic the applicant can proposes the competent authority two or three institutions for the assessment.

In Belgium and Latvia it can be the case that the technical support has relations with concerned industry.

The independence from industry or public opinion or governmental influences does not seem to be a priority in the choice of the assessment service.

6.2.1.4.4 CONCLUSIONS AND RECOMMENDATIONS

All procedures mentioned under 6.2.1.4.3 for the selection of a technical support by the competent authority are available. It is important for the competent authority on one hand to identify a technical support who has the assessment competence and on the other hand to have the knowledge about the workflow, performance and interpretation of results of the assessment by the technical support. If the competent authority do not perform the assessment by itself, or have not a mandatory technical support they have to establish appropriate measures for supervision of the selected experts or expert institutions.

Conclusions and recommendations proposed by technical support organizations or assessors of competent authority have not to be influenced by directives of government, applicants, management hierarchy, etc.

The following aspects for the selection of technical support should be foreseen:

- The competent authority should have enough experienced experts, or should be able to call upon a suitable technical support (experts, expert institutions).
- The technical support should be nominated in a national legal text.
- The responsibilities of the technical support, if needed, should be indicated in a national legal text.
- Independence of the technical support from operators and industries concerned by radioactive transportation must be assured.

6.2.1.5 ITEM: COSTS OF CERTIFICATION AND/OR ASSESSMENT

This item contains the legal basis for charging costs and who pay the costs.

6.2.1.5.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**F**
Belgium	A decree fixes the amount of fees that the applicant has to pay. The competent authority has the possibility to require a supplementary advice or analysis for a particular safety issue from other organizations.	**A**
Bulgaria	Fees shall be collected for implementation of regulatory activities under ASUNE in amount as shall be fixed in a rate schedule approved by the Council of Ministers (promulgated in O.J.No. 85 of 2003). The fees shall be paid by the applicant or by the licensee or permit holder.	**A**
Cyprus	The Protection from Ionizing Radiation Law of 2002 (N.115(I)/2002, Official Gazette No. 3621, 12/7/2002). The applicant pays the fees.	**A**
Czech Republic	Applicant pays for the assessment to contracted institution. The basis of the applicant's charging cost doesn't depend on the cost of the expert institutions. It represents "average" cost of the administrative procedure done. The payment is negligible, varies from 500 CZK (=16 EURO) to 5 000 CZK (=160 EURO) depending on the Type of the packaging. Concerning the basis of the applicant's payment for the assessment by the designated expert institution, it depends on the payment conditions, which were contracted between the applicant and the expert institution.	**B**
Denmark	A fee of 5000 DKK (= 670 euros) must be paid by the applicant – for an approval certificate of the design of special form radioactive materials, or for an approval certificate of the design of a package for transport; or for an approval certificate for the transport of radioactive materials by special arrangement. Only validations of foreign (package) designs come into question.	**A**
Estonia	There are not the legal basis for charging costs and for the approval procedure including safety assessment established in Estonia. There are no packages, which need the approval, used in Estonia and the procedures have not been established.	**E**
Finland	Act on STUK (1069/1983) Applicant pays all the costs.	**B**
France	Payment of expenses relative to the delivery of the certificates or the performance of the tests and checks mentioned in ADR and RID decrees are the responsibility of the applicant. The costs of	**C**

	the technical assessments are defined by IRSN according to the average assessment time spent depending on the type of certificate (new approval, special arrangement, extension, validation, special form material approval…). There is no additional payment required for the delivery of the certificates by the competent authority.	
Germany	Legal basis: - Regulation concerning costs for measurements at the transport of dangerous goods – (Kostenverordnung für Maßnahmen bei der Beförderung gefährlicher Güter (GGKostV)) - Instruction about the charge of fees and outlays of BfS – (Dienstanweisung über die Erhebung von Gebühren und Auslagen des BfS) - Regulation concerning costs for benefits of the Federal Institute for Materials Research and Testing – (Kostenverordnung für Nutzleistungen der Bundesanstalt für Materialforschung und –prüfung) Costs have to be paid by the applicant.	**B**
Greece	No response	**F**
Hungary	Act No, XCIII of 1999 on Dues. Decree No. 14/1997(IX. 3.) KHVM on the 'Transport and Packaging of Radioactive Materials'.	**F**
Ireland	This is not relevant in our case as package approval is not undertaken in Ireland. Therefore there is no cost issue.	**E**
Italy	Payment of expenses relative to the delivery of the certificates is mentioned in a law and a decree and is the responsibility of the applicant. The cost is related to the number of hours spent to assess the safety report.	**B**
Latvia	If operator has the licence, than no charge for safety assessment by competent authority. If licence not yet issued, then safety assessment costs are a part of licence costs.	**B**
Lithuania	We do not have the national competent authorities approval certificates for package design, special form material and shipment of radioactive material, but we guide IAEA - TECDOC - 1302. Since there is no special regulation on the question, there is no charging cost.	**E**
Luxem-bourg	*Luxembourg has no resources to assess and certify package designs and materials.*	**E**
Malta	No as no packages are designed in Malta.	**E**
The Nether-lands	No costs for certification and assessment.	**D**
Poland	No charges are made.	**D**
Portugal	No response	**F**

Romania	The costs representing the taxes and tariffs are paid by the applicant according to the Regulations for taxes and tariffs for authorization and control activities, approved by Order of the President of CNCAN and published in Official Bulletin of Romania no. 323/2002.	**A**
Slovak Republic	The costs are paid mainly from NRA budget.	**D**
Slovenia	The costs of the approval procedure including safety assessment by the competent authority or a designated expert institution are charged by the applicant. The legal basis for charging costs are Act on Administrative Procedures (Off. Gaz., RS, No. 80/1999, 70/2000 and 52/2002, ZUP) and Act on Administrative Fees (Off. Gaz., RS, No. 8/2000, 44/200, 33/2001, 41/2002, 45/2001, 42/2002 and 76/2002.	**B**
Spain	The applicants have to pay taxes indicated in law 14/1999 for the certificate delivery.	**A**
Sweden	SKI has the right to charge applicants, based on an ordinance regarding fees to SKI. Holders of radioactive material in Sweden pay an annual fee to SSI based on an ordinance regarding fees to SSI. No special fee is at present payed to SSI for transport applications.	**B/D**
Turkey	Article 14 of the Turkish Atomic Act arranges the Income of the TAEA. The responsible party will pay the costs.	**B**
United Kingdom	There are no charges for approval of packages.	**D**

6.2.1.5.2 CATEGORIZATION OF DIFFERENT PRACTICES

Category	Country specific practice	Number of practices
A	The applicant pays a fixed amount of fees	**6**
B	The applicant pays the real costs of approval procedure	**8**
C	The applicant pays the costs only for the assessment	**1**
D	No costs for the approval procedure	**5**
E	No reference practice	**5**
F	No response	**4**

6.2.1.5.3 SUMMARY AND DISCUSSION

In most of the countries the applicant has to pay the costs (A, B, C). There are differences in charge of the fees – a fixed amount or the real costs on the basis of time exposure and a fixed rate per hour or only costs for the assessment – which could not always be clearly assessed due to the incomplete information in the responses.
In five countries (Netherlands, Poland, Slovak Republic, Sweden (partly), UK) the approval procedure is free of charge (category D).

Payment of costs by applicants could be a good opportunity to allocate appropriate resources to the competent authority or technical support in order to issue the certificate in a reasonable time and to increase the reliability of assessments. Charging costs of competent authority or technical support shall not influence the independence of the assessment or approval process. A free of charge or low fixed cost application on the other hand has the danger that this system can be misused for the completion and correction of safety proofs or documents by CA and TS, what requires too much CA or TS resources.

If payment conditions are contracted between the applicant and the expert institution, it is important that the assessment organization is independent from industry for certification and/or assessment is independent from applicant. In such a case a means of avoiding any influence would be to indicate the payment conditions in a national text.

6.2.1.5.4 CONCLUSIONS AND RECOMMENDATIONS

The determination of the costs is a very specific national matter which depends on the finance and administration system specific in the country.

The following recommendation for the costs of certification and/or assessment is given without consideration of the national characteristic:

- All costs for certification (including assessment) should be charged directly to applicants or indirectly by other means of refinanziation to warrant appropriate resources for the issue of assessments and certificates.
- It should be clearly indicated in a national text who has to bear the cost of assessment and certification.
- The fee to be paid by applicant for assessment and certification should be transparent in every EU country and known by all applicants in advance.

6.2.2 APPLICATION AND REQUESTED DOCUMENTS

6.2.2.1 ITEM: DOCUMENTS REQUESTED COMPLEMENTARY TO THOSE REQUIRED BY ADR (6.4.23) FOR UNILATERAL APPROVAL

6.2.2.1.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**F**
Belgium	No guidelines for application No additional requirements (beyond minimum requirements of ADR) for application	**A**
Bulgaria	Lack of practice	**E**
Cyprus	No guidelines for application Documents for application: Safety Report, Relevant certificates (source etc), *Leak test certificate, Euratom Regulation forms for shipments*	**A**
Czech Republic	Guideline: There is Regulation of the SONS No. 317/2002 Coll. on Design Approval of Packaging for Shipment Storage or Disposal of Nuclear Materials and Assigned Radioactive Substances, on Design Approval of Ionizing Radiation Sources and on Transportation of Nuclear Materials and Assigned Radioactive Substances (Design Approval and Transport Regulation) - Article 3, which stipulate supplementary requirements beyond minimum requirements of ADR 6.4.23. Documents for application: An application for design approval shall include introducing part [a) - h)] and Safety Report [i) - r)] : a) identification of the applicant b) identification of the manufacturer, if different from the applicant c) identification of the approved packaging, name, description, identification of design type, its parts, classification, use and a limit values for its use *d)* description of an use and *a method of product introduction on the market* e) a list of legal regulations and technical standards employed in the documents for type-approval *f) specification of a period in which regular operating inspections shall be repeated and their methods and scope* g) instructions for use in Czech language, including the rules for safe handling of the packaging *h) required period of validity of the type-approval* i) description of quality assurance system established in a special legal regulation j) documents about the tests passed k) material specification of radioactive substances or nuclear materials for which the packaging has been designed,	**D**

	particularly description of their physical and chemical state l) detailed description of the packaging type, including design documents, complete technical drawings, a list of materials and technological methods employed for its manufacture m) technological and manufacturing documents with detailed description of materials and technological procedures employed in manufacture of the closing (containment) system, description of sampling and types of tests to be performed, if the packaging has been designed for the maximum normal operating overpressure higher than 100 kPa n) G. documents about radiation protection or nuclear safety assurance (if the packaging has been designed for fissile materials) under normal conditions of transport and under accident conditions of transport o) a list and reasons of assumptions concerning characteristics of the irradiated fuel, as used in safety analyses to calculate subcriticality, if the packaging has been designed for irradiated nuclear fuel *p) a list of special requirements necessary to remove heat from packagings containing nuclear materials or radioactive substances producing heat, in respect to a specific transport mode and means of transport* q) reproducible drawing of the packaging on A4 format with the maximum size 21 cm x 30 cm r) for packagings of type B(M) only - a list of additional technical, operational and administrative measures established to assure nuclear safety and radiation protection, provided the packaging fails to meet the requirements specified in paragraphs 43, 59, 60 and 63 through 70 in Part I of Appendix No. 1 of the Regulation No. 317/2003 Coll. - data about all limitations in respect to the transport mode and about all special procedures during loading, shipment, unloading or handling, - the highest and lowest levels of the ambient conditions (temperature, sunshine) which are expected to be encountered during the shipment and which have been taken into account in the design .	
Denmark	No guidelines for application Documents for application: Requirements according to IAEA, and those applicable according to the modal requirements.	**A**
Estonia	*There are no packages, which need the approval, used in Estonia and the procedures have not been established.*	**E**
Finland	No supplementary requirements. Note: In Finland there are neither manufacturers of packages requiring certification nor facilities accredited for testing these packages and Finland has never been a country of origin for a new package certificate (and thus the following answers are very theoretical in	**B**

	nature). However, written guidelines for original certification exist. Documents for application: -Technical Data (drawings, material specifications, etc) -Safety analyses -Test documentation -Relevant parts of manufacturer's QA-documentation - (associated with the package fabrication)	
France	No guidelines for application Separate instructions are dispatched concerning: needed assessment times (see 6.2.4.7), needed copies of DSR (see 6.2.2.4), certificate format (see 6.2.3.10/6.2.3.11), justifications to be provided in the DSR (see 6.2.2.4)	**C**
Germany	Requirements are in compliance with ADR 6.4.23.4 to 6.4.23.7. Additional guidelines on extent and contents of application documents are given in R003 (Guideline for the procedure for design approval of packagings for the transport of radioactive materials, of special form materials and low dispersible materials) and TRV 006 (Technical guideline about measures for quality assurance and –supervision for packages for transport of radioactive material). With the application for an approval of a new package design, a documentation is required which contains at least the applicable information according to chapter 6.4.23.4 to 6.4.23.7.of ADR/RID. The evidences that all applicable requirements are met must be in form of a safety analysis report.	**B**
Greece	No response	**F**
Hungary	In addition to the corresponding implementations of the minimum requirements of TS-R-1 in the international modal transport regulations - according to the provision of the Decree No. 14/1997(IX. 3.) KHVM on the 'Transport and Packaging of Radioactive Materials' - HAEA is authorized to show compliance with dose rate limits for non-fissile materials (e. g. Californium-252) as well. Documents for application: - Design safety report - type of the required approval, including modes - design - contents - packaging and transport operations - compliance testing - quality assurance programme	**A**
Ireland	Package designs for the transport of radioactive material are not approved by our Institute. The RPII accept the certificates provided by other competent authorities.	**E**
Italy	No guidelines for application No additional requirements (beyond minimum requirements of	**A**

	ADR) for application	
Latvia	Regarding the application documents we included all provisions from IAEA Safety requirements (TS-R-1). Due to delays for incorporation of IAEA safety standards into ADR, there are certain differences, which basically should disappear after next updates of ADR. Documents for application: - the licence in the field of transportation of radioactive material - information about ionizing radiation sources - information about packaging - emergence sheet - information about tests taken - a specification of the quality assurance programme - any proposed pre-shipment actions for use in the consignment - the proposed operating and maintenance instructions for the use - of the packaging - the details of how the precautions and administrative or operational controls - the period of time, related to the shipment, the expected modes of transport, the type of conveyance, and the probable or proposed route	**A**
Lithuania	We do not have the national competent authorities approval certificates for package design, special form material and shipment of radioactive material, but we guide IAEA - TECDOC - 1302.	**E**
Luxem-bourg	*No certification procedure*	**E**
Malta	No guidelines for application. (ADR is not yet in force and currently shipments (imports only) need only basic information). At the moment only Form 46 OHSA is needed. This form asks information about the isotope, physical form, activity, sealed or unsealed etc, the responsible person etc. In addition to this a statement from the manufacturer that the source will be returned back to him at the end of its useful life is also mandatory. The only exports that Malta has are these returns to the manufacturers. The documentation is usually that of IATA which includes certificates of both the container and the isotope. Once the Radiation Protection Board is set up, this matter will be one of the priorities for review.	**A**
The Nether-lands	No guidelines for application No additional requirements (beyond minimum requirements of ADR) for application	**A**
Poland	There are no any supplementary requirements beyond minimum requirements of ADR 6.4.23. Only documents on the basis of ADR are required.	**A**
Portugal	No response	**F**
Romania	Guidelines for application: Standards for Transport of Radioactive	

	Materials - Authorization Procedures describes the content of the application and of the supporting documents. The application shall contain: applicant identification data, type of package and identification code, identity of the person that can engage legally the applicant and address, name of the person designated to represent the applicant in relation with CNCAN during the assessment period, mail address, identity of person that can be contacted for technical issues. The supporting documents are described at the chapter 6.2.2.1. In case of transport of nuclear fuel the technical documentation is replaced by the safety analysis report. Documents for application: - copies of the payment documents for authorization taxes and tariffs - technical documentation which have to include all information according to the provisions of the Norms for the Transport of Radioactive Materials - Authorization Procedures - copies of the other authorizations or approvals issued according to the legal requirements - copies of the documents which prove that the applicant is a legal person The technical documentation includes, as applicable: - detailed description of radioactive content, including physical and chemical form and nature of radiation, - maximum transport index, - maximum criticality safety index, - maximum decay heat and supplementary measures necessary for heat dissipation, - detailed description of the package, containing relevant drawings, list of materials and fabrication procedures sufficient to demonstrate the fulfilment of the applicable requirements of TS-R-1 (when the content of the package is fissile material, not exempted, the technical documentation shall take the form of a safety report, including the definition of possible accidents and assessment of their consequences), - test results (alternatively, the proof based on a theoretical simulation, that the package fulfils the applicable requirements), - operating and maintenance manuals, - for the case when the package is designed for an operation pressure above 100 kPa gauge, the specification of the materials for the fabrication of the containment system, the samples to be taken, and tests to be made, - if the content is irradiated fuel, the applicant shall state and justify any assumption in the safety report relating characteristics of fuel and describe any pre-shipment measurements required according to TS-R-1, - any special stowage provisions necessary to ensure the safe dissipation of heat, - a reproducible illustration not larger than 21*30 cm, - a specification of QA program for design and fabrication, - copy of type approval of the country of origin (for the case of validation of a certificate for type approval), - other documents that could be required in the authorization (validation) process.	**B**

Slovak Republic	No guidelines for application Documents to be sent with application are described in Regulation on transport of nuclear materials, radioactive wastes and spent nuclear fuel No. 284/1999 Coll.	**A**
Slovenia	We consider Act on Transport of Dangerous Goods and the requirements prescribed in ADR 6.4.23. Internal procedures consider the instructions written in ADR, RID, IMDG, ICAO-TI IAEA recommendations – Regulations (1996 Edition (Revised), TS-R-1).	**A**
Spain	No guidelines for application No additional requirements (beyond minimum requirements of ADR) for application	**A**
Sweden	No additional requirements (beyond minimum requirements of ADR 6.4.23) and guidelines. The complete SAR and such additional information prescribed by ADR (etc.), see e.g. ADR 6.4.23.3.	**A**
Turkey	No guidelines for application Since ADR includes the requirements of the IAEA regulations to apply to the transport, approval and administrative requirements laid down in TS-R-1 are required should such a practice occurs. The Turkish Atomic Energy Authority has a little experience with applications for approvals. However each shipment is subject to a permit. The IAEA issues this permit. The evaluation performed essentially on an administrative basis, (e. g. the relevance of transport documents, the validity of transport documents).	**E**
United Kingdom	We choose to use IAEA since applications are multi-modal in most cases, however the information requirement is the same. These are the REQUIREMENTS. We also produce ADVICE on applications: "Guide to an application for UK competent authority approval of radioactive material in transport (IAEA 1996 regulations)". Documents for application: IN SHORT: - Requirements as ADR/IAEA, guidance as applicants guide. - The application is the letter supported by: - Design safety report. Which includes: - Design specification (either as drawing or drawing list). - Any proprietary references - Any computer input/output files	**B**

6.2.2.1.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	**No guidelines** for application **No additional requirements** (complementary requirements to ADR) for application	**13**
B	**Guidelines** for application **No additional requirements** (complementary requirements to ADR) for application	**4**
C	**No guidelines** for application **Additional requirements** (complementary requirements to ADR) for application	**1**
D	**Guidelines** for application **Additional requirements** (complementary requirements to ADR) for application	**1**
E	No approval procedure	**6**
F	No response	**3**

6.2.2.1.3 SUMMARY AND DISCUSSION

Most of the European countries (14) have no guidelines for application and do not require additional information (categories A, B) other than those required in ADR paragraph 6.4.23.
Five countries have guidelines for application (category B, D) and two countries (category C,D) require additional documents for the application complementary to ADR.
Six countries have no experience in the approval procedure.

A very comprehensive guideline for application of all package designs, special form radioactive material, low dispersible radioactive material, shipment approval and special arrangement approval is the UK "Guide to an application for UK competent authority approval of radioactive material in transport (IAEA 1996 regulations)".

The complementary requirements to ADR 6.4.23 regarding application documents or proofs refer to

Czech Republic
1. *a method of product introduction on the market,*

France
1. *needed assessment times,*
2. *needed copies of DSR for emergency teams,*
3. *justifications to be provided in the DSR.*

A guideline for application should be prepared to assist applicants in submitting the necessary information in a convenient form. Such guidance is useful for the competent authority because it is easy to verify the completeness and the accuracy of submissions. This

guidance, which is not a substitute for the regulations, could be only an advice for the applicant to send the necessary documents in the recommended way. It should quote the relevant paragraphs of the IAEA-Regulation and explain how they are to transmit in documents and proofs resulted e. g. in a Design Safety Report of a special design type.
The applicants documentation regarding the proof of the compliance with the regulations of a package design type should be given in form of a Design Safety Report. This Design Safety Report should include the complete and up-to-date description of the packaging and its contents and not only the modification in comparison with the last approval certificate. A harmonized table of contents of the Design Safety Report should be defined.

If the country of origin is a non-ADR country, the full Design Safety Report must be appraised by the competent authority in conformity with the modal regulation.

The required additional documents or proofs in Czech Republic and France have more administrative character and are not relevant deviations.

6.2.2.1.4 CONCLUSIONS AND RECOMMENDATIONS

It is highly recommendable for each competent authority to provide comprehensive guidance material for application on the basis of the requirements of the IAEA-Regulations (IAEA TS-R-1, TS-G-1.1). An example for such a guideline is the UK "Guide to an application for UK competent authority approval of radioactive material in transport (IAEA 1996 regulations)". This guideline should include the following items:

- General package design approval application
- Preparation of a Design Safety Report for package design approval (see chapter 6.2.2.4)
- Minimum contents of a Design Safety Report (see Annex 5)
- The identification of specific safety issues that deserve justifications in the package design safety, referring e. g. to the French "feedback experience document" (see chapter 6.2.4.8)
- Additional information required for fissile material
- Special form radioactive material approval
- Low dispersible radioactive material approval
- Additional information required for uranium hexafluoride package approval
- Shipment approval
- Special arrangement approval
- Quality assurance
- Validation application
- Design modification procedure

The following recommendations can be given for the application documents:

- A harmonized guideline for Design Safety Report preparation should be defined.
- Competent authorities should provide a harmonized comprehensive guidance material for each type of application on the basis of the requirements of the IAEA-Regulations (TS-R-1, TS-G-1.1). An example of such guideline is the UK "Guide to an application for UK competent authority approval of radioactive material in transport (IAEA 1996 regulations)". This guideline should include the items given in Annex 3. The European commission should organize the development of an harmonized comprehensive guidance material and should provide it to the IAEA in view of worldwide harmonization, if possible.
- Required documents for application should be standardized and include:
  a) A complete Design Safety Report. The applicants should give one Design Safety Report for any application. The Design Safety Report is either one or several documents, but includes full definition of design and complete set of safety

analyses and has to demonstrate compliance of design with each applicable paragraph of transport regulations (see chapter 6.2.2.4).

b) The application letter indicating the need.
c) The documents required in para 6.4.23 of ADR

6.2.2.2 ITEM: APPLICATION REQUIREMENTS REFERRING TO ADR FOR MULTILATERAL APPROVAL/ VALIDATION

This item contains application requirements for approval of package design containing fissile material (ADR 6.4.23.7), multilateral approval B(M) (ADR 6.4.23.5), approval for transitional arrangement (ADR 1.6.6.1 and 1.6.6.2) and contents of required parts of the Design Safety Report.

6.2.2.2.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**E**
Belgium	No additional requirements In some cases of a multilateral approval/validation the CA requires a complete package Design Safety Report (safety analysis report) depend on the duration of use of the packaging: In the case of validation other than validation of package design containing fissile materials regularly used in Belgium, only the criticality is assessed For UF6 and for the transitional arrangements, an administrative validation is made because Belgium is only a country of transit.	**A**
Bulgaria	No practice	**D**
Cyprus	No answer regarding additional requirements. In case of a multilateral approval/validation the CA requires a complete package Design Safety Report (safety analysis report).	**A**
Czech Republic	Packagings containing fissile material There are some supplementary conditions in contents of a package design approval certificate beyond minimum requirements of ADR 6.4.23.7. These conditions concern reporting of the holder of design approval certificate, i. e. SONS requires sending of the certificate of conformity for the packaging and incident report in the case. Type B(M) packaging: There would be some supplementary conditions in contents of a package design approval certificate beyond minimum requirements of ADR 6.4.23.5. These conditions concern reporting of the holder of design approval certificate, i. e. SONS requires sending of the certificate of conformity for the packaging and incident report in the case. Package designs which are subjected to the transitional arrangements: There would be some supplementary conditions in contents of a package design approval certificate beyond minimum	**B**

	requirements of ADR. These conditions concern reporting of the holder of design approval certificate, i. e. SONS requires sending of the certificate of conformity for the packaging and incident report in the case. SONS would arrange 100% inspection of shipments of package designs which is subjected to the transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2. Legally in all package design mentioned above, there are not distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country. In case of a multilateral approval/validation the CA requires a complete package Design Safety Report (safety analysis report).	
Denmark	No additional requirements In case of a multilateral approval/validation the CA requires a complete package Design Safety Report (safety analysis report).	**A**
Estonia	No practice	**D**
Finland	No additional requirements In case of a multilateral approval/validation the CA requires a complete package Design Safety Report (safety analysis report).	**A**
France	No additional requirements In case of a multilateral approval/validation the CA requires and assesses a complete package Design Safety Report (safety analysis report).	**A**
Germany	Packagings containing fissile material: Requirements are in compliance with ADR 6.4.23.7. Type B(M): Requirements are in compliance with ADR 6.4.23.5. For spent fuel casks additional demonstration of compliance with limits for non-fixed contamination is required. Package designs which are subjected to the transitional arrangements: In principle Type B(M) together with a statement with which requirements of the regulations being valid at the time of application the package design does not conform. In case of a multilateral approval/validation the CA requires a complete package Design Safety Report (safety analysis report).	**A**
Greece	No response	**E**
Hungary	Packagings containing fissile material: In addition to the corresponding implementations of the minimum requirements of TS-R-1 in the international modal transport regulations - according to the provision of the Decree No.	**A**

	14/1997(IX. 3.) KHVM on the 'Transport and Packaging of Radioactive Materials' - HAEA is authorized to show compliance with dose rate limits for non-fissile materials (e. g. Californium-252) as well. Type B(M): No additional requirements Package designs which are subjected to the transitional arrangements: No additional requirements In case of a multilateral approval/validation the CA requires a complete package Design Safety Report (safety analysis report).	
Ireland	No practice	**D**
Italy	No additional requirements A complete Design Safety Report is not required in the case of validation. Only the quality assurance program, description for use and maintenance of the package and the criticality safety analysis in the case of fissile materials, or the aspects for which the package design is classified type B(M)	**C**
Latvia	No additional requirements In case of a multilateral approval/validation the CA does not require the complete package Design Safety Report (safety analysis report).	**C**
Lithuania	No practice	**D**
Luxem-bourg	No practice	**D**
Malta	No practice	**D**
The Nether-lands	No additional requirements In case of a multilateral approval/validation the CA does not require the complete package Design Safety Report (safety analysis report): only mechanical, thermal and criticality analysis are assessed. In the case of B(M) validation, only the part associated to B(M) and not B(U) and the mechanical and thermal analysis are assessed.	**C**
Poland	No additional requirements In case of a multilateral approval/validation the CA requires the complete package Design Safety Report (safety analysis report) only for packagings containing fissile radioactive material.	**A**
Portugal	No response	**E**
Romania	Packagings containing fissile material: For approval of a package for fissile material, the technical documentation shall have the form of a safety analysis.	**A**

	Type B(M): No additional requirements Package designs which are subjected to the transitional arrangements: No additional requirements; however, in fact, for packages for fissile material no multilateral approval will be issued by Romania if full compliance with requirements of TS-R-1 regarding assurance of subcriticality (i.e. art. 671-682). As consequence, no shipment of fissile material involving Romanian territory will be allowed if package does not comply with requirements of TR-S-1 regarding assurance of subcriticality. In case of a multilateral approval/validation the CA requires a complete package Design Safety Report (safety analysis report).	
Slovak Republic	No sufficient response	**E**
Slovenia	No additional requirements In case of a multilateral approval/validation the CA requires a complete package Design Safety Report (safety analysis report).	**A**
Spain	No additional requirements In case of a multilateral approval/validation the CA does not require the complete package Design Safety Report (safety analysis report). - Only a summary of the Design Safety Report is required for validation for fissile packages and packages under transitional arrangements.	**C**
Sweden	The procedure for the issuance of a Swedish design approval certificate do not differ significantly due to whether it is a fissile or a non fissile design approval, or whether it is a unilateral or a multilateral approval. No additional requirements beyond the requirements of ADR 6.4.23.5 exists for an application for a package design of type B(M). A Type B(U) or B(M) certificate (or any package approval certificate) is issued as prescribed in ADR 6.4.23.14. Evaluation is made according to the requirements in ADR 1.6.6.1 and 1.6.6.2. Normally the CA require a complete package Design Safety Report (safety analysis report).	**A**
Turkey	No practice	**E**
United Kingdom	No additional requirements In case of a multilateral approval/validation the CA does not require the complete package Design Safety Report (safety	**C**

	analysis report).	

6.2.2.2.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	**No additional requirements** complementary to ADR The **complete Design Safety Report** is required by the competent authority	**11**
B	**Additional requirements** complementary to ADR The **complete Design Safety Report** is required by the competent authority	**1**
C	**No additional requirements** complementary to ADR Only **parts of the Design Safety Report** are required by the competent authority	**5**
D	No practice	**6**
E	No response	**5**

6.2.2.2.3 SUMMARY AND DISCUSSION

Most of the European countries (16, categories A, C) have no additional application requirements regarding approval of package design containing fissile material (ADR 6.4.23.7), multilateral approval Type B(M) (ADR 6.4.23.5) and approval for transitional arrangement (ADR 1.6.6.1 and 1.6.6.2).
One country require additional complementary proofs (category B).
The competent authority of the Czech Republic (SONS) requires for packagings containing fissile material, Type B(M) packagings and transitional arrangement to send a certificate of conformity for the packaging and incident report in the case. Additionally SONS would arrange 100% inspection of shipments of package designs which is subjected to the transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2.

Twelve countries (categories A, B) require in case of multilateral approval/validation the whole Design Safety Report of a package. Five countries (category C) require only parts of the Design Safety Report.

Six countries have no application practice in this field and five countries didn't answer.

6.2.2.2.4 CONCLUSIONS AND RECOMMENDATIONS

All countries observe the ADR paragraphs regarding the application documents for the approval of package designs containing fissile material (ADR 6.4.23.7), multilateral approval Type B(M) (ADR 6.4.23.5) and approval for transitional arrangement (ADR 1.6.6.1 and 1.6.6.2). The additional requirements to the above mentioned paragraphs which exists only in one country seems to result from special national experiences and are not exceptionally. It is noticed that in this case a harmonized procedure exist.

Regarding the contents of the Design Safety Report or requested parts of it it is to recommend that the whole report should be available for the competent authority. In case of

incidents or accidents it is useful to have the whole report what gives the opportunity to do an assessment or analyses by the competent authority of a country itself.

- Required documents for application should be standardized in a guidance
- For validation of foreign approvals, the original approval certificates should be provided
- The complete Design Safety Report should be provided. The competent authority has the option of either performing a separate safety assessment or making use of the assessment already done by the original competent authority, thus limiting the scope and extent of their own assessment.

6.2.2.3 ITEM: APPLICATION REQUIREMENTS REFERRING TO ADR FOR SHIPMENT APPROVAL AND SHIPMENT UNDER SPECIAL ARRANGEMENT

6.2.2.3.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**C**
Belgium	All relevant information on the package to be used	**A**
Bulgaria	No practice	**B**
Cyprus	Euratom Regulation forms for shipments	**A**
Czech Republic	Shipment: The supplementary paragraphs represent approvals of the particular documents: - Emergency rules, - Classification of transported nuclear materials into relevant categories from the physical protection aspect - Physical protection arrangements during transport and approval of realization of the physical protection arrangements The supplementary conditions concern reporting of the holder of shipment approval certificate, e.g. SONS requires notification about term of the shipment 40 days in advance and incident report in the case. Special arrangement: The supplementary paragraphs represent approvals of the particular documents: - Emergency rules, - Classification of transported nuclear materials into relevant categories from the physical protection aspects - Physical protection arrangements during transport and approval of realization of the physical protection arrangements The supplementary conditions concern reporting of the holder of special arrangement approval certificate, i. e. SONS requires notification about time and date of the shipment 40 days in advance and incident report in the case.	**A**
Denmark	Shipment: -State Variation DK1 – ref. ICAO-TI -On board an INF ship there must be a transport specialist competent in health physics and supplied with appropriate radiation protection measurement equipment. Special arrangement: A complete design Safety Report has to be provided	**A**
Estonia	No practice	**B**

Finland	No additional requirements	**A**
France	No additional requirements	**A**
Germany	No additional requirements	**A**
Greece	No response	**C**
Hungary	In addition to the corresponding implementations of the minimum requirements of TS-R-1 in the international modal transport regulations - according to the provision of the Decree No. 14/1997(IX. 3.) KHVM on the 'Transport and Packaging of Radioactive Materials' - HAEA is authorized to show compliance with dose rate limits for non-fissile materials (e. g. Californium-252) as well.	**A**
Ireland	No practice	**B**
Italy	- The record of the last maintenance of the package - Radiological data and transport index	**A**
Latvia	No additional requirements	**A**
Lithuania	No practice	**B**
Luxem-bourg	No practice	**B**
Malta	No additional requirements	**A**
The Nether-lands	No additional requirements	**A**
Poland	No additional requirements	**A**
Portugal	No response	**C**
Romania	For shipment of fissile material and of sources with significant activity, there are requested: radiation protection program, emergency plan and physical protection plan and arrangements. The content of shipment application and of authorization are according to the requirements of ADR.	**A**
Slovak Republic	No sufficient response	**C**
Slovenia	No additional requirements	**A**
Spain	Shipment: - Shipment details (consignor, carrier, consignee, content, packages, conveyances, personnel, itinerary, schedule) - Operational and radiological protection procedures - Emergency plan - Liability insurance	**A**

	Special arrangement: - Shipment details (consignor, carrier, consignee, content, packages, conveyances, personnel, itinerary, schedule) - Operational and radiological protection procedures - Emergency plan - Liability insurance	
Sweden	Shipment: There are no special procedures and no requirements additional to ADR. Applications for shipment approval are extremely rare (SKI has received one the last ten years). Special arrangement: There are no special procedures and no requirements additional to ADR. An important part of the application is the reason why the shipment cannot be made in full accordance with all applicable requirements and a proposal for compensatory measures, which the applicant suggests to be used to compensate for the failure to meet the applicable requirements.	**A**
Turkey	No practice	**B**
United Kingdom	Shipment approval: We do not request routeing, but we examine emergency arrangements in more detail. Special arrangement: No additional requirements	**A**

6.2.2.3.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	No additional requirements referring to ADR, or small additions	**18**
B	No practice	**6**
D	No response	**4**

6.2.2.3.3 SUMMARY AND DISCUSSION

Most of the countries (18, category A) have no additional requirements referring to ADR for shipment approval (ADR 6.4.23.2) and special arrangement approval (ADR 6.4.23.3), or only small additions.
There are no essential additional requirements referring to ADR. In some cases additional requirements for transport exist due to the national legal system regarding nuclear safety and radiation protection. These aspects are to find under chapter 6.2.2.3.1.

Six countries have no practical experience with shipment approval and special arrangement.

6.2.2.3.4 CONCLUSIONS AND RECOMMENDATIONS

For shipment approval (ADR 6.4.23.2) and special arrangement approval (ADR 6.4.23.3) in all countries a harmonized procedure exists regarding the application and the requested documents. There are no essential additional requirements referring to ADR, but there are requirements resulting from national nuclear safety and radiation protection law overlapping the transport law. Nevertheless the approval practice of the countries participated in the study show that the following documents are reasonable additions to the required application documents according to ADR:

- Design safety report
- Emergency plan or the reference to the document describing the emergency procedure

6.2.2.4 ITEM: DESIGN SAFETY REPORT

This item contains the format and contents of the DSR, language of the DSR which is accepted by competent authority and its technical support and number of copies and guidelines for applicants used for the preparation of the DSR.

6.2.2.4.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**F**
Belgium	- No format for DSR - Safety analysis reports are accepted only in English, in Dutch and in French. - Only one copy of the Design Safety Report is required. - No guidelines for applicants used for the preparation of the DSR	**B**
Bulgaria	No practice	**E**
Cyprus	- No format for DSR - Safety analysis reports are accepted only in Greek and in English. - One hard copy and one electronic copy of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	**B**
Czech Republic	- Format for DSR: A. description of quality assurance system established in national regulation B. documents about the tests passed C. material specification of radioactive substances or nuclear materials for which the packaging has been designed, particularly description of their physical and chemical state D. detailed description of the packaging type, including design documents, complete technical drawings, a list of materials and technological methods employed for its manufacture E. technological and manufacturing documents with detailed description of materials and technological procedures employed in manufacture of the closing (containment) system, description of sampling and types of tests to be performed, if the packaging has been designed for the maximum normal operating overpressure higher than 100 kPa F. documents about radiation protection or criticality under normal conditions of transport and under accident conditions of transport G. a list and reasons of assumptions concerning characteristics of the irradiated fuel, as used in safety analyses to calculate subcriticality, if the packaging has been designed for irradiated nuclear fuel H. a list of special requirements necessary to remove heat from packagings containing nuclear materials or radioactive substances producing heat, in respect to a specific transport mode and means of transport	**C**

	I. reproducible drawing of the packaging on A4 format with the maximum size 21 cm x 30 cm J. for packagings of type B(M) only 1. a list of additional technical, operational and administrative measures established to assure nuclear safety and radiation protection, provided the packaging fails to meet the requirements specified in paragraphs 43, 59, 60 and 63 through 70 in Part I of Appendix No. 1 of the Regulation No. 317/2003 Coll. 2. data about all limitations in respect to the transport mode and about all special procedures during loading, shipment, unloading or handling, 3. the highest and lowest levels of the ambient conditions (temperature, sunshine) which are expected to be encountered during the shipment and which have been taken into account in the design - Safety analysis reports are accepted only in Czech, in English and in Russian. - Two hard copies and one electronic copy (if available) of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	
Denmark	- No format for DSR - Safety analysis reports are accepted only in Danish, in Swedish, in Norwegian, in English, (German), (French). - One hard copy of the Design Safety Report is required. - No guidelines for applicants used for the preparation of the DSR	**B**
Estonia	No practice	**E**
Finland	- No standard report is required, contents of each report is evaluated case by case. - Design Safety Reports are accepted in Finnish and Swedish and if specially agreed in English and in German. - Three hard copies of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	**A**
France	- No format for DSR - Safety analysis reports accepted in French and English - Two hard copies and four electronic copies of the safety analysis reports are requested to optimise the archiving constraints (two for the CA and two for the TS) including for use in emergency response. - No guidelines for applicants used for the preparation of the DSR	**A**
Germany	- No standardized format but the guideline R003 provide the information about the content of a SAR - Generally documents have to be submitted in German language, except, BfS and BAM renounce from translation partially or completely. Documents in English are also accepted if agreed. The following documents have to be sent in German: – package design approval certificate – the instruction for the use - Two hard copies of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	**A**
Greece	No response	**F**

Hungary	- The form of the required package Design Safety Report is not standardized, however, the content has to convince the competent authority that the package design fulfills the implementations of the minimum requirements of TS-R-1 in the international modal transport regulations. - Safety analysis reports are accepted only in Hungarian and English. - Three hard copies and one electronic copy of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	**A**
Ireland	No practice	**E**
Italy	- No format for DSR - Safety analysis reports accepted in Italian, French and English - Two hard copies of the safety analysis report aimed at justifying the package compliance to the regulation and 1 electronic copy are required. An archived copy is available to speed up the technical assessment necessary for emergency response to transport accidents involving radioactive materials - No guidelines for applicants used for the preparation of the DSR	**A**
Latvia	- We require a standardized report form. The general of the content are relating to the characteristics of the radioactive material; limits of radioactivity for accordant packaging; the requirements for each type package; the requirements for provision of marking, labelling and placarding as well as the transport documents; describe any pre-shipment measurement and requirements for using of package and for bulking during the transportation and storage. - Safety analysis reports are accepted in Latvian and for international shipments in English or another official UN language which is understood by all persons involved in the shipping of consignments. - Only one hard copy of the safety report is required, an electronic copy is recommended. - No guidelines for applicants used for the preparation of the DSR	**C**
Lithuania	No practice	**E**
Luxem-bourg	No practice	**E**
Malta	No practice	**E**
The Nether-lands	- No format for DSR - Safety analysis reports are accepted only in English, in Dutch and in French. - Only one copy of the safety report is required - No guidelines for applicants used for the preparation of the DSR	**B**
Poland	- No standard format, but the report should be contain • General package description (Packaging, Operational Features, Contents of Packaging, etc.). • Structural evaluation (Structural design, Mechanical	**B**

	properties of materials, Chemical reactions, etc.). • Normal conditions of transport (Test results according to ADR 6.4.15). • Hypothetical accident conditions of transport (according to ADR 6.4.17). Special form (if need). • Fuel rods (if need). • Thermal evaluation. • Containment (Requirements for normal conditions of transport, Requirements for hypothetical accident condition). • Shielding evaluation. • Criticality evaluation (if need). • Operating procedures (instructions concerning maintenance and routine shipping container utilization). - Safety analysis reports are accepted only in Polish, in English and in Russian. - One hard copy and one electronic copy of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	
Portugal	No response	**F**
Romania	- No format for DSR (However models of safety analysis reports for packages for fissile materials approved by US NRC and DOT are taken as references, and in any cases compliance with all requirements of TS-R-1 have to be demonstrated by the report.) - Safety analysis reports are accepted only in Romanian, in English, in Russian (exceptionally). - One hard copy of the Design Safety Report is required. - No guidelines for applicants used for the preparation of the DSR	**B**
Slovak Republic	- Standardized DSR is required according to Regulation on transport of nuclear materials, radioactive wastes and spent nuclear fuel No. 284/1999 Coll. - Safety analysis reports are accepted only in Slovak, in Czech, in English, (in German). - One hard copy and one electronic copy of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	**C**
Slovenia	- We require the standardized package Design Safety Report. It shall contain • general information • structural evaluation • thermal evaluation • containment • shielding evaluation • criticality evaluation • operating procedures • acceptance test • maintenance program. - Safety analysis reports are accepted only in Slovene and in English. - It is required distinguish hard and electronic copies.	**A**

	- No guidelines for applicants used for the preparation of the DSR	
Spain	- Guidance for applicants of the approval of a package or the validation of a certificate is being developed including the documentation necessary to be included in the application and the particular format of the Safety Analysis Report. - Safety analysis reports are accepted only in Spanish and English. - Two hard copies of the safety analysis report are required - No guidelines for applicants used for the preparation of the DSR	**D**
Sweden	- No standardized package Design Safety Report (safety analysis report) - Languages for the DSR: Swedish and English. - A number of copies is not stated, but three copies are preferred. Electronic copies are accepted, but at least one hard copy is desirable. - No guidelines for applicants used for the preparation of the DSR	**A**
Turkey	- No format for DSR - Safety analysis reports are accepted in English. - One hard copy and one electronic copy of the safety analysis report are required. - No guidelines for applicants used for the preparation of the DSR	**B**
United Kingdom	- We do not REQUIRE a standardized format for DSR, but supplying information in a standard format speeds applications and so we advise applicants to use a standard format. However we understand that because of external factors this may not always be possible, so we accept any format. On occasions a cross reference document has been provided by applicants to compare our preferred format to the package safety case. - We accept all languages, however technical translation into English may result in delays in assessment. We have had documents in French, German, Spanish and Japanese in the past. - One hard copy of the Design Safety Report is required and one electronic copy is desired. - No guidelines for applicants used for the preparation of the DSR	**C**

6.2.2.4.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	- No standardized format for DSR - Design Safety Reports also accepted in English. - More than one hard copy of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	**7**
B	- No standardized format for DSR - Design Safety Reports also accepted in English. - Only one hard copy of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	**7**
C	- Standardized format for DSR - Design Safety Reports also accepted in English. - Only one hard copy of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	**4**
D	- Standardized format for DSR - Design Safety Reports also accepted in English. - More than one hard copy of the Design Safety Report are required. - No guidelines for applicants used for the preparation of the DSR	**1**
E	No practice	**6**
F	No response	**3**

6.2.2.4.3 SUMMARY AND DISCUSSION

Most of the countries (14, categories A, B) have no standardized format for the Design Safety Report (DSR). Five countries (Czech Republic, Latvia, Slovak Republic, Spain, UK – categories C, D) require or recommend a standardized DSR format.
All countries accept the DSR in English language, and many in languages which are closely related to the native language.
Eight countries require more than one hard copy of the DSR for application, for eleven countries only one hard copy is enough.
For the preparation of the DSR there are no special guidelines for the applicants in all countries.
Six countries couldn't answer because of no practical experience.

A standardized format for the Design Safety Report could be helpful for the competent authority and the applicant because the general practice for issuing and assessment is so familiar for both and can advance the application. However, most important is a guideline for the preparation including the definition of the detailed content of the DSR.
Because of the English version of IAEA-Regulations and the general spread of the language most of the expressions in English language regarding the transport of radioactive materials are known by the majority of staff or translators and so a Design Safety Report in English should be acceptable. In dedicated cases, where the competent authority has not enough English speaking staff resources or due to legal restrictions, it may be necessary to provide the DSR or parts of it in the countries language.

6.2.2.4.4 CONCLUSIONS AND RECOMMENDATIONS

- A harmonized guideline for DSR preparation including definition of the proposed contents should be issued (see also chapter 6.2.2.1 and 6.2.4.1).
- A harmonized guideline for the DSR preparation should be prepared.. Each DSR should contain:
    - A full definition of the design (packaging and contents),
    - A summary,
    - A list about the demonstration of compliance of the package design with each applicable paragraph of transport regulations
    - A complete set of safety analyses.

  The European Commission should organize the development of this harmonized guideline and should provide it to the IAEA in view of worldwide harmonization, if possible.
- When the Design Safety Report is not written in the official language(s) of the country of the application, an English written Design Safety Report should be accepted. In dedicated cases, where the competent authority has not enough English speaking staff resources or for the instructions for the use of the package, it may be necessary to provide the DSR or parts of it in the country language.
- The applicants should systematically provide additional to the hard copy an electronic copy of the Design Safety Report.

The DSR should consider the chapters given in Annex 5.

6.2.3 APPROVAL PROCEDURE

6.2.3.1 ITEM: PROCEDURE AND GUIDELINES FOR COMPETENT AUTHORITY AND TECHNICAL SUPPORT

This item contains internal procedure and guidelines used for certification, translation in national requirements of the conclusion of international meetings, checking of the approval certificate by the applicant and approval process time for different certificate types.

6.2.3.1.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**G**
Belgium	- Quality management according to ISO 9001 - Internal procedures for package approval are under preparation - No guidelines for applicants - The conclusions of international meetings are taken into account by writing reports which are distributed to the persons involved in the approval process. - The certificate is not sent to applicant for checking - The time to deliver a certificate is in average: from 6 to 24 months for a new approval, Type B(M), IF (from 4 to 6 weeks for a validation), from 6 to 9 months for special form radioactive material approval, from 4 to 6 weeks for shipment and from 6 weeks to 4 months for a special arrangement	**A/C/E**
Bulgaria	- No internal procedures for approval procedure - The time to deliver a certificate is one month	**B**
Cyprus	- No internal procedures for approval procedure - The applicant doesn't check the final version of the approval certificate	**B**
Czech Republic	- Internal procedure: There is the Procedure VDS 047 "Issuing of the approvals and other decisions", Ref. No.6107/2001. Identification No.: SP047000.doc, Date of validity: 1. 6. 2001 - The applicant doesn't check the final version of the approval certificate - The time to deliver a new approval certificate is in average 2- 3 month for all package designs excluded Low dispersible radioactive material – there is no experience. - The time to deliver a multilateral approval certificate/validation is in average 2- 3 month for all package designs excluded Low dispersible radioactive material – there is no experience.	**A/E**
Denmark	- No internal procedures for approval procedure - IAEA, ADR, RID, IMDG-Code, ICAO-TI are implemented. RTSG can be regarded as advisory. - There is a paragraph in the order on transport of radioactive material which stipulates that breaching of the requirements in the order is subject to fine.	**B/C/E**

	- The applicant doesn't check the final version of the approval certificate - The time to deliver approval certificate for all package designs, special form radioactive material, Low dispersible radioactive material, Shipment and Special arrangement is generally 1 month.	
Estonia	No practice	**F**
Finland	- Internal procedure: STUK's QA Manual: YTV-Guide 5.2 "Regulation of Transport of Nuclear and other Radioactive Material" , STUK's Guide YVL 6.4 " Packages and Packagings of Radioactive Material". - The applicant doesn't check the final version of the approval certificate - For a new approval certificate for shipment and special arrangement, 3 months are needed, for the other package designs there are no experience, but the estimated time is 6 months. The time to deliver a validation is no more than 3 months for all package designs, shipment and special arrangement excluded Low dispersible radioactive material – there is no experience.	**A/E**
France	- Internal procedures for certification - No exhaustive guideline for applicants but feedback experience document is considered as a guideline. - Additional requirements are imposed by letters from competent authorities sent to applicants. National decrees written by the competent authority. No systematic procedure dealing with applications of the conclusions of international meetings - A draft of the certificate is sent to the applicant for checking. - The time to deliver a certificate is at least: 12 months for a new approval, 6 months for renewal, shipment and validation, 4 months for extension and two months for the other cases.	**A/C/D**
Germany	- There are internal guidelines, checklists and sample reports for various approval types as part of a QA program - Meetings at IAEA or within RTSG are used to discuss problems/ questions arising during the application of TS-R-1 provisions or TS-G-1.1 guidelines in the approval procedure and to find a common approach or solution which is then applied in the assessment process. The Competent Authority is able to enforce the compliance with these arrangements a) through specific requests to the applicant b) through specific provisions in the approval certificate c) through proposals to IAEA to amend or improve Regulations or Advisory Material. - The certificate is sent to applicant for checking. - The time to deliver a certificate is for Type B(U)/ B(U)F, Type B(M)/ B(M)F, Type IF/AF from some months to some years for new approval and multilateral approval/validation. For shipment approval and special arrangement the time to deliver a certificate is from some weeks to some months.	**A/C/D**
Greece	No response	**G**

Hungary	- Both the HAEA (CA) and the IISC (TS) have ISO 9001 certificate. As one of the consequences the administrative part of the approval process has written internal procedure. - The ADR and the other international mode specific agreements provide the legal framework. - The IAEA regulations and advisory materials and the informal discussions in the RTSG serve as a background. - The compliance assurance is primarily based on regular inspections performed by the HAEA - The certificate is sent to applicant for checking. -The time to deliver a certificate is for Type B(U)/ B(U)F, Type B(M)/ B(M)F for a new approval from 6 to 7 month. A time of 2 to 3 months is needed for certificates for Type IF, Special form radioactive material, shipment and special arrangement for a new approval and also multilateral approval/validation for Type B(U)/ B(U)F, Type B(M)/ B(M)F, Type IF and Special form radioactive material.	**A/C/D**
Ireland	No practice	**F**
Italy	- No internal procedures for the assessment of the package Design Safety Report, the preparation of the assessment report and the certificate. - A guideline for applicants summarizing the documentation that the applicants shall provide to the competent authority in their application. The conclusions of international meetings are taken into account by writing reports that are distributed to the persons involved in the approval process. - Additional requirements are imposed by letters to competent authorities sent to applicants. - The certificate signed by the competent authority is not sent to applicant for checking - The time to deliver a certificate is in average: from 12 to 18 months for a new approval of Type B (in the other case, it is 2 months / 6 months), 3 months for shipment and 6 months for a special arrangement.	**B/C/E**
Latvia	- The action of Radiation Safety Centre is given in the Regulation of Cabinet of Ministers on Protection against Ionising Radiation transporting Radioactive Materials (03.07.2001). There are also certain procedures prescribed by the Licensing regulations, which could be used for this purpose as guidance. RDC is in early stages to prepare internal QA program. - By the Law, the Authority is authorised for cooperation activities with international organization etc. in this field, accordingly, experts and/or information, other assistance from the IAEA, ADR could be requested and used by Radiation Safety Centre and used for the assessment. - The Competent Authority is able to enforce the compliance with the arrangements between the Competent Authority with IAEA, ADR and RTSG through regulations and license conditions. - The certificate is sent to applicant for checking. - The time to deliver a certificate is for Type B(U)/ B(U)F, Type B(M)/ B(M)F, Type C and Type H(U)/ H(U)F for a new approval less than 40 days, but could be extended if additional investigations and/or assessments needed. The time for deliver a	**B/C/D**

	certificate for Type IF, Special form radioactive material, Low dispersible radioactive material, shipment and special arrangement is less than 20 days, but could be extended if additional investigations needed. For all multilateral approval/validation the time is less than 20 days, but could be extended if additional investigations needed.	
Lithuania	No practice The time to deliver a certificate is for Type B(U)/ B(U)F, Type B(M)/ B(M)F as multilateral approval/validation is 30 days.	**F**
Luxem-bourg	*No certification*	**F**
Malta	No practice For shipment approval 2 days are needed.	**F**
The Nether-lands	- No guidelines for applicants - No internal procedures for assessment and certification - No taking into account of the conclusions of international meetings. Only the modal regulations and IAEA requirements are considered. - The certificate is not sent to applicant for checking - The time to deliver a certificate is in average: from 12 to 24 months for approval (and 1 month for a validation), from 6 to 12 months for a special form radioactive material approval, 2 months for shipment and 2 to 6 months for special arrangement.	**B/E**
Poland	- There are no written any internal procedures or instructions. - So far we do not cooperate with IAEA, ADR and RTSG in the assessment process. - The certificate is sent to applicant for checking. - The time to deliver a certificate is for Type B(U)/ B(U)F, Type IF, special form radioactive material, shipment and special arrangement for a multilateral approval from 1 to 2 months.	**A/D**
Portugal	No response	**G**
Romania	- No specific standard working instructions- the assessment is done on a case by case approach, as most of applications refer to validation of foreign certificates; the assessment follows the fulfilment of the requirements of Romanian regulations, i.e. of IAEA requirements with the supplementary requirements mentioned before. For completion of approval certificate: Order no. 378/2001 of the President of CNCAN regarding the models for authorization forms (i.e. of authorisations) and models for inspection reports. - The requirements of IAEA regulations are transposed in national regulations, that are in some aspects more stringent (regarding approval requirements). - The Competent Authority is able to enforce the compliance with the arrangements between the Competent Authority with IAEA, ADR and RTSG through authorization and inspection system. - The certificate is not sent to applicant for checking - The time to deliver a certificate is for Type B(U)/ B(U)F, Type B(M)/ B(M)F, Type IF for a new approval 2 to 3 months, for shipment and special arrangement 1 to 2 months. For multilateral	**B/C/E**

	approval/validation of the mentioned Types 1 to 2 months are needed.	
Slovak Republic	- NRA (CA) has an internal QA system, which we follow. - The time for deliver a certificate for Type B(U)/ B(U)F, Type B(M)/ B(M)F, Type C as new approval or multilateral approval validation depends on the case.	**A**
Slovenia	- Internal procedures are available. The international procedures consider the instructions written in ADR, RID, IMDG, ICAO-TI, IAEA recommendations – Regulations (1996 Edition (Revised), TS-R-1). - Arrangements between the competent authority with IAEA, ADR, RTSG are introduced in the assessment process through application of legal binding instruments (ADR, etc.). - The Competent Authority is able to enforce the compliance with the arrangements between the Competent Authority with IAEA, ADR and RTSG through issuing the appropriate legislation and inspections. - The certificate is not sent to applicant for checking. - 2 months to deliver the approval certificate to the applicants.	**A/C/E**
Spain	- Internal procedures for the evaluation for the approval and validation of transport packages. These internal procedures include the quality assurance program. - Guidance for applicants of the approval of a package or the validation of a certificate is being developed including the documentation necessary to be included in the application and the particular format of the DSR - National decrees written by the competent authority - The assessment procedure is rewritten to take into account the conclusions of international meetings estimated influencing the certification process. - The applicants check the final version of the approval certificate. -The time to deliver a certificate is in average: 18 months for a new approval (and 6 months for validation), 12 months for a type IF package (4 months for validation of this package), 2 months for shipment and 3 months for special arrangement.	**A/C/D**
Sweden	- There are written internal procedures only on a very high level, not specific for applications relative to dangerous goods. - Sometimes for complicated certificates the applicant checks the final version of the approval certificate. In addition possible uncertainties are discussed with the applicant. - Time to deliver an approval certificate varies very much depending on the complexity of the case. We have no statistical follow-up of the time needed. There are only a handful of Swedish package designs and we seldom receive an application for approval of a new package design. There are years between such applications. Multilateral approvals of foreign package designs are in Sweden usually issued by validation of the original certificate. The handling time varies for a validation from a few weeks when the design is already known in Sweden, up to several years for a new package design where Sweden is the country of origin of design.	**B/D**

Turkey	- There are no internal procedures. - No practice	**B/F**
United Kingdom	- There are written internal procedures. These are split in to different technical areas (one for mechanical engineers, one for QA, and one for criticality). There are also standard templates for the completion of certificates. - Our requirements are set out in our applicants guide, including any necessary guidance on regulatory issues (e.g. from RTSG). - The Competent Authority is able to enforce the compliance with the arrangements between the Competent Authority with IAEA, ADR and RTSG by various methods. For example on section carries out peer reviews of work. Another way is that all technical specialists take part in a meeting once a month to discuss work and ensure a common technical standard exists. - The certificate is not sent to applicant for checking, but this option is available on request. - For a new approval certificate of Type B(U)/ B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/ H(U)F and special arrangement 6 months are needed, for a new approval certificate of special form radioactive material 3 months and 1 week for shipment. The time for deliver a multilateral approval/validation certificate of Type B(U)/ B(U)F, Type B(M)/ B(M)F, Type C, Type IF, Type H(U)/ H(U)F and special arrangement is 3 months, for shipment certificate 1 week.	**A/C/E**

6.2.3.1.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	Internal procedures for approval procedure	**11**
B	No internal procedures for approval procedure	**9**
C	Consideration and enforcement of arrangements between competent authority and IAEA, UN and RTSG in the assessment procedure	**11**
D	Applicant checks the final version of approval certificate	**7**
E	No checking of the final version of approval certificate by the applicant	**9**
F	No practice	**6**
G	No response	**4**

6.2.3.1.3 SUMMARY AND DISCUSSION

Eleven countries (category A) have written internal procedures for the approval process but nine countries (category B) have no procedures.

Eleven of 24 countries having answered (Category C) consider and enforce in the assessment process of the package design arrangements between the competent authority and the IAEA, UN and RTSG.

In seven countries (Category D - France, Germany, Hungary, Latvia, Poland, Spain, Sweden) the applicant gets the possibility to check the final version of the approval certificate. In nine countries (Category E), the applicants do not check the approval certificate.

Six countries (Category F – Estonia, Ireland, Lithuania, Luxembourg, Malta, Turkey) have no practical experience regarding approval procedure.

The necessity for preparing a guideline for applicants is discussed in 6.2.2.1.

To obtain a quality assessment and in conformity with a quality assurance program, internal procedures or guidelines for certification process should be prepared. These guideline or/and procedures should comply with the ISO 9001:2000 or an equivalent standard. The purpose of this guideline or/and procedure is to define the approval provisions from reception of the application for approval certificate until archiving of the issued approval certificate. This guideline or procedures should indicate:

- The administrative procedure
- Checklist of the content of the application
- if the preliminary review of the Design Safety Report is necessary,
- which parts of the Design Safety Report must be provided and assessed,
- minimum information in a Design Safety Report (see chapter 6.2.2.4)
- the practices (including the process to index the certificate) in the case of
    - o Assessment of test program
    - o Certificate renewal without change of package design

    - Package design modification procedure for unilateral approval
    - Approval procedure for an unilateral approval
    - Validation of a multilateral approval B(M), an approval of package design containing fissile material, an approval for transitional arrangements, a shipment approval, a special arrangement
- calls upon external experts for assessment
- exchanges with applicants
- exchanges with other competent authorities or/and its technical supports for assessment of the same Design Safety Report
- accepted calculations in the Design Safety Report
- checking methods of applicants demonstrations (demonstration of compliance of package design with each applicable paragraph of transport regulations)
- structure and contents of the approval certificate
- time schedule for assessment and certification, depending on milestones (like applicant responses to open questions)
- validity time of certificates
- quality assurance for the package design

To improve the safety or to organize the certification work, the competent authority has the option to demand additional requirements others than those required by modal regulations. These requests should be required by official letter and sent to concerned applicants. For that, a current list of applicants concerned by the transports of radioactive materials should be maintained. These official letters written by the competent authorities could include the conclusions of international or national meetings.

If the competent authorities have to issue approval certificates, a draft of the certificate should be sent to the applicant for checking in order to avoid errors and cancellations of certificates.

The typical approval process time of the answered EU- and applicant countries for the different package design types or transport approvals is as follows:

Typical approval process time (after complete DSR transmittal)	***New approval***	***Validation in a second country***
Type B(U)/ B(U)F	12 months	6 months
Type B(M)/ B(M)F	12 months	6 months
Type C	no sufficient experience	no sufficient experience
Type IF	6 months	6 months
Type H(U)/H(M)	12 months	12 months
Special form radioactive material	12 months	6 months
Low dispersible radioactive material	no sufficient experience	no sufficient experience
Shipment	2 months	2 months
Special arrangement	6 months	4 months

The approval process time varies for different countries and different types of certificate. This time must include the assessment time (with the pre-review, review of the Design Safety Report and the writing of an assessment report) and the time of checking of the certificate by the applicants. To dissuade applicants from sending their application too late, a minimum process time, after complete Design Safety Report transmittal (what requires e. g. the finalization of all tests in case of a new design), should be defined. This minimum time is required by the CA or the TS for a competent assessment and decision. In the preceding table, typical values for approval process times are rough estimates of time generally necessary to assess the safety documents provided with the application and then to issue the certificate. These times may be much underestimated in case of difficulties encountered in the assessment in particular when additional justifications are requested. Times needed by the applicant for revision of their documents have to be added.

Note that ADR or RID paragraph 6.4.22.6 requires that the compliance of the package design to all technical requirements of ADR and RID is certified or countersigned by the first country Contracting Party to ADR or RID reached by the consignment. This implies that a new approval certificate should be issued by the first country contracting party to ADR or RID. According to the extent of the assessment decided by the competent authority, the assessment time may correspond to either one or the other column of the preceding table.

6.2.3.1.4 CONCLUSIONS AND RECOMMENDATIONS

- A general harmonized guideline for the approval procedure or procedures for the competent authority and the technical support should be defined. The European commission should organize the development of this harmonized guideline and should provide it to the IAEA in view of worldwide harmonization, if possible.

- This guideline or/and procedures should comply with the ISO 9001:2000 or an equivalent standard.

- The contents of these guidelines should be defined.

- The first country contracting party to ADR or RID which is reached by a consignment from a country non-ADR or RID contracting party, should issue the required approval certificate.

- A current list of applicants concerned by the transports of radioactive materials should be maintained.

- For additional instructions, circular letters or appropriate documents should be issued to applicants (instructions of the competent authority can include conclusions of international or national meetings).

- A draft of the certificate should be sent to the applicant for checking.

- Minimum approval process time should be defined after the complete design safety documentation transmittal (this time can be prolonged in case of difficulties encountered in the assessment of the safety design package)

- The applicants should transmit the complete set of safety documentation to the competent authority with due consideration of the following minimum times to allow the correct assessment of these application documents by the competent authority. Times the applicant needs for revision of documents have to be added.

	New design	Renewal	Extension	Special arrangement	Shipment approval	Validation
Minimum approval process time recommended after the complete DSR transmittal (months)	12	6	4	6	2	6

- The information on minimum approval process time should be provided to applicants so that they apply for license in due time.

- Standard formats and contents for the assessment report and for certificate should be defined (see respectively the chapters 6.2.4.6 and 6.2.3.10).

6.2.3.2 ITEM: PACKAGE DESIGN MODIFICATION PROCEDURE FOR UNILATERAL APPROVAL

This item contains the description of the procedure of certification relative to the modifications on the package design or on handling and maintenance procedures.

6.2.3.2.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**E**
Belgium	- Each modification that impacts the safety is subject to a new assessment and to a new revision of approval certificate. - There are no special procedures for minor changes; they are treated on a case-by-case basis. - All changes of the package design and procedures for handling and maintenance of the package are subject to competent authority assessment/approval.	**A/B**
Bulgaria	No practice	**D**
Cyprus	- All changes of the package design and procedures for handling and maintenance of the package are subject to competent authority assessment/approval.	**B**
Czech Republic	- The packaging changed in design having nuclear safety or radiation protection significance or the change of the radiation contents of the packaging is considered to be a new package and such package is subjected to new competent authority assessment and approval. The approval is usually issued as a revision of the original approval. The modifications of procedures for handling and maintenance of the package (if are not a part of design approval) may be made by the change of the conditions of relevant approval (for example Approval of Limits and Conditions for Safe Operation of Spent Fuel Interim Storage). - Subject of competent authority approval are only changes of the package design and procedures for handling and maintenance having nuclear safety or radiation protection significance. SONS is in charge to decide if such changes have nuclear safety or radiation protection significance or not.	**A/C**
Denmark	- Revision of validation will be issued by NIRH - Only validations are made. If the applicant wants a change to be approved this will be a new case.	**D**
Estonia	No practice	**D**
Finland	- The significance of the modifications will be assessed by STUK. Slight modifications may be approved within the scope of the existing certificate. In case of significant modifications, the certificate shall be revised. - All changes of the package design and procedures for handling and maintenance of the package are subject to competent authority assessment/approval.	**A/C**

France	- Design changes can be classified under two different types: - Changes not planned in the early stage of design (for example, deviation during manufacture or change of material characteristics after difficulties with material supplies). In general such changes are not affecting the safety and shall be documented according to quality assurance provisions. The competent authority may subsequently inspect the quality assurance program and the related documentation. In the case where the change is not compatible with the approval certificate, an extension of the certificate will be issued. - Volunteer changes (to improve design, for example). The competent authority considers two definitions: - A minor change is the situation where applicant may be able to demonstrate that the design change will not affect the safety, by using the same demonstration process and by providing the same order of magnitude for safety margin than in the original safety analysis report. For minor changes, it is expected that the applicant informs systematically the competent authority of his country and accordingly, gives the demonstration that the safety is not altered. The foreign competent authority should be informed. In the case where the minor change is not compatible with the approval certificate, an extension of the certificate will be issued. - Major changes include all other situations: in this case, a new certificate will be issued. If the minor change is not compatible with the approval certificate, an extension of the certificate is to be issued.	**A/B**
Germany	- Changes of the contents of an approved package design and any other change with effect on the safety analysis report lead to a revision of the approval certificate. With the application the applicant has to provide all necessary documents to show that the requirements of the regulations are met. The documents must cover all required information according to application for an approval of a new package design which contains at least the applicable information according to chapter 6.4.23.4 to 6.4.23.7 of ADR/RID due to the change. For other changes other procedures are implemented with no need to change the approval certificate the following procedures are applicable: - BfS decided to introduce a “design type list” into the design approval certificate which includes the actual and all previous (if needed) revisions of the main parts list. A benefit of the introduction of the design type list was that changes and improvements that are non-safety relevant or where the safety is equivalent to the examined one as laid down in the Safety Analysis Report can be handled in an easy way. Because of signing the design type list separately it can be replaced without making a revision of the whole certificate. - In some cases the change of a drawing or a sub parts list can lead also to many changes in other related drawings and parts list, which would result in a very intensive work to create a new design type list. In addition to that it is not possible to change the parts list of manufactured casks if design	**A/B**

	improvements are desirable. Another procedure to handle changes and improvements was therefore developed in such a way that the applicant provides a “certificate of modification” with a detailed description of the change itself and the justification why it is non-safety relevant. - Both the revised parts list as well as the certificate of modification will be examined by BAM as the competent authority for the evaluation of mechanical, thermal and leaktightness properties as well as for the quality assurance programmes of a cask and by BfS for the evaluation of sufficient shielding and sub-criticality. If the evaluation has a positive result either – an extended design type list will be issued by BfS and becomes part of the approval certificate if a revision of the parts list had been made, or – an agreement will be given by BfS if the applicant applies for the accepting of a certificate of modification. Both the agreement and the certificate of modification becomes part of the cask documentation. If some more casks shall be built all modifications have to be included into the constructional documentation when the applicant will apply for the next revision of the certificate approval. - In the case that an approved instruction which is part of the approval certificate has to be modified due to practical experiences either a statement is included in the main instruction or an additional provision is included in the approval certificate how to handle these cases without the need of hanging the approval certificate. At least the clearance by BAM, for instructions concerning e.g. the testing of contamination or shielding in cooperation with BfS, is required sometimes in addition an endorsement by BfS is needed. - Since the implementation of these procedures it can be stated that on the one hand the descriptions/provisions are detailed enough to comply with the applicable requirements of the Regulations and on the other hand they provide a certain degree of flexibility to cover practical needs. - All changes of the package design and procedures for handling and maintenance of the package are subject to competent authority assessment/approval.	
Greece	No response	**E**
Hungary	- Safety related modifications require an approval procedure (results in a new revision). At the same time, however, earlier compliance testing results can be presented if they are applicable. As an example, some years ago the specification of the radioactive content of a B(U) type package design was extended. In addition to the max. 185 TBq special form Ir192 and max. 185 GBq special form Co60, transport of max. 185 GBq special form Cs137 was approved as well. - All the safety related modification are subject to competent authority approval.	**A/C**
Ireland	No practice	**D**

Italy	- A revision of the approval certificate is reissued in the case of modifications in the package design after checking the safety but without distinction between changes impacting the safety or not. - All changes of the package design and procedures for handling and maintenance of the package are subject to competent authority assessment/approval.	**A/B**
Latvia	- For example, we had some cases when the radiation level is the higher than needed for appropriate package or the package hasn't accordingly fixed in load. But such change don't incorporate in approval certificate, therefore particular cases had been solved by use of special arrangements. In general, should be used procedures set up by Regulations - If a producer, supplier of the source of ionising radiation or other operator who performs operations with the relevant source learns that the source of ionising radiation or operations therewith may be dangerous to human life, health, personal property or the environment it shall without delay: • directly or through the mediation of the Centre inform other operators who perform activities with sources of ionising radiation of the relevant type of the unsafe source of ionising radiation or operations therewith, as well as other deficiencies of the source of ionising radiation; • perform intervention activities – rectify the relevant deficiencies; • take measures to withdraw the unsafe source of ionising radiation from circulation. Then information about relevant modifications should be included into description of package and safety file for transportation. - All the safety related modification are subject to competent authority approval.	**A/C**
Lithuania	No practice	**D**
Luxem-bourg	No practice	**D**
Malta	No practice	**D**
The Nether-lands	- In case of accepted modifications of the package or procedures it will be written in the certificate with reference to the appropriate documents. - As far as relevant for the safety: Yes. Furthermore the changes have to be within the issued certificate. In case changes are conflicting with the specifications of the certificate or the underlying documents contact and/or approval of the competent authority is necessary.	**A/C**
Poland	- We have no appropriate procedures and practices. - All the safety related modification are subject to competent authority approval.	**C**
Portugal	No response	**E**
Romania	- Any modification of a package design requires a new	

	authorization. - All changes of the package design and procedures for handling and maintenance are subject to competent authority assessment/approval.	**A/B**
Slovak Republic	No response	**E**
Slovenia	- Procedures for package design modifications (packaging and contents) including modifications to procedures for handling and maintenance of the package are issued according to the procedures written in ADR, RID, IMGD, ICAO-TI, IAEA recommendations – Regulations No. TS-R-1 (ST-1, Revised). - Yes, all changes of the package design and procedures for handling and maintenance of the package are subjected to competent authority assessment/approval.	**A/B**
Spain	- The general procedure for modifications in nuclear facilities is used: all modifications of the design, operating conditions affecting the nuclear safety or radiological protection and the performance of tests, should previously be analyzed by the designer in order to check for continued compliance with the criteria, standards and conditions on which the authorization is based. When the analysis concludes that the requirements listed above continue to be guaranteed, the modification or test may be carried out. A periodic report (annual generally) about those modifications has to be sent to the competent authority and to the TS. An authorization for the modification is requested when the design modification supposes a modification of the criteria, standards and conditions on which the operating permit was based. Each modification even if it does not affect the safety should be subjected to the competent authority who decides if the modification affects or not the safety and if it is necessary to reissue a certificate.	**A/B**
Sweden	- Changes that affects the content of the SAR require a revised approval certificate. - Changes of the package design require competent authority approval, but there may be changed procedures that do not affect the SAR and thereby not require competent authority approval.	**A/C**
Turkey	No practice	**D**
United Kingdom	- All approvals follow the same process. Each application is dealt with by one person from each of the three areas (except for some specified special forms where criticality review is not required). The procedure undertaken varies according to the type of modification, the applicants guide deals with modifications during the life of a certificate in Part X, and sets out the criteria which determine how modifications are included in a certificate. Should a new certificate be required a new issue number is given to the certificate. - All changes of the package design and procedures for handling and maintenance of the package are subject to	**A/B**

	competent authority assessment/approval (either directly or indirectly) however minor changes (concessions) made to an approved procedure need not be notified immediately (e.g. changing the name of suppliers of consumable goods).	

6.2.3.2.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	All changes of content or modification that impacts the safety of a package design is subject to a new revision of the approval certificate	**14**
B	**All changes** of the package design and procedures for handling and maintenance of the package **are subject to competent authority assessment/approval**	**9**
C	**All changes** of the package design and procedures for handling and maintenance of the package **that impacts the safety** of a package design **are subject to competent authority assessment/approval**	**7**
D	No practice	**8**
E	No response	**4**

6.2.3.2.3 SUMMARY AND DISCUSSION

All countries (categories A) which have practice relative to package design modification for an unilateral approval of package design safety reissue a new revision of the approval certificate in the case of relevant modifications.

Furthermore in all countries (categories A, B) all changes of the package design and procedures for handling and maintenance that impacts the safety are subject to competent authority assessment/ approval.
Seven countries (category C) focus regarding assessment/approval of changes of the package design and procedures for handling and maintenance of the package only on changes which impact the safety of a package design.

Eight countries (category D) have no practice or procedure concerning package design modification.

There are different ways to classify design changes/modifications and to assign them in the approval certificate. But changes of content or modification that impact the safety of a package design should be subject to a new revision of the approval certificate by all competent authorities.

6.2.3.2.4 CONCLUSIONS AND RECOMMENDATIONS

- Package design modification that impacts the safety of package design is subject to a revision of the design certificate. There is a harmonized procedure in all countries with experience.

- All changes to the package design and procedures for handling and maintenance of the package are subject to competent authority assessment/ approval according to the procedure described in following paragraph to make sure that actual design status is always known to competent authority and is in compliance with the design specifications of the certificate. Appropriate procedures between competent authority and the certificate holder should be established to meet this requirement.
- The procedure in case of package design modification for unilateral approval should be clearly defined by written circulated letter or any appropriate process (e. g. in a guideline, see chapter 6.2.3.1 and Annex 4) to applicants.

6.2.3.3 ITEM: CERTIFICATE RENEWAL WITHOUT CHANGE OF PACKAGE DESIGN

This item contains the proofs for certificate renewal without change of package design.

6.2.3.3.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**E**
Belgium	- A written confirmation that there are no changes to the design and an attestation of conformity of each packaging with the design and with the provisions for maintenance described in the safety file and in the approval certificate.	**B**
Bulgaria	No practice	**D**
Cyprus	No practice	**D**
Czech Republic	- SONS requires proof that materials from which packaging was manufactured are in the state corresponding the state described in the Safety Report.	**B**
Denmark	No practice	**D**
Estonia	No practice	**D**
Finland	- None.	**C**
France	- The applicant must take into account the feedback experience document.	**A**
Germany	- Proofs are necessary if changes in the applicable regulatory requirements exist. Experiences are taken into account.	**A**
Greece	No response	**E**
Hungary	- A complete Design Safety Report is required (although it might be identical with the previous one).	**A**
Ireland	No practice	**D**
Italy	- It depends from the kind of package. For example in case of Type B package used as radiographic device we ask to carry out non destructive tests, like penetrating liquids, on specific parts of the package (welds, etc.).	**B**
Latvia	- The applicants confirm that they did not change anything in the packing design.	**B**
Lithuania	No practice	**D**

Luxem-bourg	No practice	**D**
Malta	No practice	**D**
The Nether-lands	- No proof, but then assurance that the package still meets all the requirements.	**A**
Poland	- Old certificate and a statement that no change was made.	**B**
Portugal	No response	**E**
Romania	Not applicable.	**D**
Slovak Republic	- Obviously the same proofs as for new.	**A**
Slovenia	- It is required the Design Safety Report from which it shall be concluded that the package design fulfil all prescribed requirements.	**A**
Spain	- No additional documents are required for application.	**C**
Sweden	- Renewal is made if nothing has showed up, that could influence the safety of the design.	**C**
Turkey	- No practice	**D**
United Kingdom	- At first no change renewal (3 years) we require a letter stating that there is no change. At the second no-change renewal (6 years) we require evidence of a design review. At the third no-change renewal and onward (9 years +) we reserve the right to require a re-work of any aspect of the safety case - this is normally notified to the applicant around three years in advance.	**B**

6.2.3.3.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	Additional proofs or documents for certificate renewal: consideration of evolutions of regulatory requirements, consideration of the feedback experience	**6**
B	Additional proofs or documents for certificate renewal : confirmation of no changes on the package design, additional inspection of the packages	**6**
C	No additional proofs or documents for certificate renewal	**3**
D	No practice	**10**
E	No response	**3**

6.2.3.3.3 SUMMARY AND DISCUSSION

12 countries require additional proofs for certificate renewal without change of package design (categories A and B):

- either by considering evolutions of the applicable regulatory requirements, the feedback experiences and the last technological knowledge
- or by requiring a confirmation of no changes on the package design and/or maintenance controls, non-destructive tests or additional inspection of the manufactured packages.

Among the answers classified in category A and B, there is no consistent procedure relative to certificate renewal without change of package design.

10 countries (category C) have no practice or experience to this item and 3 countries (category D) did not answer.

6.2.3.3.4 CONCLUSIONS AND RECOMMENDATIONS

A process of certificate renewal without change of package design should be defined and consider:

- The latest evolutions of the regulation in force, in particular the provisions for transitional arrangements and
- Practicable experience of use of the package or general experience feedback of package design assessments (based on an experience feedback document described in chapter 6.2.4.8).

6.2.3.4 ITEM: ADDITIONAL PRACTICE FOR VALIDATION OF A MULTILATERAL APPROVAL FOR PACKAGE DESIGNS FOR FISSILE MATERIAL (CERTIFICATE AF, IF, B(U)F, B(M)F AND CF)

6.2.3.4.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**E**
Belgium	- If foreign approval certificate is subject to multilateral approval (fissile) and if the package will be used on a regular basis in Belgium then we will make a full assessment of the Design Safety Report. If it will only be used once or just a few times we will validate, with only a short assessment of the criticality analysis. The only exception is UF6 package designs which will always be validated taking into account that Belgium is only a country of transit. - For fissile materials and if the package design is regularly used in Belgium, a full assessment of the safety analysis report is made. - For non-ADR country validation, a full assessment of the safety analysis report is made. - In the case of validation other than validation of package design containing fissile materials regularly used in Belgium, only the criticality is assessed	**A**
Bulgaria	No practice	**D**
Cyprus	No practice	**D**
Czech Republic	- There are some supplementary conditions in contents of a package design approval certificate beyond minimum requirements of ADR 6.4.23.7. These conditions concern reporting of the holder of design approval certificate, i. e. SONS requires sending of the certificate of conformity for the packaging and incident report in the case. Legally, there are not distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country. - For multilateral approval/validation in case of package designs for fissile material SONS assesses in detail especially the subcriticality analysis and the parts containing results of the obligatory tests of the package Design Safety Report. Legally, there are not distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country.	**B**
Denmark	- Nothing in addition to the modal regulations. - The whole of the Design Safety Report is studied.	**A**
Estonia	No practice	**D**

Finland	- nothing beyond ADR - criticality calculations	**C**
France	- Appraisal of the full Design Safety Report, - Appraisal limited to a preliminary review and complete appraisal of regulatory tests and criticality analysis at minimum when a complete appraisal is not possible due to lack of resources and to time delays.	**A/B**
Germany	- Requirements are in compliance with ADR 6.4.23.7. - Criticality safety report and if necessary applicable documentation to demonstrate assumptions taken for the most reactive configuration	**C**
Greece	No response	**E**
Hungary	- HAEA is authorized to show compliance with dose rate limits for non-fissile materials (e. g. Californium-252) as well. The complete Design Safety Report is assessed.	**A**
Ireland	No practice	**D**
Italy	- No special practices - A complete Design Safety Report is not required in the case of validation. Only the quality assurance program, description for use and maintenance of the package and the criticality safety analysis in the case of fissile materials - For a validation, no distinction is made between an ADR-country, a non-ADR country, a EU country and a EU applicant country.	**C**
Latvia	- No special practice. - About the quantity of fissile material; determination of criticality; the criticality safety of the contents; the ambient temperature range.	**C**
Lithuania	No practice	**D**
Luxem-bourg	No practice	**D**
Malta	- No designs for packages containing fissile material are approved in Malta. - Not applicable	**D**
The Nether-lands	- No special practices - Full Design Safety Report in new approval certificate - In case the Netherlands should be the first ADR country to validate a non-ADR certificate a thorough examination is necessary and the SAR is needed but not if the Netherlands is not the first country concerned by the transport. - In the case of validation, only mechanical, thermal and criticality analysis are assessed.	**C**
Poland	- There are no any additional requirements beyond minimum	

	requirements of ADR 6.4.23.7. - Part that concern analysis of critical possibilities.	**C**
Portugal	No response	**E**
Romania	- According to TS-R-1, except that for approval of a package for fissile material, the technical documentation shall have the form of a safety analysis report. - All safety analysis report and supporting documents. Main issues of concern are sub criticality and heat removal (both in normal and accident conditions), accident analysis (this requires, inter alia, structural analysis and test results). Also QA and CA aspects related to handling and maintenance are analysed. However, fulfilment of all TS-R-1requirements is controlled.	**A**
Slovak Republic	No response	**E**
Slovenia	- We consider the requirements of ADR 6.4.23.7. - In the case of package designs for fissile material we check all parts of the package Design Safety Report.	**A**
Spain	- No special practices - A complete safety analysis report is required except for validation where essentially criticality analysis is assessed, - No distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country	**C**
Sweden	- No special practice - The criticality assessment.	**C**
Turkey	No practice	**D**
United Kingdom	- We specify in terms of IAEA, which is identical to ADR 6.4.23.7. Generally we require less information for approval of a foreign design than for a UK design - We assess the criticality safety case and any other multilateral aspects of the design. We also review any parts of the tests which affect criticality safety.	**C**

6.2.3.4.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	For validation of package designs containing fissile material, **full assessment of the Design Safety Report**	**6**
B	For validation of package designs containing fissile material, **assessment of the criticality analysis, regulatory tests results and any other items when reduced safety margins are suspected**	**9**
C	For validation of package designs containing fissile material, **assessment of the criticality analysis and the results of the regulatory tests**	**2**
D	No practice	**8**
E	No response	**4**

6.2.3.4.3 SUMMARY AND DISCUSSION

All countries work in conformity with ADR 6.4.23.7 in case of multilateral approval/validation for package designs containing fissile material even if the assessment procedure of the package design is different according to the countries.

9 countries (category B) assess only the part of the criticality analysis and the results of the regulatory tests, 6 countries (category A) assess the whole Design Safety Report and 2 countries assess criticality analysis and regulatory tests results and any other items when reduced safety margins are suspected.

Eight countries (category D) have no experience with this item. Four countries (category E) did not answer.
According to ADR 6.4.23.7 an application of approval of packagings for fissile material has to contain all details which convince the competent authority that the package design is in compliance with the requirements of ADR 6.4.11.1 and a quality assurance program according to ADR 1.7.3. Briefly ADR 6.4.11.1 requires that fissile material has to be transported in such a way that under normal and accident transport conditions sub-criticality is ensured. For these purposes, 9 countries consider that it is sufficient to assess in case of a multilateral approval/validation the criticality analysis, the proofs about the behavior of the package design under normal and accident conditions and the leakage proof of the Design Safety Report.

If in the preliminary review of the package design not sufficient safety margins are determined, or if doubts on the package design safety are suspected, the competent authority should have the possibility to assess any part of the Design Safety Report.

6.2.3.4.4 CONCLUSIONS AND RECOMMENDATIONS

- A guideline or procedures for certification should be prepared for the same reasons as those explained in the chapter 6.2.3.1. The European commission should organize the development of this harmonized guideline and should provide it to the IAEA in view of worldwide harmonization, if possible.

- A complete Design Safety Report should be required independently of the type of certificate (see chapter 6.2.2.2)

- The competent authority should have the possibility of either performing a separate safety assessment or making use of the assessment already done by the original competent authority, thus limiting the scope and extent of their own assessment. In this case, the main Design Safety Report chapters to be assessed should be defined (see chapter 6.2.2.4). In addition, it is implied that the competent authority of the country of origin of the design should make available to other competent authorities its assessment report.

- The competent authority should have the possibility of performing a preliminary review of the Design Safety Report and, if there are sufficient margins on safety (or no doubts on the safety), the extent of the detailed assessment may then be limited to criticality analysis and regulatory tests results. The competent authority should also have the possibility of performing the detailed assessment of any other items when reduced safety margins are suspected.

6.2.3.5 ITEM: ADDITIONAL PRACTICE FOR VALIDATION OF A MULTILATERAL APPROVAL FOR TYPE B(M) PACKAGE DESIGN

6.2.3.5.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**E**
Belgium	- If foreign approval certificate is subject to multilateral approval for reasons B(M) and if the package will be used on a regular basis in Belgium then we will make a full assessment of the Design Safety Report. If it will only be used once or just a few times we will validate, with only an assessment with respect to the features requiring the multilateral approval. - If validation only the particular features leading to a B(M) certificate. If approval: the whole SAR.	**C**
Bulgaria	No practice	**D**
Cyprus	No practice	**D**
Czech Republic	- There would be some supplementary conditions in contents of a package design approval certificate beyond minimum requirements of ADR 6.4.23.5. These conditions concern reporting of the holder of design approval certificate, i. e. SONS requires sending of the certificate of conformity for the packaging and incident report in the case. Above mentioned statement is based on theoretical basis - there is not any practical experience. Legally, there are not distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country. - For multilateral approval/validation in case of package Type B(M) SONS would assess in detail especially following parts of the package Design Safety Report: results of the obligatory tests and the part concerning non-compliance with particular requirements. Above mentioned statement is based on theoretical basis - there is not any practical experience. Legally, there are not distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country.	**C**
Denmark	- None - Type B(M) not foreseen, but the whole of the Design Safety Report would be studied.	**A**
Estonia	No practice	**D**
Finland	- nothing beyond ADR	**C**
France	- Appraisal of the full Design Safety Report, - The assessment includes at least a preliminary review and the detailed assessment of the items for which the package is classified as Type B(M) when a complete appraisal is not	**A/B**

	possible due to lack of resources and to time delays.	
Germany	- Requirements are in compliance with ADR 6.4.23.5. - The whole Safety Analysis Report will be assessed.	**A**
Greece	No response	**E**
Hungary	- No special practice. - The complete Design Safety Report is assessed.	**A**
Ireland	No practice	**D**
Italy	- For the approval of a Type B(M) package design no additional requirements are existing. - The part dealing with the aspects for which the package is classified as Type B(M) and the description of quality assurance program.	**C**
Latvia	- No special practice. - The range of ambient conditions (temperature, solar radiation) which are expected to be encountered during transport and which have been taken into account in the design; the maximal difference of pressure, if ferry the package; freezing temperature, if transport the liquids; maximal work pressure in package; maximal temperature on the surface of package.	**C**
Lithuania	No practice	**D**
Luxem-bourg	No practice	**D**
Malta	Not applicable	**D**
The Nether-lands	- No special practices - In the case of B(M) validation, only the deviation from B(U) and the mechanical and thermal analysis are assessed.	**C**
Poland	- There are no additional requirements beyond minimum requirements of ADR 6.4.23.5. - Parts which concern conditions other than those given in ADR 6.4.7.5, 6.4.8.4, 6.4.8.5 and 6.4.8.8 - 6.4.8.15 for Type B(U) packages are required.	**C**
Portugal	No response	**E**
Romania	- There are no supplementary requirements. Generally, the requirements of ADR 6.4.23.5 letters b, c, and d are mentioned as conditions in the multilateral approval, which takes the form of validation of the original certificate. - All the technical documentation (Design Safety Report, if the documentation takes this form). Main concerns are related to assurance of equivalent safety as for B(U) packages.	**C**
Slovak	No response	**E**

Republic		
Slovenia	- In the case of Type B(M) package design we consider only the requirements of ADR 6.4.23.5. - We check in general the whole package Design Safety Report.	**B**

Spain	- No special practices
	- A complete safety analysis report is required except for validation where essentially criticality analysis is assessed.
	- The evaluation would consider specially:
	  - The features of the package (This analyse may conduct to a more detailed evaluation of some aspects that may be considered as critical for the safety of the package)
	  - Prove that the tests had been conducted according to the procedures established in the Regulations.
	  - Deviations respect to B(U) requirements.
	  - The handling and maintenance procedures.
	  - Special conditions and restrictions included in the original certificate
	- No distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country
		B

Sweden	- No additional requirements beyond the requirements of ADR 6.4.23.5 exist for an application for a package design of type B(M). - During the validation procedure special attention is put on why the design is only multilateral and determination of supplementary operational controls.	**C**
Turkey	No practice	**D**
United Kingdom	- We apply the regulatory standard. However we are permitted to challenge any aspect of a package design that we become concerned about. - Generally it is the variations from the B(U) that are assessed. However we retain the right to look at the full design should we consider there is a reason to do so.	**B**

6.2.3.5.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	For validation of Type B(M) package, **full assessment of the Design Safety Report**	**4**
B	For validation of Type B(M) package, **assessment of the aspects for which the package is classified as Type B(M) and any other items when reduced safety margins are suspected**	**4**
C	For validation of Type B(M) package, **assessment of the regulatory tests and the parts concerning non-compliance with particular requirements**	**9**
D	No practice	**8**
E	No response	**4**

6.2.3.5.3 SUMMARY AND DISCUSSION

There are differences in the extent of the assessment procedure of multilateral approval for Type B(M) package design. 9 countries (category C) assess the parts of regulatory tests and the parts concerning non-compliance with particular requirements of the Design Safety Report , 4 countries (category A) assess the whole Design Safety Report and 4 countries assess the aspects for which the package is classified as Type B(M) and any other items when reduced safety margins are suspected.

Eight countries (category D) have no practical experience with this item and 4 countries (category E) did not answer.

If in the preliminary review of the package design not safety margins are determined or if doubts on the package design safety are suspected, the competent authority should have the possibility to assess any part of the Design Safety Report.

6.2.3.5.4 CONCLUSIONS AND RECOMMENDATIONS

- The first three recommendations given in 6.2.3.4.4 also apply to practices for validation of a multilateral approval of type B(M) package design;

- In addition, the competent authority should have the possibility of performing a preliminary review of the Design Safety Report and, if there are sufficient margins on safety (or no doubts on the safety), the extent of the detailed assessment may then be limited to items for which the package is classified as Type B(M). The competent authority should also have the possibility of performing the detailed assessment of any other items when reduced safety margins are suspected.

6.2.3.6 ITEM: ADDITIONAL PRACTICE FOR VALIDATION OF PACKAGE DESIGNS SUBJECT TO TRANSITIONAL ARRANGEMENTS ACCORDING TO ADR 1.6.6.1 AND 1.6.6.2

6.2.3.6.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**F**
Belgium	- For the transitional arrangements the validation process is only of an administrative nature and based only on the approval certificate of the country of origin.	**D**
Bulgaria	No practice	**E**
Cyprus	No practice	**E**
Czech Republic	- SONS would arrange 100% inspection of shipments of package designs which is subjected to the transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2. Above mentioned statement is based on theoretical basis - there is not any practical experience. Legally, there are not distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country. - For multilateral approval/validation in case of transitional arrangement SONS would assess in detail all the package Design Safety Report. Above mentioned statement is based on theoretical basis - there is not any practical experience. Legally, there are not distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country.	**A**
Denmark	- None - The whole of the Design Safety Report will be studied	**A**
Estonia	No practice	**E**
Finland	- Nothing beyond ADR - Parts effected by the changes in requirements.	**C**
France	- Appraisal of the full Design Safety Report, - Appraisal limited to a pre review and complete appraisal of the parts affected by the changes in regulatory provisions at minimum when a complete appraisal is not possible due to lack of resources and to time delays.	**A/B**
Germany	- In principle as in multilateral approval /validation for package designs for fissile material (see 6.2.3.4) and Type B (M) (see 6.2.3.5) and in addition a statement with which requirements of the regulations being valid at the time of application the package design does not conform. - In principle the whole Safety Analysis Report will be assessed but the extent of the specific assessment work depends on the	**A**

	specific design. For a validation of a package BAM is involved with the evaluation of the instructions for the use of the package and the quality assurance programme and if necessary for specific design aspects regarding mechanical and thermal stability. For the validation of package designs containing fissile material see chapter 6.2.3.4. Also shielding aspects will be evaluated by BfS if the design gives rise for it.	
Greece	No response	**F**
Hungary	- The provisions of paras 816-817 in TS-R-1 are considered during the assessment as well. - The complete Design Safety Report is assessed.	**A**
Ireland	No practice	**E**
Italy	- For the approval of a package design in case of transitional arrangement no additional requirements are existing. No distinction is made on the nature of the applicant country. - The part of the safety report dealing with the maintenance procedures.	**D**
Latvia	- If such case will be, then, requirements from international agreements (e.g. ADR, RID) should be used as the guidance together with IAEA safety standards, but legally will be applied national regulations from all countries concerned for that case and if significant differences would occur, then an expert group from all relevant parties should work out formal arrangements. - If any precedent exist for similar cases and what is the level of QA for designers and producers.	**E**
Lithuania	No practice	**E**
Luxem-bourg	No practice	**E**
Malta	Not applicable	**E**
The Nether-lands	- No additional requirements. - QA programme. Packages not validated before will not be validated anymore.	**D**
Poland	- We have no additional requirements. - We assess in detail test results.	**C**
Portugal	No response	**F**
Romania	No additional requirements; however, in fact, for packages for fissile material no multilateral approval will be issued by Romania if full compliance with requirements of TS-R-1 regarding assurance of sub criticality (i.e. art. 671-682). As consequence, no shipment of fissile material involving Romanian territory will be allowed if package does not comply with requirements of TR-S-1 regarding assurance of sub criticality.	**C**
Slovak	No response	**F**

Republic		
Slovenia	- We consider only the requirements of ADR 1.6.6.1 and 1.6.6.2. - We check in general the whole package Design Safety Report.	**A**
Spain	When the package has been very well known along its B(U) period, special requirements are not required for the first validation of the original certificate. Then is usually enough: the original certificate and information about the modifications in the different re-issues, including the documentation supporting those modifications when they are important for the safety. When the design is not known and the applicant ask for the first validation in the country, a more depth study is carried out. For the first validation the evaluation would consider specially: - The features of the packages (This analyse may conduct to a more detailed evaluation of some aspects that may be critical for the safety of the package). - Prove that the tests had been conducted according to the procedures established in the Regulations. - Deviations respect to the edition in force of the Regulations. - The handling and maintenance procedures. This area is considered very important for this case, especially the maintenance and periodical revisions, considering that some packages may be very old. - Special conditions and restrictions included in the original certificate. - No distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country.	**B**
Sweden	- Evaluation is made according to the requirements in ADR 1.6.6.1 and 1.6.6.2. - If -85 or -73: The complete SAR, although focus is put on the criticality assessment. For non–fissile packages focus is put on the test report and determination of approved contents.	**B**
Turkey	No practice	**E**
United Kingdom	- We apply the standard regulatory requirements. - We examine the same aspects as for a "non-transitional" package (For fissile material - we assess the criticality safety case and any other multilateral aspects of the design. We also review any parts of the tests which affect criticality safety.) - except we compare to the old regulations for most aspects, and to the new regulations for those aspects specifically mentioned in 1.6.6.1 and 1.6.6.2	**B**

6.2.3.6.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	For validation of package designs subject to transitional arrangement, **full assessment of the Design Safety Report**	**6**
B	For validation of package designs subject to transitional arrangement, **assessment includes the parts affected by the changes in the regulations and any other items when reduced safety margins are suspected**	**4**
C	For validation of package designs subject to transitional arrangement, **the assessment is limited to the parts affected by the changes in the regulations**	**3**
D	For validation of package designs subject to transitional arrangement, **only administrative procedure or only assessment of QA program**	**3**
E	No practice	**9**
F	No response	**4**

6.2.3.6.3 SUMMARY AND DISCUSSION

The assessment procedure for validation of package designs subject to transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 is different according to the countries. 6 countries assess the whole Design Safety Report (category A), 4 countries assess the parts affected by the changes in the regulations and any other items when reduced safety margins are suspected (category B) and 3 countries (category C) assess only the parts affected by the changes in the regulations. 3 countries have a procedure of administrative nature or assess only the QA program or parts of it (category D).

The competent authority of the Czech Republic would arrange 100% inspection of shipments of package designs which are subjected to the transitional arrangements.

Nine countries (category D) have no experience with this item. Four countries (category E) did not answer.

For transitional arrangements, the whole Design Safety Report should be assessed but the assessment can be limited to a preliminary review and the parts affected by the changes in the regulations and on the quality assurance program.

6.2.3.6.4 CONCLUSIONS AND RECOMMENDATIONS

- A harmonized guideline or procedures for certification should be prepared for the same reasons than those explained in the chapter 6.2.3.1.
  The European commission should organize the development of this harmonized guideline and should provide it to the IAEA in view of worldwide harmonization, if possible.
- The competent authority should have the option of either performing a separate safety assessment or making use of the assessment already done by the original competent

authority, thus limiting the scope and extent of their own assessment. In this case, the main Design Safety Report chapters to be assessed should be defined. The competent authority has to have the possibility:

  - of performing a preliminary review of the Design Safety Report and assessment of the parts affected by the changes in the regulations if there are sufficient high margins on safety (or no doubts on the safety) and on the quality assurance program,
  - the option of performing assessment of any other items when reduced safety margins are suspected.

- The package design safety shall be checked taking into account the current regulations, last knowledge/experience obtained and the provisions of transitional arrangements.

6.2.3.7 ITEM: ADDITIONAL PRACTICE FOR SHIPMENT APPROVAL

6.2.3.7.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**D**
Belgium	No additional practice	**B**
Bulgaria	No practice	**C**
Cyprus	No practice	**C**
Czech Republic	There are some supplementary paragraphs and conditions in contents of a shipment approval certificate beyond minimum requirements of ADR 6.4.23.2. The supplementary paragraphs represent approvals of the particular documents: Emergency rules, Classification of transported nuclear materials into relevant categories from the physical protection aspect and Physical protection arrangements during transport and approval of realization of the physical protection arrangements. The supplementary conditions concern reporting of the holder of shipment approval certificate, i. e. SONS requires notification about term of the shipment 40 days in advance and incident report in the case. Legally, there are not distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country.	**A**
Denmark	- Special requirements: 1) State Variation DK 1 – ref. ICAO-TI 2) On board an INF ship there must be a transport specialist competent in health physics and supplied with appropriate radiation protection measurement equipment.	**A**
Estonia	No practice	**C**
Finland	no additional requirements	**B**
France	- Appraisal of the full Design Safety Report, - Appraisal limited to a pre review and operating instructions of the packaging., the details of how the precautions and administrative or operational controls, referred to in the package design approval certificates are to be put into effect when a complete appraisal is not possible due to lack of resources and to time delays. -	**B**
Germany	- Requirements are in compliance with ADR 6.4.23.	**B**
Greece	No response	**D**
Hungary	In addition to the corresponding implementations	

	of the minimum requirements of TS-R-1 in the international modal transport regulations - according to the provision of the Decree No. 14/1997(IX. 3.) KHVM on the 'Transport and Packaging of Radioactive Materials' - HAEA is authorized to show compliance with dose rate limits for non-fissile materials (e. g. Californium-252) as well.	**B**
Ireland	No practice	**C**
Italy	- The record of the last maintenance of the package used for the shipment is required. If available the radiological data like the surface radiation level of the package and the transport index. No distinction is made on the nature of the applicant country.	**B**
Latvia	No additional practice	**B**
Lithuania	No practice	**C**
Luxem-bourg	No practice	**C**
Malta	- The current system does not exceed minimum requirements of ADR 6.4.23.2	**B**
The Nether-lands	- No additional practices	**B**
Poland	- No additional practices	**B**
Portugal	No response	**D**
Romania	- Any international shipment of radioactive materials involving Romanian territory has to be authorized by CNCAN (with exception of shipments in exempted packages). - No additional practices	**B**
Slovak Republic	No response	**D**
Slovenia	No additional practices	**B**
Spain	In addition to the information on the shipment that is considered in ADR 6.4.23.2 an analyse of the package is necessary. For shipments of fissile material a previous notification to the CSN is required (seven days in advance). In case of many shipments during a long period, a more general notification (planning) would be also required three months in advance. No distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country.	**A**
Sweden	- There are no special procedures additional to ADR.	**B**
Turkey	No practice	**C**
United Kingdom	- We do not request routeing, but we examine emergency arrangements in more detail.	**B**

6.2.3.7.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	For shipment approval, additional practice to ADR 6.4.23.2 (as notification or controls of contamination and/or radiation level…)	**4**
B	For shipment approval, practice according to ADR 6.4.23.2 (assessment is limited to operating instructions of the packaging, the details of how the precautions and administrative or operational controls, referred to in the package design approval certificates are to be put into effect)	**13**
C	No practice	**7**
D	No response	**4**

6.2.3.7.3 SUMMARY AND DISCUSSION

13 countries have a practice in compliance with requirements of ADR 6.4.23.2 (category B). There are additional complementary practices in 4 countries (category A). These practices concern

- Classification of transported nuclear materials into relevant categories from the physical protection aspect. (Czech Republic)
- On board an INF ship there must be a transport specialist competent in health physics and supplied with appropriate radiation protection measurement equipment. (Denmark)
- For shipments of fissile material a previous notification to the competent authority is required (seven days in advance). In case of many shipments during a long period, a more general notification (planning) would be also required three months in advance.(Spain)

These are no essential additional practices referring to ADR. Additional complementary practices are not essential for transport safety or are resulting from national nuclear safety and radiation protection law overlapping the transport law.

Seven countries have no practice in this field and four countries did not answer.

6.2.3.7.4 CONCLUSIONS AND RECOMMENDATIONS

There is a nearly harmonized practice for special arrangement according to ADR 6.4.23.2 in all countries. The following recommendations can be given:

- A harmonized guideline or procedures for certification should be prepared for the same reasons than those explained in the chapter 6.2.3.1.
  The European commission should organize the development of this harmonized guideline and should provide it to the IAEA in view of worldwide harmonization, if possible.
- The competent authority should assess the specific measures taken for the shipment, if applicable.

6.2.3.8 ITEM: ADDITIONAL PRACTICE FOR SHIPMENT APPROVAL UNDER SPECIAL ARRANGEMENT

6.2.3.8.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**D**
Belgium	- All shipment approvals under special arrangements are validated in Belgium, by means of a transport licence in compliance with the provisions of the royal decree of 20/07/2001 in particular chapter VII. A full application for transport licence as determined in the royal decree is required together with all relevant information on the package to be used and the reason for special arrangement together with a proposal for compensating measures.	**A**
Bulgaria	No practice	**C**
Cyprus	No practice	**C**
Czech Republic	- There are some supplementary paragraphs and conditions in contents of a special arrangement approval certificate beyond minimum requirements of ADR 6.4.23.3. The supplementary paragraphs represent approvals of the particular documents: Emergency rules, Classification of transported nuclear materials into relevant categories from the physical protection aspects and Physical protection arrangements during transport and approval of realization of the physical protection arrangements. The supplementary conditions concern reporting of the holder of shipment approval certificate, i. e. SONS requires notification about time and date of the shipment 40 days in advance and incident report in the case. Legally, there are not distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country.	**A**
Denmark	- The whole of the Design Safety Report will be studied.	**B**
Estonia	No practice	**C**
Finland	Depending on the case (no cases so far)	**C**
France	- Full assessment of the transport safety documentation specifying compensatory measures. It is necessary to precisely identify the deficiencies of the package design.	**A**
Germany	- Requirements are in compliance with ADR 6.4.23.2. Special arrangement is considered to be the exceptional case and is handled in a very restrictive manner in Germany. There must be a reasonable justification and the demonstration of the need for a special arrangement by the applicant. It must be	**A**

	demonstrated that the same level of safety is provided by the special arrangement as for a fully approved package design.	
Greece	No response	**D**
Hungary	In addition to the corresponding implementations of the minimum requirements of TS-R-1 in the international modal transport regulations - according to the provision of the Decree No. 14/1997(IX. 3.) KHVM on the 'Transport and Packaging of Radioactive Materials' - HAEA is authorized to show compliance with dose rate limits for non-fissile materials (e. g. Californium-252) as well.	**A**
Ireland	No practice	**C**
Italy	- The record of the last maintenance of the package used for the shipment under special arrangement is required. If available the radiological data like the surface radiation level of the package and the transport index. No distinction is made on the nature of the applicant country.	**A**
Latvia	- Regarding the requirements for the special arrangement we included all provisions from IAEA Safety requirements (TS-R-1). Due to delays for incorporation of IAEA safety standards into ADR, there are certain differences, which basically should disappear after next updates of ADR.	**A**
Lithuania	No practice	**C**
Luxem-bourg	No practice	**C**
Malta	- None	**A**
The Nether-lands	- No additional requirements	**A**
Poland	- There are no additional requirements for the special arrangement.	**A**
Portugal	No response	**D**
Romania	No response	**D**
Slovak Republic	No response	**D**
Slovenia	- According to the Act on Transport of Dangerous Goods the application for special arrangement must contain: data on the producer, consignor, carrier, and recipient; identification number, data and approvals specified in the internationals regulations (ADR, RID, IMGD, ICAO-TI); data on quantity and physical characteristics; specification of the transportation route; specification of the place of unloading; time of commencement and scheduled time of completion of the transportation; time and place scheduled for stops during transportation; data on the vehicle used in and the driver	**A**

	carrying out the transportation of dangerous goods. We consider also the requirements prescribed in ADR 6.4.23.3. -	
Spain	No special practices	**A**
Sweden	- There are no special procedures additional to ADR.	**A**
Turkey	No practice	**C**
United Kingdom	- We consider that special arrangements need to be justified and equivalent safety levels established against relevant requirements of TS-R-1.	**A**

6.2.3.8.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	For shipment approval under special arrangement practice according to 6.4.23.3 (assessment is limited to the reasons why the consignment cannot be made in full accordance with the applicable requirements of ADR; and to the special precautions or special administrative or operational controls which are to be employed during carriage to compensate for the failure to meet the applicable requirements of ADR)	**14**
B	Full assessment of Design and Operation safety report for shipment approval under special arrangement	**1**
C	No practice	**8**
D	No response	**5**

6.2.3.8.3 SUMMARY AND DISCUSSION

Most of the countries (14, category A) have no additional practice referring ADR for special arrangement approval (ADR 6.4.23.3).
There are no essential additional requirements referring ADR. In some cases additional requirements for transport exist due to the national legal system regarding nuclear safety and radiation protection. These aspects are to find in the table of answers of each country.

Eight countries have no practice in this field and five countries did not answer.

6.2.3.8.4 CONCLUSIONS AND RECOMMENDATIONS

There is a nearly harmonized practice for shipment approval under special arrangement according to ADR 6.4.23.3 in all countries. The following recommendations can be given:

- A harmonized guideline or procedures for certification should be prepared for the same reasons than those explained in the chapter 6.2.3.1.
- The European commission should organize the development of this harmonized guideline and should provide it to the IAEA in view of worldwide harmonization, if possible.
- From the experience of the countries participated on the study it is recommended:
  - Special arrangement should be treated as an exceptional case taking into account the necessity of justification of shipment with the transport regulations and
  - Applicants should propose compensatory measurements
- A complete transport safety documentation to demonstrate the compensatory measures capability to reach an equivalent level of safety, and emergency plans should be required.
- The special arrangement must be sufficiently justified (e. g. in form of a Design Safety Report containing analysis of shipment conditions).

6.2.3.9 ITEM: VALIDITY OF CERTIFICATES

This item contains the validity time of certificate according to type of approval certificate.

6.2.3.9.1 LIST OF PRACTICES

Country	Country specific practice to the above named item		Category of practice
Austria	No response		**G**
Belgium	Type AF	Maximum 5 years. In case of multilateral approval the certificate has besides some exceptions the same validity period as the certificate of the country of origin.	**A/D**
	Type B(U)/ B(U)F		
	Type B(M)		
	Type C		
	Type IF		
	Type H(U)		
	Special form radioactive material		
	Low dispersible radioactive material		
	Shipment	Maximum 5 years or the time necessary to execute the transport or transport sequence. In any case limited to the validity period of the certificate of the country of origin.	
	Special arrangement		
Bulgaria	No practice		**F**
Cyprus	No practice		**F**
Czech Republic	Type AF	5 years	**A/E**
	Type B(U)/ B(U)F	3 - 5years	
	Type B(M)	1 - 5 years	
	Type C	no experience	
	Type IF	5 years	
	Type H(U)	no experience	
	Special form radioactive material	5 years	
	Low dispersible radioactive material	no experience	
	Shipment	1 - 5 years	
	Special arrangement	1 - 5 years	
Denmark	Type AF	On average one year or more – ad hoc	**B/E**
	Type B(U)/ B(U)F	On average one year or more (only applicable for fissile)	
	Type B(M)	n.a. (no application received)	
	Type C	n.a. (no application received)	
	Type IF	On average one year or more – ad hoc	
	Type H(U)	n.a. (no application received)	
	Special form radioactive material	2 years	

	Low dispersible radioactive material	n.a.	
	Shipment	On average ½ year or less – ad hoc	
	Special arrangement	On average ½ year or less – ad hoc	
Estonia	No practice		**F**
Finland	Type AF	as applied by the applicant (or shorter, if deemed necessary)	**C**
	Type B(U)/ B(U)F	as applied by the applicant (or shorter, if deemed necessary)	
	Type B(M)	as applied by the applicant (or shorter, if deemed necessary)	
	Type C	as applied by the applicant (or shorter, if deemed necessary)	
	Type IF	as applied by the applicant (or shorter, if deemed necessary)	
	Type H(U)	as applied by the applicant (or shorter, if deemed necessary)	
	Special form radioactive material	as applied by the applicant (or shorter, if deemed necessary)	
	Low dispersible radioactive material	as applied by the applicant (or shorter, if deemed necessary)	
	Shipment	as applied by the applicant (or shorter, if deemed necessary)	
	Special arrangement	as applied by the applicant (or shorter, if deemed necessary)	
France	- Validity of new approval = five years but the limit is decreased if additional justifications are needed to solve uncertainties. Validity of special arrangement is generally one year or less and 10 years for special form.		**A/D**
Germany	Type AF	mainly 3 but also up to 5 years	**A/D**
	Type B(U)/ B(U)F	mainly 3 but also up to 5 years	
	Type B(M)	mainly 3 but also up to 5 years	
	Type C, CF	mainly 3 but also up to 5 years	
	Type IF	mainly 3 but also up to 5 years	
	Type H(U)	No approval up to now	
	Special form radioactive material	5 years	
	Low dispersible radioactive material	No approval up to now	
	Shipment	varies from some month to about 1 year	
	Special arrangement	varies from some month to about 1 year	
Greece	No response		**G**
Hungary	Type AF	3-5 years	**A/D**
	Type B(U)/ B(U)F	3-5 years	
	Type B(M)	3-5 years	

	Type C	3 years	
	Type IF	3-5 years	
	Type H(U)	3 years	
	Special form radioactive material	3-5 years	
	Low dispersible radioactive material	3 years	
	Shipment	several weeks	
	Special arrangement	several weeks	
Ireland	No practice		**F**
Italy	Type AF	No package certified	**B/D**
	Type B(U)/ B(U)F	Three years	
	Type B(M)	Three years	
	Type C	No approved package	
	Type IF	No approved package	
	Type H(U)	No approved package	
	Special form radioactive material	No approved special form	
	Low dispersible radioactive material	No approved LDRM	
	Shipment	Three months	
	Special arrangement	Three months	
Latvia	Type AF	up to 3 y, the extension based on information	**B/D**
	Type B(U)/ B(U)F	up to 3 y, the extension based on information	
	Type B(M)	up to 3 y, the extension based on information	
	Type C	up to 3 y, the extension based on information	
	Type IF	up to 3 y, the extension based on information	
	Type H(U)	up to 3 y, the extension based on information	
	Special form radioactive material	up to 3 y, the extension based on information	
	Low dispersible radioactive material	up to 3 y, the extension based on information	
	Shipment	for each shipment or for group of similar shipments	
	Special arrangement	for each shipment or for group of similar shipments	
Lithuania	No practice		**F**
Luxem-bourg	No practice		**F**
Malta	Type AF	Not applicable	**D**
	Type B(U)/ B(U)F	Not applicable	
	Type B(M)	Not applicable	
	Type C	Not applicable	
	Type IF Type H(U)	Not applicable Not applicable	

	Special form radioactive material	Not applicable	
	Low dispersible radioactive material	Not applicable	
	Shipment	Per shipment or period of 1 year	
	Special arrangement	Not applicable	
The Nether-lands	Type AF	less than3 years	**B/D**
	Type B(U)/ B(U)F	less than 3 years	
	Type B(M)	less than 3 years	
	Type C	No data	
	Type IF	less than 3 years	
	Type H(U)	less than 3 years	
	Special form radioactive material	less than 3 years	
	Low dispersible radioactive material	No data	
	Shipment	As long as necessary	
	Special arrangement	As long as necessary	
Poland	Type AF		**A/D**
	Type B(U)/ B(U)F		
	Type B(M)	Usually not longer than 5 years.	
	Type C		
	Type IF		
	Type H(U)		
	Special form radioactive material	Usually no longer than 5 years.	
	Low dispersible radioactive material		
	Shipment	Time Depends on transport period.	
	Special arrangement	Time Depends on transport period.	
Portugal	No response		**G**
Romania	Type AF	max. 5 years, but in case of validation, not more as original certificate	**A/D**
	Type B(U)/ B(U)F	5 years, but in case of validation, not more as original certificate	
	Type B(M)	max. 5 years, but in case of validation, not more as original certificate	
	Type C	5 years, but in case of validation, not more as original certificate	
	Type IF	max. 5 years, but in case of validation, not more as original certificate	
	Type H(U)	5 years, but in case of validation, not more as original certificate	

	Special form radioactive material	max. 5 years, but in case of validation, not more as original certificate	
	Low dispersible radioactive material	5 years, but in case of validation, not more as original certificate	
	Shipment	the certificate is valid on the estimated shipment period	
	Special arrangement	the certificate is valid on the estimated shipment period	
Slovak Republic	Type AF	Obviously max. 5 years.	**A**
	Type B(U)/ B(U)F	Obviously max. 5 years.	
	Type B(M)	Obviously max. 5 years.	
	Type C	Obviously max. 5 years.	
	Type IF		
	Type H(U)		
	Special form radioactive material		
	Low dispersible radioactive material		
	Shipment		
	Special arrangement		
Slovenia	- According to the Act on Ionising Radiation Protection and Nuclear Safety the longest validity period of the approval is 10 years. In that particular case the validity period of approval certificate for package design shall be 3 years.		**B**
Spain	Type AF	A fixed period is not established. It will depend on the particular case	**C/D**
	Type B(U)/ B(U)F		
	Type B(M)		
	Type C		
	Type IF		
	Type H(U)		
	Special form radioactive material		
	Low dispersible radioactive material		
	Shipment		
	Special arrangement	As short as possible. The validity period generally covers only particular shipments.	
Sweden	Three years.		**B/E**
Turkey	No practice		**F**
United Kingdom	Type AF	3 years	**B/D**
	Type B(U)/ B(U)F	3 years	
	Type B(M)	3 years	
	Type C	3 years	
	Type IF	3 years	
	Type H(U)	3 years	
	Special form radioactive material	3 years	

	Low dispersible radioactive material	3 years	
	Shipment	As design	
	Special arrangement	Varies (normally short term)	

6.2.3.9.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	For certificate of approval for Type AF, Type B(U)/ B(U)F, Type B(M), Type C, Type IF, Type H(U), Special form radioactive material, Low dispersible radioactive material **validity time in maximum 5 years**	**8**
B	For certificate of approval for Type AF, Type B(U)/ B(U)F, Type B(M), Type C, Type IF, Type H(U), Special form radioactive material, Low dispersible radioactive material **validity time in maximum 3 years or lower**	**7**
C	For certificate of approval for Type AF, Type B(U)/ B(U)F, Type B(M), Type C, Type IF, Type H(U), Special form radioactive material, Low dispersible radioactive material **no fixed validity time, depending on the particular case**	**2**
D	For shipment and special arrangement approval validity time is according to the time of shipment, **in maximum up to 1 year**	**12**
E	For shipment and special arrangement approval **validity time more than 1 year**	**3**
F	No practice	**7**
G	No response	**3**

6.2.3.9.3 SUMMARY AND DISCUSSION

There are two nearly commensurate groups of countries which define the validity time for certificate of approval for Type AF, Type B(U)/ B(U)F, Type B(M), Type C, Type IF, Type H(U), Special form radioactive material, Low dispersible radioactive material in maximum up to 5 years (category A – 8 countries) or in maximum 3 years (category B – 7 countries). Two countries decide to have no fixed validity time. They arrange for each particular case for which time the certificate is available guaranteed.

For shipment and special arrangement approval nearly all countries with practice (category D – 12 countries) fix a validity time which conforms to the time of the shipment and in general, validity time is not more than 1 year. Only 3 countries have validity times greater than 1 year (category E).

Seven countries have no practice and 3 countries did not answer.

6.2.3.9.4 CONCLUSIONS AND RECOMMENDATIONS

The following recommendations can be given:

- A validity time of 3 to 5 years is reasonable for certificates of approval for a package design.
- For shipment approval and shipment approval under special arrangement the validity time should be the period of operation needed or not exceed 1 year.
- For a validation certificate, the validity period should not exceed the validity period of the certificate of the country of origin of the design.
- For certificate of approval for special form radioactive material the validity time should not exceed 10 years.

6.2.3.10 ITEM: STRUCTURE OF UNILATERAL APPROVAL CERTIFICATE

This item contains additional information indicated in each approval certificate beyond minimum requirements of ADR 6.4.23.14, which documents are referenced and who sign of the approval certificate.

6.2.3.10.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**C**

Belgium	- Description of the internal arrangements which are important to the safety of the package highlights for handling and maintenance of the package are specified. A revision list of the certificate (history of the approval certificate) is added.
	- Documents which are referenced and demonstrate the compliance with the regulations: The safety analyse report with a specific reference to the drawings of the packaging and the relevant internal structures, the material specifications, manufacturing procedures and acceptance tests and reference to the description of the QA program. The application for approval of the package. All other documents received during the assessment and which contain relevant information.
	- The approval certificate contains:
	  - A description of the package, including a figure,
	  - A description of the allowed content and any internal structures, including figures,
	  - A description of the criticality assessment, if applicable,
	  - A summary of the safety related handling instructions,
	  - A summary of the maintenance program.
	- The Federal Agency for Nuclear Controll (FANC). The certificates are signed by the director general of the FANC or his delegate.
		A

Bulgaria	No practice	**B**
Cyprus	- Design Safety Reports, evaluation reports - Drawings, Tests, Instructions for Safe Use and Disposal - The Minister of Labour and Social Insurance (or any Officer to whom he delegates such power)	**A**

Czech Republic	- There are some supplementary conditions in contents of a package design approval certificate beyond minimum requirements of ADR 6.4.23.14. These conditions concern reporting of the holder of design approval certificate, i. e. SONS requires sending certificate of conformity of the packaging and incident report in the case. Standard format of a package design approval certificate is as follows:
	  1) applicant identification and type of certificate
	  2) packaging identification, packaging type and assigned identification mark
	  3) packaging description and manufacturer identification
	  4) authorized radioactive contents
		A

	5) dosimetric control - permissible limits 6) quality assurance and scope and method of conformity assessment 7) packaging marking and labelling 8) general conditions of use and incident reporting 9) validity and expiry date 10) reasons and references 11) signature and stamp drawing of the packaging. - There are two possibilities for indicating documents which demonstrate the compliance with the regulations, depending on the nature of the materials submitted by applicant: 1) Safety Analysis Report is referenced as a material "en bloc" 2) Particular documents is referenced - Design drawing, quality assurance program and instruction for use and maintenance are regularly mentioned in the approval certificate. - State Office for Nuclear Safety (SONS) issues approval certificates. Deputy chairman of SONS signs design approval certificates of packagings for spent nuclear fuel and approval certificates for international transit shipments through Czech Republic. Director of Department of Nuclear Materials signs all other approval certificates.	
Denmark	- See appended template of validation of approval for package design - Documents which are referenced and demonstrate the compliance with the regulations: Referenced in the validation - NIRH – road and rail CAA – Air DMA – sea	**B**
Estonia	No practice	**B**
Finland	- no additional priorities to ADR - The certificate is given in text form, no standard template. The basic text includes: - Identification mark or number (ref. TS-R-1, para 838), date of issue, - terms (conditions) of validity, special handling requirements, etc. - text: "This certificate does not relieve…" (IAEA TS-R-1 para 833 (f)) - expiration date, signatures - references to the regulations, description of the package (technical data in brief) - All relevant technical documentation are indicate as documents for compliance with the regulations - Only short description of the package is written in the certificate. List of references (including technical documentation) is given in the certificate - STUK issues. Section Head and Introducing Officer sign.	**A**

	(Introducing officer is the person who responsible for the coordination of the approval process at STUK.)	
France	- the additional information required in certificate is: - The reference to Design Safety Report - The reference to letter of applicant - The criticality safety index - Special provisions during loading, transport… - A revision index of previous issues of the certificate - reference to design drawings, instructions for use and maintenance - the competent authority signs the certificate	**A**
Germany	- The specification of the authorized contents has very high priority to meet all applicable safety requirements of the package in practice. In particular the maximum permissible contents is specified in such a way that compliance with this specification in the certificate (e.g. nuclide specific activity inventory, cooling time, total activity, gamma/neutron source strength ...) results in compliance with the permissible dose rate limits on the package surface and at the conveyance. (an example of a type B(U)F certificate is attached) - Safety Analysis Report (SAR). Documents which are relevant for criticality safety analysis (they can also be part of SAR). Other documents which are necessary to demonstrate the safety of the package design (which are not part of the SAR). BAM assessment report. - the package design is prescribed by a parts list which is referenced in the approval certificate (the parts list contains the list of all drawings) - in the approval certificate are also referenced: – the instruction for use and maintenance – necessary documents for re-inspection - specific provisions to ensure some implementation aspects of the certificate requirements - the responsible project leader after clearing procedure within the department signs the approval certificate	**A**
Greece	No response	**C**
Hungary	- The format of the package design approval certificate is no standardized. The content, however, is defined in the corresponding one of pars 830-834 in TS-R-1. - The approval certificate is primarily based on the assessment of the Design Safety Report, but it is not referenced directly. - Procedures for handling and maintenance are can be found in the quality assurance programme of the package design, specified in the approval certificate. - The approval certificate is issued by the HAEA and signed by the DDG of the HAEA.	**A**
Ireland	No practice	**B**
Italy	- We do not specify additional priorities beyond the requirements of ADR 6.4.23.14.	**A**

	- The document describing the quality assurance program for the use of the package - Design drawing, instruction for use and maintenance, general description of the package (dimensions, weight, etc.) - APAT that is the competent authority responsible for issuing of the approval certificate. The approval certificate is signed by the APAT director.	
Latvia	- Regards to contents of a package design approval certificate we include all requirements of TS-R-1 to our regulation of Cabinet of Ministers on Protection against Ionising Radiation transporting Radioactive Materials (03.07.2001). Due to delays for incorporation of IAEA safety standards into ADR, there are certain differences, which basely should disappear after next updates of ADR. As there is no any case yet, no such template prepared. - certificates for alternative radioactive contents, other competent authority validation, or additional technical data or information, as deemed appropriate by the competent authority in special arrangement approval certificates - information provided by the applicant relating to the use of the packaging or specific actions to be taken prior to the shipment - the applicable design approval certificate(s) was issued in other institution - the drawings or specification of the design - Design specifications for the special form radioactive material or low dispersible radioactive material; a specification of the radioactive contents; specification of the applicable quality assurance programme; certificates for alternative radioactive contents, other competent authority validation, or additional technical data; specification of the design. - The approval certificate is issued by Radiation Safety Centre and our director sign this certificate. This approval certificate we conform to police.	**A**
Lithuania	No practice	**B**
Luxem-bourg	No practice	**B**
Malta	- OHSA Form 46 mentioned previously is filled in by the importer and will be forwarded on to the Occupational Health and Safety Authority (OHSA). An OHSA officer reviews the form and if approval is given by the Radiation Protection Section, an OHSA Officer will sign the form.	**B**
The Nether-lands	- Reference will be made to the documents delivered by the applicant. Reference will also be made to IAEA safety Series 113. - Documents which are referenced and demonstrate the compliance with the regulations: Reference to the document delivered by the applicant. -The minister of Housing, Spatial Planning and the Environment. Signed by Head of Radiation Protection, Nuclear and Biosafety Division sign the approval certificate	**A**
Poland	- We have no additional priorities. - Documents which are referenced and demonstrate the	**A**

	compliance with the regulations: Design safety report. - Short description and design drawing. - President of National Atomic Energy Agency issues and signs the approval certificate.	
Portugal	No response	**C**
Romania	- All documents submitted by the applicant are referenced in the certificate (directly or not directly) - Generally, as most of certificates issued by CNCAN are validations, the same specifications as in original certificate). If the validation is partial, only the relevant specifications of the original certificate. - the certificate is issued by CNCAN and signed by the CNCAN President	**A**
Slovak Republic	No response	**C**
Slovenia	- We have not had any additional priorities. The content of the format or template of a package design approval certificate consider information prescribed in 6.4.23.14. - Slovenia has not issued any certificate yet. In the approval certificate, it shall be reference on Design Safety Report, evaluation reports etc. - Documents which are referenced and demonstrate the compliance with the regulations: In the approval certificate it shall be mentioned e.g. design drawing, manufacture drawing, instructions for use and maintenance etc. - At the moment, the approval certificate is issued and signed by the Slovenian Nuclear Safety Administration.	**A**
Spain	- The standard format is basically adapted to ADR 6.4.23.14. When it is necessary for a particular design, specific conditions are included in addition. - Design Safety Report is referenced to demonstrate compliance with the regulations. - Reference to Handling and Maintenance Instructions and Fundamental Design Drawings are included. A brief description of package and a basic drawing is also included. - The Dirección General de Política Energética y Minas belonging to the Ministry of Economy issues the package and shipment certificates. The Director General signs the certificate.	**A**
Sweden	- The requirements in ADR etc. are followed, implemented through the use of a standardized format, see attached document for a fissile materials package design approval certificate. - Documents which are referenced and demonstrate the compliance with the regulations: Usually only the Design Safety Report (including test reports) and evaluation reports. - A few major drawings are referred to. Then it is stated that the valid instructions for handling and maintenance shall be followed. These are usually part of the SAR and if they are not, then they are referred to.	**A**

	- SKI or SSI. The department head and the handling specialist usually signs (after delegation decided by the Director General).	
Turkey	No practice	**B**
United Kingdom	- In addition to 6.4.23.14 we have adopted the procedure established in German certificates of giving a table of certificate history. We also have additional legal text on the first page. - This depends on requirements. The Design Safety Report (and criticality report if appropriate) along with the design specification is always references. Other documents which may be referenced include the handling and packing instructions, maintenance instructions, quality assurance, emergency arrangements etc. It is the responsibility of the applicant to demonstrate safety - so all references are external to the competent authority (the signature and stamp of the competent authority signify acceptance of these). - Documents which are referenced and demonstrate the compliance with the regulations: Design specification (either as drawing or drawing list). Plus any other specifications considered necessary to ensure safety is assured. (generally - as above). - Head of RMTD signs the certificates based on the signature of three assessors attesting the fact that the safety case demonstrates compliance with the regulations for all applicable modes of transport.	**A**

6.2.3.10.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	The content of approval certificate conforms to ADR 6.4.23.14	**16**
B	No practice	**8**
C	No response	**4**

6.2.3.10.3 SUMMARY AND DISCUSSION

All countries (category A) have unilateral approval certificate content which conforms to ADR 6.4.23.14. If the minimum content is defined, there are some differences between the countries regarding the structure and the extent of special paragraphs of the certificate.

Most countries add complementary information. In general, the main information added in the approval certificate, in the case of unilateral approval certificate is:

- the reference to Design Safety Report,
- the reference to assessment report,
- the reference to all documents delivered by the applicants for assessment,
- and a revision table of previous issues of the certificate, which permits to have an overview about the history of the approval certificate.

The extent of the approval certificate as an administrative document should not be too long and complex. That is why it is advisable to give references to the appropriate submitted and evaluated documents rather than to rewrite these texts,.

In the approval certificate, nearly all competent authorities indicate the references of the Design Safety Report and the packaging drawings. Regarding the drawings, it is important to distinguish design drawings from manufacture drawings. The design drawing gives minimum and maximum limit values so that the package design meets the safety requirements while the manufacture drawing contains package tolerances considering the production process, but always in the limit of the design drawing.

Eight countries have no experience in the field of unilateral approval certificates and four countries did not respond.

6.2.3.10.4 CONCLUSIONS AND RECOMMENDATIONS

The content of the unilateral approval certificate is predetermined by the requirements of ADR 6.4.23.14 which give the required minimum content. However there is no required format.

- A harmonized format for the certificate should be defined. The European Commission should organize the development of this harmonized format and should provide it to the IAEA in view of worldwide harmonization, if possible.

- The certificate structure should contain three essential areas:
  1. Legal basis
  2. Specification of the packaging and its allowed contents (package design)
  3. Other requirements to ensure compliance with regulations

- It is recommended to consider in a harmonized structure a revision list for the overview about the history of the approval certificate.

- The format of certificate should be complemented by a drafting guide.

- A list of minimum content for a certificate is given in Annex 9.

- A further harmonization effect could be reached by bilingual certificates giving the content in country of origin language plus English version for international transport of radioactive materials.

6.2.3.11 ITEM: STRUCTURE OF MULTILATERAL APPROVAL CERTIFICATES, SHIPMENT APPROVAL AND SHIPMENT APPROVAL UNDER SPECIAL ARRANGEMENT

This item contains additional information indicated in each above named approval certificate beyond minimum requirements of ADR.

6.2.3.11.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**E**
Belgium	No information about the approval certificate structure or template	**E**
Bulgaria	No information about the approval certificate structure or template	**E**
Cyprus	No information about the approval certificate structure or template	**E**
Czech Republic	- Standard format for validation of a package design approval certificate: 12) applicant identification and type of certificate 13) packaging identification, packaging type and assigned identification mark 14) packaging description and manufacturer identification 15) authorized radioactive contents 16) dosimetric control - permissible limits 17) quality assurance and scope and method of conformity assessment 18) packaging marking and labelling 19) general conditions of use and incident reporting 20) validity and expiry date 21) reasons and references 22) signature and stamp drawing of the packaging. - There are some supplementary paragraphs and conditions in contents of a shipment approval certificate beyond minimum requirements of ADR 6.4.23.13. Standard format of a shipment approval certificate is as follows: 1) applicant identification and type of certificate 2) approvals of particular documents 3) approval of realization of the physical protection arrangements 4) authorized packagings and assigned identification mark 5) dosimetric control of packagings and conveyances - permissible limits 6) marking, labelling and placarding 7) general conditions for realization of the transport 8) general conditions for the physical protection arrangements 9) emergency rules and incident reporting 10) validity and expiry date	**B/C**

	11) reasons and references 12) signature and stamp - There are some supplementary paragraphs and conditions in contents of a special arrangement approval certificate beyond minimum requirements of ADR 6.4.23.12. Standard format of a special arrangement approval certificate: 1) applicant identification and type of certificate 2) approvals of particular documents 3) approval of realization of the physical protection arrangements 4) authorized packagings and assigned identification mark 5) dosimetric control of packagings and conveyances - permissible limits 6) marking, labelling and placarding 7) general conditions for realization of the transport 8) general conditions for the physical protection arrangements 9) emergency rules and incident reporting 10) validity and expiry date 11) reasons and references 12) signature and stamp Legally, there are not distinctions between an ADR country, a non-ADR country, an EU country and an EU applicant country.	
Denmark	Validation of original certificates mainly with the reference to the provisions of the original certificate.	**A**
Estonia	No information about the approval certificate structure or template	**E**
Finland	No information about the approval certificate structure or template	**E**
France	The additional information required in the case of shipment approval and shipment approval under special arrangement is: - The reference to Design Safety Report - The reference to letter of applicant - reference to design drawings, instructions for use and maintenance (in the case of shipment approval under special arrangement) the format is the same as that used for unilateral approval in the case of validation, the additional information containing in the certificate is - The reference to Design Safety Report - The reference to letter of applicant - A revision index of previous issues of the certificate - French translation of original certificate - Additional precautions	**B/C**
Germany	- Validation of original certificates with the reference to the instruction for use in German language - Certificate for shipment approval and shipment approval under special provision are according to ADR.	**B/C**
Greece	No response	**E**
Hungary	- Certificate for validation of package designs for fissile material: The content is defined by para. 833 in TS-R-1 by the	**B/C**

	corresponding one of the paras 816-817 in TS-R-1. - Certificate for validation of a Type B(M) package design: The format of the package design approval certificate is not standardized. The content, however, is defined by para. 833 in TS-R-1 and by the corresponding one of the paras 816-817 in TS-R-1. - The format of the shipment approval certificate is not standardized. The content, however, is defined by para. 832 in TS-R-1. - The format of the special arrangement approval certificate is not standardized. The content, however, is defined by para. 831 in TS-R-1.	
Ireland	No practice	**D**
Italy	No information about the approval certificate structure or template	**E**
Latvia	We have not such templates yet.	**D**
Lithuania	No information about the approval certificate structure or template	**E**
Luxem-bourg	No practice	**D**
Malta	No information about the approval certificate structure or template	**E**
The Nether-lands	6.4.23.16 will be used. Validation of original certificates mainly with the reference to the provisions of the original certificate.	**A**
Poland	No information about the approval certificate structure or template	**E**
Portugal	No response	**E**
Romania	- According to TS-R-1, except that for approval of a package for fissile material, the technical documentation shall have the form of a safety analysis report. (See attachments.) - Certificate for validation of a Type B(M) package design: Generally, the requirements of ADR 6.4.23.5 letters b, c, and d are mentioned as conditions in the multilateral approval, which takes the form of validation of the original certificate. The standard format is similar as per B(U) approval. - Shipment approval certificate: For standard format see example in attachments.	**B/C**
Slovak Republic	No information about the approval certificate structure or template	**E**
Slovenia	- In the case of type B(M) package design the content of format or template of a package design approval certificate consider information prescribed in ADR. - Transitional arrangement according to ADR 1.6.6.1 and 1.6.6.2 : The content of format or template of a package design approval certificate consider information prescribed in ADR. - Shipment approval: The content of format or template of a package design approval certificate consider information prescribed in ADR (6.4.23.13).	**B/C**

	- Shipment approval under special arrangement: The content of format or template of a package design approval certificate consider information prescribed in ADR (6.4.23.12).	
Spain	No information about the approval certificate structure or template	**E**
Sweden	- Multilateral approvals are in Sweden effected by validation of the original certificate. The procedure for the issuance of a Swedish design approval certificate do not differ significantly due to whether it is a fissile or a non fissile design approval, or whether it is a unilateral or a multilateral approval. The validation document issued by SKI for the validation of foreign certificates, is rather similar to a certificate but contains less information about the package. No Swedish identification mark is given, as stated in IAEA TS-R-1 paragraph 829(b). A standardized format is used. - A Type B(U) or B(M) certificate (or any package approval certificate) is issued as prescribed in ADR 6.4.23.14. - For transitional arrangement according to ADR 1.6.6.1 and 1.6.6.2. The validation document looks the same as for other validations. - Applications for shipment approval are extremely rare (SKI has received one the last ten years). - The certificate we issue looks basically the same as a package approval certificate. The consignor and consignee are defined together with transport modes, reasons for special arrangement, compensatory measures and other special conditions for the shipment.	**A**
Turkey	No practice	**D**
United Kingdom	The content of format of a validation of a package design approval certificate and a shipment approval certificate consider information prescribed in ADR and additional more specific and detailed information (Templates are available).	**B/C**

6.2.3.11.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	The content of validation of foreign approval certificates for fissile package designs, Type B(M) and transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 conforms to ADR 6.4.23.16	**3**
B	The content of validation of foreign approval certificates for fissile package designs, Type B(M) and transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 conforms to ADR 6.4.23.16 and additional more specific and detailed information	**7**
C	The content of approval certificates for shipment approval and shipment approval under special arrangement conforms to ADR and additional more specific and detailed information	**7**
D	No practice	**4**
E	No response	**14**

6.2.3.11.3 SUMMARY AND DISCUSSION

Only 10 countries gave sufficient answers referring to multilateral certificates/validations.
The content of validation of approval certificates for package designs for fissile material, Type B(M) package designs and transitional arrangements according to ADR 1.6.6.1 and 1.6.6.2 in 3 countries consist mainly of a reference to the original certificate. In addition of the reference to the original certificate 7 countries give additionally more specific and detailed information. This information concerns:

- Owner of the validation
- Description of the package and manufacturer identification
- Allowed radioactive contents
- Quality assurance and scope and method of conformity assessment
- General conditions of use and incident reporting
- The reference to Design Safety Report
- The reference to letter of applicant
- A revision index of previous issues of the certificate
- A translation of original certificate
- Additional precautions

Regarding the content of approval certificates for shipment approval and shipment approval under special arrangement, all countries answered are in conformity with ADR requirements. In the case of France, the additional information given is the reference to Design Safety Report, the reference to letter of applicant and the reference to design drawings, instructions for use and maintenance (in the case of shipment approval under special arrangement).

6.2.3.11.4 CONCLUSIONS AND RECOMMENDATIONS

There is no harmonized format of a validation of foreign approval certificates.

- The European Commission should organize the development of a harmonized validation format and should provide it to the IAEA for worldwide harmonization, if possible.

- The format of the validation of certificates should contain the following essential parts:

    1. Legal basis,
    2. Administrative matters (e. g. owner of the validation, manufacturer identification, expiry date, marking of the packaging),
    3. Allowed contents,
    4. Other national specifications or requirements to ensure compliance with regulations,
    5. Annex – Original approval certificate in the language of the validating country or if acceptable in English.

6.2.4 SAFETY ASSESSMENT PROCEDURE

6.2.4.1 ITEM: PROCEDURE AND GUIDELINES FOR COMPETENT AUTHORITY, TECHNICAL SUPPORT AND THE APPLICANTS

This item contains the use of internal procedures or guidelines for the organization of work, the assessment of the Design Safety Report and the national or international guidelines or standards for the assessment of different technical items in the DSR.

6.2.4.1.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**E**

Belgium	- Quality management according to ISO 9001
	- The internal procedures are in a developing phase. The general structure of an assessment consists of the following phases:
	  - reception of the application;
	  - preliminary examination of the Design Safety Report and writing of a assessment proposal;
	  - assessment according to the proposal accepted by the head of service;
	  - writing of the approval or validation certificate;
		A

Bulgaria	No practice	**D**
Cyprus	No practice	**D**
Czech Republic	- There are no such instructions. Depending on the case the SONS chairman establishes "ad hoc" assessment team and its leader by written instruction. - 1. Act No. 18/1997 Coll. of 24 January 1997 on Peaceful Utilisation of Nuclear Energy and Ionising Radiation (the Atomic Act) and on Amendments and Additions to Related Acts, as Amended. - 2. Regulation of the SONS No. 317/2002 Coll. on Design Approval of Packaging for Shipment Storage or Disposal of Nuclear Materials and Assigned Radioactive Substances, on Design Approval of Ionising Radiation Sources and on Transportation of Nuclear Materials and Assigned Radioactive Substances (Design Approval and Transport Regulation. - 3. Regulation No. 307/2002 Coll. on the Radiation Protection. - 4. Regulation No.214/1997 Coll., on Quality Assurance in Activities Related to the Utilization of Nuclear Energy and in Radiation Practices, and Laying Down Criteria for the Assignment and Categorization of Classified Equipment into Safety Classes. - 5. Regulation No.144/1997 Coll., on Physical Protection of Nuclear Material and Nuclear Facilities and their Classification. - 6. IAEA Safety Standards Series No. TS-R-1, Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), Vienna, 2000.	**C**

	- 7. IAEA Safety Standards Series No. TS-G-1.1, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material, Vienna, 2000.	
Denmark	- Not formalized assessment procedure - No guidelines	**C**
Estonia	No practice	**D**
Finland	- No internal procedures	**C**
France	- Internal procedures for assessment under consistent with ISO 9001:2000 - No exhaustive guideline for applicants but experience feedback document is considered as a guideline.	**A/B**
Germany	- There are internal guidelines, checklists and sample reports for various approval types as part of a QA program. - - R 003 - Guideline for the procedure for design approval of packagings for the transport of radioactive materials, of special form materials and low dispersible materials - KTA-3905 Guideline (as additional support for calculation of lifting devices) - BAM GGR 007 for ductile cast iron - BAM GGR 008 for numerical safety proofs within the scope of package design test of casks for the transport and storage of radioactive material - TRV 006 - Technical guideline about measures for quality assurance and quality control of packages for the transport of radioactive material	**A/B**
Greece	No response	**E**
Hungary	- The administrative part/framework has written procedure, however, the assessment is not standardized. - TS-R-1, TS-G-1.1, TS-G-1.2, Safety Series 113	**C**
Ireland	No practice	**D**
Italy	No internal procedures for assessment	**D**
Latvia	- The action of Radiation Safety Centre is given in the Regulation of Cabinet of Ministers on Protection against Ionising Radiation transporting Radioactive Materials (03.07.2001). There are also certain procedures prescribed by the Licensing regulations, which could be used for this purpose as guidance. RDC is in early stages to prepare internal QA program. - We have only the Regulations of Cabinet of Ministers on Protection against Ionising Radiation during the Transport of Radioactive Materials. - IAEA Safety requirements (TS-R-1); ADR	**C**
Lithuania	No practice	**D**

Luxem-bourg	No practice	**D**
Malta	No practice	**D**
The Nether-lands	- No internal procedures for assessment	**C**
Poland	- There are no written internal procedures. - ADR, RID, IMDG-Code, IATA	**C**
Portugal	No response	**E**
Romania	- No internal procedures for assessment - As already mentioned, almost all design certification in Romania refers to validation of original certificates issued by foreign countries. As result, the standards consulted in the assessment process for the different technical items of the package design safety analysis report are those declared in the safety analysis report and in the supporting documentation. CNCAN generally checks the correspondence between those standards and guides and the national and international standards used in Romania for authorization of Cernavoda NPP.	**C**
Slovak Republic	- No internal procedures for assessment - TS-R-1, ADR, RID	**C**
Slovenia	- Yes, the internal procedures consider requirements in ADR. - Mainly, it is used IAEA, Safety Standards Series, and Regulations for the Safe Transport of Radioactive Material, No. TS-R-1 (ST-1, Revised) and European regulations in Slovenia.	**A**
Spain	- Internal procedures for the evaluation for the approval and validation of transport packages. These internal procedures include the quality assurance program.	**A**
Sweden	- No - Not defined.	**C**
Turkey	- The review and assessment process is carried out to the basic safety standards and IAEA Safety Series TS-R-1. Check is made to observe the package, and special form certificates are applicable and in data and the applicability of the special form material to the ISO designation for use.	**C**
United Kingdom	- Instructions are split in to different technical areas (one for mechanical engineers, one for QA, and one for criticality). - We call them desk instructions. This is an old term used in the civil service which describes the rule book which tells you how to carry out your job. - 'Guide to an application for UK competent authority approval of radioactive material in transport (IAEA 1996 regulations)' this is an advisory guide. It contains also elements regarding the assessment procedure for the applicant. - ISO 9001:1994; ISO 9001:2000; Safety Series 112 and 113;	**A/B**

	TS-G-1.1; Safety Series 50-C/SG-Q; Many other ISO and BS standards (e.g. 5500 on pressure vessels) TCSC (industry standardisation committee) codes of practice.	

6.2.4.1.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	Available internal procedures for assessment of the DSR	**6**
B	Guidelines for applicant regarding the requirements for proofs in the DSR	**3**
C	No internal procedures or applicant guidelines for proofs in the DSR	**10**
D	No practice	**9**
E	No response	**3**

6.2.4.1.3 SUMMARY AND DISCUSSION

Most of the countries (10, category C) with practice in the field of package design assessment have no internal procedures for the assessment of the Design Safety Report.
Competent authorities of only six countries have internal procedures for the assessment of the DSR (category A – Belgium, France, Germany, Slovenia, Spain, UK).
Only 3 countries (France, Germany, UK) have guidelines for the applicant regarding the performance of proofs and criteria for assessment.

There is obviously a lack of information for the applicant regarding the performance of proofs and criteria for assessment. The necessity for preparing a guidance for assessment and the contents of this guideline is discussed in chapter 6.2.3.1.

Important national and international guidelines or standards for the assessment of the different technical items in the package Design Safety Report are:

- IAEA Safety Standards Series No. TS-R-1, Regulations for the Safe Transport of Radioactive Material [4],
- IAEA Safety Standards Series No. TS-G-1.1, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material [56],
- IAEA Safety Series 112 [58] and 113 [59],
- IAEA Safety Series 50-C/SG-Q,
- The Radioactive Materials Packaging Handbook, Oak Ridge National Lab., TN (United States) [60],
- UK ‘Applicants guide’ [24],
- German R 003 ‘Guideline for the procedure for design approval of packagings for the transport of radioactive materials, of special form materials and low dispersible materials’ [34],
- German TRV 006 - Technical guideline about measures for quality assurance and quality control of packages for the transport of radioactive material [61],
- BAM GGR 007 ‘Guideline for use of ductile cast iron for casks for the transport and storage of radioactive material’ [42],

- BAM GGR 008 ‘Guideline for numerical safety proofs within the scope of package design test of casks for the transport and storage of radioactive material’ [44],
- KTA-Guideline 3905 (as additional support for calculation of lifting devices) [62],
- Many other ISO and BS standards (e.g. 5500 on pressure vessels),
- UK TCSC (Transport Container Standardisation Committee), Codes of Practice and Standards “to examine the requirements for containers for the safe transport of radioactive material with a view to standardisation and, as appropriate, to produce and maintain guidance in the form of standards documentation”, especially
  TCSC 1006 – The Securing/Retention of RAM Packages on Conveyances,
  TCSC 1042 – Design of Transport Packaging for RAM,
  TCSC 1056 – Shielding Integrity Testing of RAM Packages,
  TCSC 1068 – Leakage tests on Packages for Transport of RAM,
  TSCS 1079 – Lifting Points for RAM Packages, [63].

There are only a few guidelines and standards for assessment of package designs outside the IAEA Safety Standards Series.
Assessment procedures are now implemented by concerned organizations, but it is desirable that these procedures are consistent with a harmonized assessment guideline.

6.2.4.1.4 CONCLUSIONS AND RECOMMENDATIONS

Guidelines or/and procedures for the competent authority and its technical support should be defined for assessment as follows:

‘For procedures referring to the applicant (External procedures)’

- The competent authorities should issue a guideline for preparing the Design Safety Report defined in Annex 5, including general recommendations and details about accepted calculations and test methods, acceptance criteria, and other detailed assessment requirements that should be addressed. This guideline can be used by evaluating the DSR how far it meets the requirements.
- Based on existing guidelines a harmonized guideline should be developed to be used in European Countries. The European commission should organize the development of this harmonized guideline and should provide it to the IAEA in view of worldwide harmonization, if possible.

‘For procedures for assessment referring to the competent authority and the technical support/assessment service (Internal procedures)’

- The competent authorities should define a harmonized guideline for assessing the package Design Safety Report including general recommendations and details about accepted calculations or accepted demonstrations.
- Based on existing guidelines a harmonized guideline should be developed to be used in European Countries. The European commission should organize the development of this harmonized guideline and should provide it to the IAEA in view of worldwide harmonization, if possible.
- The assessment procedure is the essential part for the evaluation of a package design safety. Because of this high requirement, the competent authority and its technical support (or assessment service) should have a QA management system for the evaluation of the package design (see 6.2.3.1).
- Procedures should comply with the ISO 9000:2000 or equivalent standard.

6.2.4.2 ITEM: ORGANIZATION OF SAFETY ASSESSMENT PROCEDURE

This item contains the organization of work regarding selected assessment items.

6.2.4.2.1 LIST OF PRACTICES

Country	Country specific practice to the above named item					Category of practice
Austria	No response					**E**
Belgium		Functional speciali-zation	object-oriented specialization	a combination of both	Other organization	**B/C**
	Structural analysis		#			
	Thermal analysis		#			
	Containment system		#			
	Shielding design		#			
	Criticality safety			#		
	- The package approval unit consists of two reviewers. Normally, the entire assessment of a Design Safety Report is performed by a single reviewer. However, informal discussion among the reviewers is possible. For the criticality safety aspect, the Agency's criticality expert can be consulted. - The assessment is based on two steps, the preliminary review and the appraisal. - organization of work is according to a object-oriented specialization (there is an organizational unit or assessor which covers all necessary functions and responsibilities for identified groups of applications and package designs)					
Bulgaria	No practice					**D**
Cyprus	No practice					**D**
Czech Republic		Functional speciali-zation	object-oriented specialization	a combination of both	Other organization	**A**
	Structural analysis	#				
	Thermal analysis	#				
	Containment system	#				
	Shielding design	#				
	Criticality safety	#				

<table>
<tr><td></td><td colspan="5">- SONS reviews the submitted safety analysis report according to its exact character, either by one person or by a team of personnel led by a leader or even with the use of experts and expert organizations. In the case of complex and demanding assessment, the SONS chairman establishes the assessment team and its leader. The members of such team assess particular part or parts of the safety analysis report and work up relevant safety evaluation report. Experts of SONS also perform independent calculation analyses to support its own reviews, e.g. for subcritical assessment. If necessary, every member of the team is allowed to use independent analyses at university and other expert workplaces in assessments of the safety analysis report. SONS performs documentation of the safety documentation assessment by elaborating the summary safety evaluation report for the entire safety documentation.</td><td></td></tr>
<tr><td>Denmark</td><td colspan="5">- NIRH will do the analysis. Other institutions may be involved.</td><td>C</td></tr>
<tr><td>Estonia</td><td colspan="5">No practice</td><td>D</td></tr>
<tr><td rowspan="6">Finland</td><td></td><td>Functional specialization</td><td>object-oriented specialization</td><td>a combination of both</td><td>Other organization</td><td rowspan="6">A</td></tr>
<tr><td>Structural analysis</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Thermal analysis</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Containment system</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Shielding design</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Criticality safety</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>France</td><td colspan="5">- The assessment is based on two steps, the preliminary review and the appraisal.
- The preliminary review and the appraisal are structured by a combination of functional analysis and object-oriented specialization</td><td>C</td></tr>
<tr><td rowspan="6">Germany</td><td></td><td>Functional specialization</td><td>object-oriented specialization</td><td>a combination of both</td><td>Other organization</td><td rowspan="6">C</td></tr>
<tr><td>Structural analysis</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal analysis</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Containment system</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding design</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td></td><td></td><td>#</td><td></td></tr>
</table>

<table>
<tr><td></td><td colspan="5">- In the BfS the application for a package design approval is handled in project-oriented way according to German guide R003. That means that the main responsible person has to coordinate all the necessary work within the section SE 1.6 where all evaluations regarding criticality and shielding are made. He has also the contact to BAM and the applicant if necessary. He is responsible for the internal BfS assessment reports, which are created according to internal guidelines, checklists and sample reports.
- There is specialized manpower for shielding and criticality evaluation available in Section 1.6 which is used within the object-oriented approval procedure.
- In BAM a similar project-orientated structure is used. In BAM section III.32 a main responsible person has to coordinate the assessment of the mechanical, thermal, release behaviour and the quality assurance. He has to decide if experimental investigations are necessary and has to coordinate them. Also the supervision of all qualifications of materials and procedures are his responsibilities. He has to contact the different internal assessors, the BfS and the applicant and he has to create the BAM assessment report.</td><td></td></tr>
<tr><td>Greece</td><td colspan="5">No response</td><td>E</td></tr>
<tr><td rowspan="6">Hungary</td><td></td><td>Functional specialization</td><td>object-oriented specialization</td><td>a combination of both</td><td>Other organization</td><td rowspan="6">C</td></tr>
<tr><td>Structural analysis</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal analysis</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Containment system</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding design</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Ireland</td><td colspan="5">No practice</td><td>D</td></tr>
<tr><td rowspan="6">Italy</td><td></td><td>Functional speciali-zation</td><td>object-oriented specialization</td><td>a combination of both</td><td>Other organization</td><td rowspan="6">A/C</td></tr>
<tr><td>Structural analysis</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal analysis</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Containment system</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding design</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td>#</td><td></td><td></td><td></td></tr>
</table>

<table>
<tr><td></td><td colspan="5">- A preliminary review is occasionally made.
- The appraisal is structured by a functional and object-oriented analysis except for criticality safety where a functional specialization is used</td><td></td></tr>
<tr><td rowspan="8">Latvia</td><td></td><td>Functional speciali-zation</td><td>object-oriented speciali-zation</td><td>a combination of both</td><td>Other organization</td><td rowspan="8">C</td></tr>
<tr><td>Structural analysis</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal analysis</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Containment system</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding design</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td colspan="5">- This is an intention, but as no real cases, then expertise system is based on available technical competence of available experts and no formal procedures established yet.</td></tr>
<tr><td>Lithuania</td><td colspan="5">No practice</td><td>D</td></tr>
<tr><td>Luxem-bourg</td><td colspan="5">No practice</td><td>D</td></tr>
<tr><td>Malta</td><td colspan="5">Not applicable</td><td>D</td></tr>
<tr><td>The Nether-lands</td><td colspan="5">- The assessment is based on two steps in the case of new approval, the preliminary review and the appraisal.
- The assessment is based on functional and object-oriented specializations.</td><td>C</td></tr>
<tr><td>Poland</td><td colspan="5">No response</td><td>E</td></tr>
<tr><td>Portugal</td><td colspan="5">No response</td><td>E</td></tr>
<tr><td rowspan="8">Romania</td><td></td><td>Functional speciali-zation</td><td>object-oriented speciali-zation</td><td>a combination of both</td><td>Other organization</td><td rowspan="8">C</td></tr>
<tr><td>Structural analysis</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal analysis</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Containment system</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding design</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td></td><td></td><td>#</td><td></td></tr>
</table>

<table>
<tr><td></td><td colspan="5">- The assessment is performed by one group of experts. There is one expert of CNCAN responsible for each of the subjects of the package design safety analysis report mentioned above. In case that the safety analysis report is not concluded, external expertise is required, via AIEA, or EU or by requiring the applicant to extend and/or validate the results of the report through specialised organizations and regulatory bodies of the country of origin of the package.</td><td></td></tr>
<tr><td>Slovak Republic</td><td colspan="5">No response</td><td>E</td></tr>
<tr><td>Slovenia</td><td colspan="5">- There is an organization unit or assessor which covers all necessary functions and responsibilities for identified groups of applications and package designs.</td><td>B</td></tr>
<tr><td rowspan="8">Spain</td><td></td><td>Functional specialization</td><td>object-oriented specialization</td><td>a combination of both</td><td>Other organization</td><td rowspan="8">A</td></tr>
<tr><td>Structural analysis</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Thermal analysis</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Containmen t system</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Shielding design</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Criticality safety</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td colspan="5">- The Transport Unit receives the application and carry out the first analysis respect the compliance of the requirements of the regulations. When the Transport Unit considers that a particular technical assessment is necessary ask for it to an expert Unit: mechanical, thermal, criticality, shielding, etc. These experts are not specialised in the transport matter, they carry out any kind of evaluation for the nuclear field on its particular subject. The experts make a report that will be part of the final assessment report that the Transport Unit will issue.</td></tr>
<tr><td>Sweden</td><td colspan="5">- Object-oriented specialization, but special functions are incorporated from case to case when needed.</td><td>B</td></tr>
<tr><td>Turkey</td><td colspan="5">No practice</td><td>D</td></tr>
<tr><td rowspan="4">United Kingdom</td><td></td><td>Functional speciali-zation</td><td>object-oriented speciali-zation</td><td>a combination of both</td><td>Other organization</td><td rowspan="4">A</td></tr>
<tr><td>Structural analysis</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Thermal analysis</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Containment system</td><td>#</td><td></td><td></td><td></td></tr>
</table>

	Shielding design	#				
	Criticality safety	#				
	- There are three sections involved in assessment. One deals with QA aspects, another with mechanical and thermal aspects and the third with nuclear and radiological safety aspects. All three sections are required to approve a design.					

6.2.4.2.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	Functional specialization	**5**
B	object-oriented specialization	**3**
C	combination of A and B	**9**
D	No practice	**8**
E	No response	**5**

6.2.4.2.3 SUMMARY AND DISCUSSION

The organization of the safety assessment procedure firstly depends on the amount of high qualified staff which has to be provided to the amount and the extent of applications. Because of the scientific and technical development in the fields of structural design, thermal design, containment system, shielding design and criticality safety it seems to be good to have experts for special fields (functional specialization). Most of the countries (14, category A and C) use this organization of work or a combination between functional specialization and object-oriented specialization where an organizational unit or assessor covers all necessary functions and responsibilities for identified groups of applications and package designs. Only 3 countries (Belgium, Slovenia, Sweden - category B) use mainly this object-oriented specialization.
Eight countries (category D) have no assessment practice.

In most cases for the assessment procedure in general there is one responsible person who organizes the contact to the applicant and to the experts in special fields.
The assessment is based in general on two steps:

- a preliminary review
- and an assessment based on a
  a) functional specialization (a certain organizational unit or assessor dealing with one subject for all applications/kinds of package design), or
  b) object-oriented specialization (there is an organizational unit or assessor which covers all necessary functions and responsibilities for identified groups of applications and package designs) or
  c) a combination of both.

The preliminary review is an important step which permits to:
- Identify the packaging, the contents and the hazards associated with the transported materials,
- Identify functions and performances which have to be guaranteed,
- Identify the components guaranteeing such performances,
- Check that the justifications of the regulatory package performances are available,
- Determine the missing elements and request them to the applicant
- Check the completeness of demonstration of compliance of the package design with each applicable paragraph of transport regulations.

The preliminary review should take into account experience of evaluation work e. g. the feedback experience document (Annex 8) and the recommendations for assessment given in the chapters 6.2.4.1 and 6.2.3.1.
The organization of work for assessment should be developped in a procedure for assessment (discussed in the chapters 6.2.4.1 and 6.2.3.1). This procedure should include instructions about the following items:

- The administrative procedure
- Determine the persons (for the applicant, the competent authority and its technical support) involved in the assessment process
- if the preliminary review of the safety design report is necessary
- which parts of the safety design report must be provided and assessed,
- Completeness of demonstration of compliance of the package design with each applicable paragraph of transport regulations
- minimum information in a safety design report (see also feedback experience document to integrate the difficulties most frequently encountered in Design Safety Report assessment)
- the practices in the case of
    - assessment of test program
    - Certificate renewal without change of package design
    - Package design modification procedure for unilateral approval
    - Approval procedure for an unilateral approval
    - validation of a multilateral approval B(M), an approval of package design containing fissile material, an approval for transitional arrangements, a shipment approval, a special arrangement
- calls upon external experts for assessment
- exchanges with applicants with questions-answers
- exchanges between competent authority and the technical support
- exchanges with other competent authorities or/and their technical supports for assessment of the same Design Safety Report
- acceptable calculations in the Design Safety Report
- checking methods of applicants demonstrations
- structure and contents of the assessment report
- times for assessment and certification
- quality management

6.2.4.2.4 CONCLUSIONS AND RECOMMENDATIONS

- An internal procedure should describe the organization of work for assessment.
- An assessment procedure should be prepared (see chapter 6.2.4.1 and 6.2.3.1).
- The organization of the assessment work should include at least the following actions:
    i. determination of the persons (for the applicant, the competent authority and its technical support) involved in the assessment process,
    ii. planning of the assessment work,
    iii. checking of contents of the application
    iv. work practices for assessment (indicate if the organizational unit or the assessor deals with one subject for all applications/kinds of package design, or if there is an organizational unit or assessor which covers all necessary functions and responsibilities for identified groups of applications and package designs, or if it is a combination of both),
    v. The assessment should be started with a preliminary review supported, e. g. by a feedback experience document (see also chapter 6.2.4.8 and Annex 8 in order to identify the missing elements)
    vi. Determine the exchange with applicants
    vii. If needed, determine the exchange with competent authority
    viii. Determine the possibilty to call upon external experts, safety committees…
    ix. Drafting of the assessment report

6.2.4.3 ITEM: ACCEPTED CALCULATION METHODS FOR ASSESSMENT

This item contains accepted calculation methods by the assessor and their verification, the main used computer software and the way for checking calculations.

6.2.4.3.1 LIST OF PRACTICES

<table>
<tr><th>Country</th><th colspan="5">Country specific practice
to the above named item</th><th>Category of practice</th></tr>
<tr><td>Austria</td><td colspan="5">No response</td><td>F</td></tr>
<tr><td rowspan="5">Belgium</td><td>Calculation method</td><td colspan="4">Verified by</td><td rowspan="5">A/B/C</td></tr>
<tr><td>Validated computer codes and models</td><td colspan="4">- check of the applicability of the code or model
- check of the input data</td></tr>
<tr><td>Analytical calculation using formulae</td><td colspan="4">Retrieval in text books or proper derivation of the formulae.</td></tr>
<tr><td>Comparison with similar package designs</td><td colspan="4">Verification of similarity aspects – material properties, dimensional aspects.</td></tr>
<tr><td colspan="5">- Any appropriate calculation method for safety proof is allowed subject to justification of the method validity;
- Any computer software can be used if their validity is justified.
- For mechanical, thermal, shielding, criticality and leaktightness analysis, only a comparison of the results with the maximum allowable values is made. According to the security factor, a recalculation with the same method is made and if needed a recalculation with another method is performed.
- Comparison with similar package designs accepted</td></tr>
<tr><td>Bulgaria</td><td colspan="5">No practice</td><td>E</td></tr>
<tr><td>Cyprus</td><td colspan="5">No practice</td><td>E</td></tr>
<tr><td rowspan="9">Czech Republic</td><td>Calculation method</td><td colspan="4">Verified by</td><td rowspan="9">A/B/D</td></tr>
<tr><td>ANSYS</td><td colspan="4">Procedure VDS 030 "Guide for the evaluation of calculation codes for assessment of nuclear safety", Ref. No.6544/200, Identification No.: SP030100, Date of validity: 4. 4. 2001</td></tr>
<tr><td>COSYMA</td><td colspan="4"></td></tr>
<tr><td>DYN3D/M2</td><td colspan="4"></td></tr>
<tr><td>MELCOR</td><td colspan="4"></td></tr>
<tr><td>MCNP4B</td><td colspan="4"></td></tr>
<tr><td>ORIGEN-2, ORIGEN-2.1</td><td colspan="4"></td></tr>
<tr><td>PAM-CRASH, SIMQ, TRAK…</td><td colspan="4"></td></tr>
<tr><td></td><td>Full checking and recalculation with other calculation methods</td><td>Full recalculation with the same method</td><td>Comparison of the results with the maximum allowable values</td><td>Other Method</td></tr>
</table>

<table>
<tr><td></td><td><table>
<tr><td>Mechanical stability</td><td>yes</td><td>second possibility</td><td></td><td></td></tr>
<tr><td>Thermal stability</td><td>yes</td><td>second possibility</td><td></td><td></td></tr>
<tr><td>Leaktight-ness</td><td>yes</td><td>second possibility</td><td></td><td></td></tr>
<tr><td>Shielding</td><td>yes</td><td>second possibility</td><td></td><td></td></tr>
<tr><td>Criticality safety</td><td>yes</td><td>second possibility</td><td></td><td></td></tr>
</table>
- SONS performs own calculations and/or independent recalculation for confirmation of the proof in cases the full scope tests were not realized.</td><td></td></tr>
<tr><td>Denmark</td><td>- Only validations are made. A general check is performed for all the points mentioned.
- General reliance on the applicant’s data.</td><td>C</td></tr>
<tr><td>Estonia</td><td>No practice</td><td>E</td></tr>
<tr><td>Finland</td><td><table>
<tr><td></td><td>Full checking and recalculation with other calculation methods</td><td>Full recalculation with the same method</td><td>Comparison of the results with the maximum allowable values</td><td>Other Method</td></tr>
<tr><td>Mechanical stability</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal stability</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Leaktight-ness</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td>#</td><td></td><td></td><td></td></tr>
</table>
- Own criticality calculations were performed.</td><td>C/D</td></tr>
<tr><td>France</td><td>- Any appropriate calculation method for safety proof is allowed subject to justification of the method validity; same thing for the computer software.
- For criticality analysis, systematic checks by independent calculation of the most reactive arrangement.
- For mechanical, thermal and leaktightness analyses, an independent calculation is performed when analysis validity is doubtful.</td><td>A/B/C/D</td></tr>
</table>

<table>
<tr><td>Germany</td><td>

BfS and BAM accepts all standards, codes and computer software provided the applicant can give evidence for the applicability of the standard, code and computer software and the correctness of the calculated results (validated and quality assured codes and computer software). For computer based numerical calculations, e.g. FEM, BAM has a draft guideline BAM GGR 008.
BfS is using modern three-dimensional Monte Carlo computer codes, i.e. the SCALE code system, for the evaluation of criticality and shielding analysis of the applicant. If appropriate and applicable in some cases also simpler, one-dimensional codes like MICROSHIELD are used. BAM is using ABAQUS, ANSYS, LS-DYNA, for FEM-analysis, MATHEMATICA for different mechanical calculations; for thermal calculations ANSYS and also self developed and validated tools are used.

<table>
<tr><td></td><td>Full checking and recalculation with other calculation methods</td><td>Full recalculation with the same method</td><td>Comparison of the results with the maximum allowable values</td><td>Other Method</td></tr>
<tr><td>Mechanical stability</td><td>Depending from the safety margin</td><td>#</td><td>#</td><td>comparison with measure-ments by tests</td></tr>
<tr><td>Thermal stability</td><td>Depending from the safety margin</td><td>#</td><td>#</td><td>comparison with measure-ments by tests</td></tr>
<tr><td>Leaktight-ness (Activity leakage rate)</td><td>#</td><td>#</td><td></td><td></td></tr>
<tr><td>Shielding</td><td>#</td><td>#</td><td>#</td><td>comparison with measure-ment</td></tr>
<tr><td>Criticality safety</td><td>#</td><td>#</td><td>#</td><td>comparison with similar designs</td></tr>
</table>

In the case of shielding, criticality, mechanical or thermal behaviour evaluation own calculations are made. Additionally, in the case of shielding, mechanical and thermal evaluation own test measurement are made.

</td><td>A/B/C/D</td></tr>
<tr><td>Greece</td><td>No response</td><td>F</td></tr>
</table>

<table>
<tr><td>Hungary</td><td>
<table>
<tr><td></td><td>Full checking and recalculation with other calculation methods</td><td>Full recalculation with the same method</td><td>Comparison of the results with the maximum allowable values</td><td>Other Method</td></tr>
<tr><td>Mechanical stability</td><td>an option</td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal stability</td><td>an option</td><td></td><td>#</td><td></td></tr>
<tr><td>Leaktight-ness</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding</td><td>an option</td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td>an option</td><td></td><td>#</td><td></td></tr>
</table>
- The Design Safety Report has to convince the experts performing the assessment. To perform own calculations is a rather rare option.
</td><td>A/C/D</td></tr>
<tr><td>Ireland</td><td>No practice</td><td>E</td></tr>
<tr><td>Italy</td><td>
<table>
<tr><td>Calculation method</td><td>Verified by</td></tr>
<tr><td>Mechanical analysis</td><td>Independent evaluation</td></tr>
<tr><td>Thermical analysis</td><td>Independent evaluation</td></tr>
<tr><td>Shielding analysis</td><td>Independent evaluation</td></tr>
<tr><td>Criticality analysis</td><td>Independent evaluation</td></tr>
</table>
<table>
<tr><td></td><td>Full checking and recalculation with other calculation methods</td><td>Full recalculation with the same method</td><td>Comparison of the results with the maximum allowable values</td><td>Other Method</td></tr>
<tr><td>Mechanical stability</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal stability</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Leaktight-ness</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Criticality safety</td><td>#</td><td></td><td></td><td></td></tr>
</table>
- We require only calculation by the applicant

- Any appropriate calculation method for safety proof is allowed subject to justification of the method validity; same thing for the computer software.
- For criticality, thermal and shielding analysis, systematically checks by independent calculation.
- Comparison of the results with the maximum allowable values for mechanical and shielding analysis
</td><td>A/C/D</td></tr>
<tr><td>Latvia</td><td>- No real case yet</td><td></td></tr>
</table>

<table>
<tr><td></td><td><table>
<tr><td></td><td>Full checking and recalculation with other calculation methods</td><td>Full recalculation with the same method</td><td>Comparison of the results with the maximum allowable values</td><td>Other Method</td></tr>
<tr><td>Mechanical stability</td><td>#</td><td></td><td></td><td>#</td></tr>
<tr><td>Thermal stability</td><td>#</td><td></td><td></td><td></td></tr>
<tr><td>Leaktight-ness</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding</td><td>#</td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td></td><td></td><td>#</td><td></td></tr>
</table>
- Calculations are performed by the applicant.</td><td>A/C</td></tr>
<tr><td>Lithuania</td><td>No practice</td><td>E</td></tr>
<tr><td>Luxem-bourg</td><td>No practice</td><td>E</td></tr>
<tr><td>Malta</td><td>No practice</td><td>E</td></tr>
<tr><td>The Nether-lands</td><td><table>
<tr><td></td><td>Full checking and recalculation with other calculation methods</td><td>Full recalculation with the same method</td><td>Comparison of the results with the maximum allowable values</td><td>Other Method</td></tr>
<tr><td>Mechanical stability</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal stability</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Leaktight-ness</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td></td><td></td><td>#</td><td></td></tr>
</table>
- Any appropriate calculation method for safety proof is allowed; same thing for the computer software.
- For mechanical, thermal, shielding, criticality and leaktightness analysis, only a comparison of the results with the maximum allowable values is made. According to the security factor, a recalculation with the same method is made and if needed a recalculation with another method is performed.
- Verification by independent calculations of methods used by applicants</td><td>C</td></tr>
<tr><td>Poland</td><td><table>
<tr><td></td><td>Full checking and recalculation with other calculation methods</td><td>Full recalculation with the same method</td><td>Comparison of the results with the maximum allowable values</td><td>Other Method</td></tr>
</table></td><td>C</td></tr>
</table>

<table>
<tr><td></td><td><table>
<tr><td>Mechanical stability</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal stability</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Leaktight-ness</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td></td><td></td><td>#</td><td></td></tr>
</table>
- No own calculations.</td><td></td></tr>
<tr><td>Portugal</td><td>No response</td><td>F</td></tr>
<tr><td>Romania</td><td><table>
<tr><td>Calculation method</td><td>Verified by</td></tr>
<tr><td>The calculation methods already accepted by the country of origin of the package, provided that the method is generally accepted.</td><td>The expert organization recognized by the regulatory body of the country of origin of the package</td></tr>
</table>
<table>
<tr><td></td><td>Full checking and recalculation with other calculation methods</td><td>Full recalculation with the same method</td><td>Comparison of the results with the maximum allowable values</td><td>Other Method</td></tr>
<tr><td>Mechanical stability</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Thermal stability</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Leaktight-ness</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Shielding</td><td></td><td></td><td>#</td><td></td></tr>
<tr><td>Criticality safety</td><td>#</td><td></td><td>#</td><td></td></tr>
</table>
- For calculations, independent review can be requested to be assured by the applicant.</td><td>C/D</td></tr>
<tr><td>Slovak Republic</td><td>- No response</td><td>F</td></tr>
<tr><td>Slovenia</td><td>- Usually accepted method is numerical (Finite element method, Finite difference method, Finite volume method, Finite volume method, and Boundary element Method) and if it is possible analytical evaluations too.
- We have never made such detailed checking.
- It is required calculations performed by the applicant.</td><td>C</td></tr>
</table>

<table>
<tr><td>Spain</td><td>The same methods used by the CSN are accepted to be used by the applicant (see answer under 6.2.4.6 , “Evaluation for the approval and validation of transport packages”. PT.IV.28. Rev. 0. 26/03/01). In case that different model or calculation methods are used, the applicant have to justify its validity for the particular case: a justification usually accepted is to compare the results of calculations with results of practical tests conducted for similar packages previously approved. In some occasions the CSN requires to perform part of the tests to verify the results of the calculation methods.
<table>
<tr><td></td><td>Full checking and recalculation with other calculation methods</td><td>Full recalculation with the same method</td><td>Comparison of the results with the maximum allowable values</td><td>Other Method</td></tr>
<tr><td>Mechanical stability</td><td colspan="4">Full checking of calculations made by the applicant. When it is considered necessary a full recalculation with the same or different method may be used for some particular cases.</td></tr>
<tr><td>Thermal stability</td><td colspan="4">Full checking of calculations made by the applicant. When it is considered necessary a full recalculation with the same or different method may be used for some particular cases.</td></tr>
<tr><td>Leaktight-ness</td><td colspan="4">Full checking of calculations made by the applicant. When it is considered necessary a full recalculation with the same or different method may be used for some particular cases.</td></tr>
<tr><td>Shielding</td><td>#</td><td>#</td><td></td><td></td></tr>
<tr><td>Criticality safety</td><td colspan="4">Full checking of calculations made by the applicant. When it is considered necessary a full recalculation with the same or different method may be used for some particular cases.</td></tr>
</table>
- At present, only calculations by the applicant are required.

- Any appropriate calculation method for safety proof is allowed subject to justification of the method validity; same thing for the computer software.
- A full checking of mechanical, thermal, leaktightness, shielding and criticality analysis is made only if it is considered necessary.</td><td>A/B/C/D</td></tr>
<tr><td>Sweden</td><td>- Acceptable calculation methods are not defined.
- For validations: Own calculations are only made when we find uncertainties in the methods used in the SAR or when the result is questioned. For package design approvals: A more detailed examination is made but usually not complete recalculations.
- We only require calculations made by the applicant.</td><td>C</td></tr>
<tr><td>Turkey</td><td>No practice</td><td>E</td></tr>
<tr><td>United</td><td>- Anything which is justified and verified</td><td></td></tr>
</table>

Kingdom		Full checking and recalculation with other calculation methods	Full recalculation with the same method	Comparison of the results with the maximum allowable values	Other Method	**A/B/C/D**
	Mechanical stability	Yes	Yes	Where there are large safety margins		
	Thermal stability	Yes	Yes			
	Leaktight-ness		Yes			
	Shielding		Where the accident conditions vary from the normal conditions w.r.t. shielding	Normal conditions of transport		
	Criticality safety	Yes - the most appropriate method is used.	Yes	Yes - normally for very low content packages	Yes	
	- We perform our own calculations in appropriate cases.					

6.2.4.3.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	Check of DSR calculation proofs by **full checking and recalculation with other calculation methods**	**9**
B	Check of DSR calculation proofs by **full recalculation with the same method**	**6**
C	Check of DSR calculation proofs by **comparison of the results with the maximum allowable values**	**15**
D	Check of criticality safety proof in general by full checking and recalculation with other calculation methods	**9**
E	No practice	**8**
F	No response	**4**

6.2.4.3.3 SUMMARY AND DISCUSSION

For calculated proofs of a package design's safety aspect the competent authorities accept in general any calculation method (standard, code and computer software) which is justified and verified. The applicant has to give the evidence for the applicability of the method and the verification of the calculated results.

The procedure regarding the assessment of calculated proofs of a package design in the areas of mechanical stability, thermal stability, leaktightness (activity leakage rates), shielding and criticality safety can be divided into the groups:

- Full checking and recalculation with other calculation methods (category A)
- Full recalculation with the same method (category B)
- Comparison of the results with the maximum allowable values (category C)
- Other Method

Nine countries apply in their procedure mainly an assessment of full checking and recalculation with other calculation methods (category A).
Six countries apply a full recalculation with the same method (category B).
All countries with assessment practice (15 – category C, except Czech Republic) apply the comparison of the calculated results with the maximum allowable values which is the first assessment step. The competent authority of the Czech Republic or independent assessors perform in any cases a full recalculation with the same or other calculation method.

A detailed recalculation of the proof is not in any case performed, it depends for some experienced competent authorities on the value of the safety margins, the experience with the assessment of similar package designs, or if there are doubts on the applied calculation method. Then an additional recalculation is necessary.
A recalculation is performed in eight countries by the competent authority or independent assessors and in two countries by the applicant on request of the competent authority.

The assessment of the criticality safety is a special area. In nine countries the competent authority or independent assessors check the criticality safety proof in general by full checking or recalculation with other calculation methods.

For FEM analysis with calculation codes like DYNA, ANSYS and ABAQUS exist the problem of the verification of the calculation model, that means e.g. for codes for the mechanical accident analysis that verification has to be done for

- All packagings and their components (cask, bolted assembly, shock absorber, content, shielding)
- All drop tests (9 m, 1 m)
- All drop positions/drop angles.

There are further requirements for computer based numerical calculations regarding the completeness, modelling, the extent of data, the demonstration of data and the justification of the results.

In addition to full-scale tests of a package, reference to previous demonstrations of a sufficiently similar nature, scale model tests, calculations, reasoned arguments or combinations of thereof may be used to demonstrate compliance.

When considering reference to previously satisfactory demonstrations of a similar nature, it is necessary to consider all the similarities and the differences between two packages. The areas of difference may require modification of the results of the demonstration.

When scale models are used, certain parameters cannot be adjusted such as damage due to the effect of scaling for all areas of difference.

To extrapolate the results of scale model testing, calculations can be used. In this case, any appropriate calculation method for safety proof and any computer software is allowed subject to justification of validity. It is necessary to check if the calculation method is applicable for the intended calculation and if it adequately represents the packaging under review for the purpose of compliance. To check the applicants' calculations, the EU countries should use the relevant ISO standards and codes such as ANSI, ASME, DIN, CODAP…

6.2.4.3.4 CONCLUSIONS AND RECOMMENDATIONS

- See also chapter 6.2.4.5
- Any appropriate calculation method for safety proof should be allowed subject to justification of the method validity.
- The competent authority should ensure that proper codes and models have been used, that they have been adequately verified by appropriate experiments and that all input data have been defined conservatively or correctly.
- A procedure for the use of computer based numerical analysis like FEM for calculation proof should be developed (see BAM GGR 008 – chapter 6.2.4.1).

6.2.4.4 ITEM: TEST PROGRAM FOR PACKAGE DESIGN

This item contains the requirement of a test program for the package, the kind of justifications concerning the most damaging package attitudes for the drop and fire test and if the CA require before acceptance of test program a description and design of the safety features.

6.2.4.4.1 LIST OF PRACTICES FOR THE ITEM AND ISSUE ABOVE

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**E**
Belgium	- For packages where Belgium is the country of origin we do ask to discuss a proposed test program. The applicant has the freedom of justification methodology (calculation, testing or a combination). However he is invited to discuss his methodology in an early stage in the design process, including the proposed physical test program. - We can only accept a testing program if a minimum information concerning the package design is transmitted such as the purpose of the package and the safety features meant to satisfy the requirements.	**A/B**
Bulgaria	No practice	**D**
Cyprus	No practice	**D**
Czech Republic	SONS does not require a test program for the package. SONS requires justification analysis concerning the selection of the most damaging package attitudes for the drop tests and for the fire test.	**C**
Denmark	No a priori requirements (i. e. in addition to the IAEA Regs.)	**C**
Estonia	No practice	**D**
Finland	No practice	**D**
France	- A test program is required and approved by the competent authority - Before acceptance of the test program, a functional report of the package safety is required	**A/B**
Germany	- The demonstration of compliance has to be performed according to IAEA para 701. BAM accepts all kinds of qualifications provided that the applicant can demonstrate the applicability of the method and the correctness of the results. BAM require in general the Design Safety Report of the submitted design type. BAM require appropriate pre-calculations which should establish the drop positions, the drop sequence and the instrumentation of the test model.	**A/B**
Greece	No response	**E**

Hungary	- The Design Safety Report has to contain the test program and the justification for the selection of the most damaging attitudes. It should be noted, however, that it is a common practice, that the corresponding experts of the HAEA and the IISC are present during the domestic tests and - if it seems to be necessary - they can raise concern prior to them. - It is not required. It is enough if the Design Safety Report is convincing for the experts performing the assessment. It should be noted, however, that it is a common practice to discuss the test programme with the domestic applicant prior to the tests.	**A**
Ireland	No practice	**D**
Italy	- A test program is required for the package. Normally the test program is made by the applicant in accordance with the competent authority. The selection of the most damaging package attitudes for the drop tests and the fire test conditions are discussed with the applicant taking also into account previous national or international experiences. - Before acceptance of the test program, a functional report of the package safety is required	**A/B**
Latvia	We require the reference to tests performed in other countries. We haven't such possibilities to do the tests yet.	**D**
Lithuania	No practice	**D**
Luxem-bourg	No practice	**D**
Malta	No practice	**D**
The Nether-lands	- Acceptance of national programmes performed and/or used in other countries in case of a Dutch certificate (no validation) a programme will be set up in close cooperation with the applicant. - No functional report of the package safety is required before acceptance of the test program.	**A**
Poland	- Only documents on the basis of ADR are required. - No functional report of the package safety is required before acceptance of the test program.	**C**
Portugal	No response	**E**
Romania	Yes; results of similar tests performed previously for different package attitudes for the drop test and fire test or, sound engineering judgment.	**A**
Slovak Republic	No response	**E**
Slovenia	- Yes, the test program shall consider the requirements	

	prescribed in ADR or IAEA, Safety Standards Series, Regulations for the Safe Transport of Radioactive Material, No. TS-R-1 (ST-1, Revised). - It is required the description of intended containment system, confinement system, heat dissipation system and expected performances in accident conditions. -	**A/B**
Spain	- In case of the approval of package a justification of the compliance with the test requirements established in the regulations are required. This justification may be carried out trough the ways permitted by the regulations: arguments, calculations, reference to similar packages or practical tests. In case of the practical tests option the applicant have to present the test program for evaluation by the competent authority. In this process is discussed the different aspects of the tests, i. e. the package attitudes for the mechanical and thermal tests. No particular methods to justify this aspect or another are established; the applicant can use calculations, test modelling or any technical arguments. After the test programme is accepted the competent authority would attend to the whole programme or to the main parts. This process usually happens before the final (official) application is presented; so, a final report about the tests (process and results) will be a part of the application for the approval of the package. - Of course, a detailed description of the packages are absolutely necessary for an adequate analyse of the test programme.	**A/B**
Sweden	- The applicant has to defend his approaches and the suggested testing program may be assessed by the “Swedish National Testing and Research Institute” or any other expert chosen by the Competent Authority. - A test program does not need to be accepted in advance but is usually discussed in advance with the Competent Authority (see above). It is up to the applicant to convince the authority that he has fulfilled the regulations when he applies for a certificate.	**C**
Turkey	No practice	**D**
United Kingdom	- Yes. We require a QA programme for the tests. Worst orientation may be justified by multiple tests, preliminary analysis, reasoned argument - comparison, hand calculations, numerical analysis. It is noted that there may be more than one "most" damaging attitude depending on the safety feature being tested. - Although not required this would be expected. Experience has shown that earlier involvement of the regulators in the test programme has removed risks (for example the regulator may identify a pre/post test measurement that they consider essential that is outside the plan). The more information supplied in advance the more likely it is that such problems can be identified.	**A/B**

6.2.4.4.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	A test program is required and approved by the competent authority	**10**
B	Before acceptance of the test program, a functional report of the package safety is required/expected	**7**
C	No test program is required	**4**
D	No practice	**10**
E	No response	**4**

6.2.4.4.3 SUMMARY AND DISCUSSION

Most of the countries with test practice (10, category A) require in case of package design tests a test program which has to be approved by the competent authority. Seven of these countries (category B) require before the acceptance of the test program additionally the transmittal of a functional report of the package safety (description of intended containment system, confinement system, heat dissipation system, expected performances in accident conditions).
Only four countries (category C) do not require a test program.

In the test program several countries require a justification analysis concerning the selection of the most damaging package attitudes for the drop tests and for the fire test).

Ten countries have no practical experience in this field.

Establishing a test program gives confidence that tests will provide the adequate demonstrations. On the contrary, if the test program is not submitted to competent authority approval, the competent authority may later request additional testing which represents time and cost drawbacks.

6.2.4.4.4 CONCLUSIONS AND RECOMMENDATIONS

- See chapter 6.2.1.3

- A test program should be required. The test program should include the items and should be implemented according to the considerations given in Annex 6.

6.2.4.5 ITEM: PERFORMANCE OF PACKAGE DESIGN TESTS BY THE APPLICANT AND TESTS FOR SPECIAL PROOFS

This item contains the control and reliability of tests if they are carried out by the applicant and the performance of tests for the confirmation of proofs by the CA itself in special cases.

6.2.4.5.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**G**
Belgium	- Concerning the completeness of a test programme, we review the documents in which the actual tests have been justified. However, if we think that a test which has not been performed could result in serious safety problems, we will ask for additional justifications. To verify the reliability of the performed test, we would like to witness the tests. For Belgian applicants, we also ask to be involved in the setup of the test programme.	**A/D**
Bulgaria	No practice	**E**
Cyprus	No practice	**E**
Czech Republic	- SONS controls the completeness and reliability of tests by presence of its inspectors during realization of the tests, if it is possible. - SONS does not perform own tests.	**A**
Denmark	- General reliance on the applicant's data	**B**
Estonia	No practice	**E**
Finland	- STUK should be informed about the tests in advance and be enabled to view the tests on site (if deemed necessary)	**A**
France	- To demonstrate the compliance with required tests and expected results, test and calculations, if justified, are accepted	
Germany	- For specific investigations, like corrosion, non-destructive material tests, tests on plastics or ease of decontamination, BAM can cooperate with their own experts and with other institutions or can require additional proofs by the applicant.	**A/C/D**
Greece	No response	**F**
Hungary	- The experts of the HAEA and the IISC are present during the domestic tests.	**A**
Ireland	No practice	**E**
Italy	- By the evaluation of the test program and by the analysis of	

	the quality assurance program of the applicant and by the presence during the tests. - We require only tests and no calculations by the applicant.	**A/D**
Latvia	- Tests shall be done at internationally recognised test facilities by their experts, Authority can perform only comparison of the results with the maximum allowable values.	**A/D**
Lithuania	No practice	**E**
Luxem-bourg	No practice	**E**
Malta	Not practice	**E**
The Nether-lands	- Discussion before the tests before with the applicant and presence of CA during the tests. - Only tests are required and tests are performed by the applicants	**A/D**
Poland	- Completeness we control by analyse obtained documents from applicant. - Only tests are required	**B/D**
Portugal	No response	**F**
Romania	- Through the test certificate issued by the approved test facility, and in some cases through inspections and audits performed at the approved test facility - Tests are requested to be performed by approved test facility. For validation of original certificates, test recognized by original competent authority are recognized by CNCAN.	**A**
Slovak Republic	- Independent control of tests. - No own tests.	**A**
Slovenia	- Through inspections. - It is required tests	**A**
Spain	- The test programme is evaluated and experts of the competent authority attend to the tests. - At present, only tests by the applicant are required.	**A/D**
Sweden	- The tests are usually witnessed by experts which represents the competent authority, such as the “Swedish National Testing and Research Institute” together with representatives of the competent authority. And since there are years between this type of applications, this has to be treated on a case by case basis. - We only require tests made by the applicant.	**A/D**
Turkey	No practice	**E**
United Kingdom	- Review, inspection and oversight. The test programme is assessed. We examine the results. We may require ANY additional tests we wish - including non-regulatory tests.	**A/D**

6.2.4.5.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	Independent control of performance of package design test by the applicant by independent witnessing the tests	**14**
B	No independent control of performance of package design test by the applicant	**2**
C	Own additional tests for special proofs are possible	**1**
D	Additional tests for special proofs by the applicant are possible	**9**
E	No practice	**9**
F	No response	**3**

6.2.4.5.3 SUMMARY AND DISCUSSION

In case of the performance of tests by the applicant nearly all countries with practice (14, category A, see also chapter 6.2.4.4) control the test performance by independent witnessing. Two countries (category B) check only the documents about the tests.
For the consideration of the test results in the assessment process it is very important for the assessor to have the guarantee that the tests are performed in a complete and reliable manner.

Tests for special proofs can be required by all competent authority of the countries but in nine countries only the applicant is responsible for these additional tests. Only in Germany there is the possibility to perform own tests or investigations by a nominated responsible Federal institution.
In case of new scientific and technical development or practical uncertainties in the field of package design assessment it is important for the competent authority to require additional tests or experiments. These necessary tests or investigations should be actively accompanied by the competent authority to use the results for increasing the assessment competence. The performance of such tests by the competent authority or the technical support increase additionally the technical knowledge in special fields and improve the assessment methodology.

6.2.4.5.4 CONCLUSIONS AND RECOMMENDATIONS

- See chapter 6.2.1.3.4
- A witness of experimental package design tests by independent experts who confirm the completeness and reliability should be required in all cases by the competent authority.
- Necessary tests or investigations in case of new developments or in case of practical uncertainties in the field of package design assessment should be actively accompanied by the competent authority to increase its assessment competence.

6.2.4.6 ITEM: ISSUE OF AN ASSESSMENT REPORT AND ITS STRUCTURE

This item contains procedures for the preparation of the assessment report, the issue of an assessment report and its structure.

6.2.4.6.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**F**
Belgium	– The internal procedures are in a developing phase. The general structure of an assessment consists of the following phases: • Reception of the application; • Preliminary examination of the Design Safety Report and writing of a assessment proposal; • Assessment according to the proposal accepted by the head of service; • Writing of the approval or validation certificate – The competent authority writes an assessment report. The assessment report is not sent to applicants. – The assessment report has to following structures: • Summary of relevant information about the application; • Brief description of the packaging and the allowed contents; • The findings of the assessment, which are structured according to the various safety aspects: – Description of packaging and allowed content; – Mechanical analysis; – Thermal analysis; – Containment analysis; – Criticality analysis; – Handling procedures; – Maintenance and acceptance tests; – Quality Assurance; • The conclusion of the assessment.	**A/C**
Bulgaria	No practice	**E**
Cyprus	No practice	**E**

Czech Republic	There are not such instructions. Depending on the case the SONS chairman establishes "ad hoc" assessment team and its leader by written instruction. The structure of Safety Evaluation Report (SER) is analogical to the structure of SER for other similar cases i. e. approval of NPP operation. The competent authority writes an assessment report. Structure of the assessment report (Safety Evaluation Report): A) contents B) list of used abbreviations C) reason of the evaluation D) brief description of the evaluated Safety Analysis Report or its part E) methodology of the evaluation, criteria used F) description of the evaluation procedure G) results of the evaluation H) requirements for the Safety Analysis Report completion I) remarks of the assessor J) summary evaluation	**B/C**
Denmark	No practice	**E**
Estonia	No practice	**E**
Finland	- No internal procedures for the preparation of the assessment report - When the original foreign method of assessment or calculation program is not known, the values (usually criticality safety) are recalculated by STUK. In addition to this STUK may order a reference assessment from an independent (Finnish) organization.	**B/D**
France	– Technical support issues an assessment report. The assessment report is sent to applicants.	**C**

Germany	Yes, there are internal guidelines, checklists and sample reports for various design types (BAM) and approval types (BfS) as part of a QA program. The competent authorities write an assessment report. The assessment report contains the following information: – general information about the application (applicant, date of application, name of package design, transport mode, Safety Analysis Report) – reference to BAM assessment report – identification mark for the package design – responsible project leader – results of detailed checking of: – completeness – shielding analysis report – criticality analysis report – specific provisions for the certificate, if necessary – results of detailed checking of – mechanical behaviour of all safety relevant components – thermal behaviour of all safety relevant components – release behaviour of the package – quality assurance	**A/C**
Greece	No response	**F**
Hungary	– The administrative part/framework has written procedure, however, the assessment is not standardized. – The competent authority writes an assessment report. – The assessment report does not have a standardized structure. However, it has to assess the corresponding implementations of the minimum requirements of TS-R-1 in the international modal transport regulation.	**A/C**
Ireland	No practice	**E**
Italy	– No internal procedures for the preparation of the assessment report – The competent authority writes an assessment report. The assessment report is not sent to applicants. – The structure of the assessment report is essentially a list of all the paragraphs of IAEA Regulations that are relevant for the approval. For each paragraph an analysis of compliance between the requirements or provisions requested by the IAEA paragraph and what is reported in the safety report to satisfy those requirements or provisions is made.	**B/C**
Latvia	No practice	**E**
Lithuania	No practice	**E**
Luxem-bourg	No practice	**E**
Malta	No practice	**E**

The Nether-lands	No assessment report	**B/D**
Poland	– There are no written internal procedures. – No assessment report	**B/D**
Portugal	No response	**F**
Romania	– No written internal procedures for the preparation of an assessment report – No assessment report	**B/D**
Slovak Republic	No response	**F**
Slovenia	– Yes, the internal procedures consider requirements in ADR. – It is the technical support organization assessment report. – The structure of the assessment report shall be: Scope of Work; Codes, Standards and Regulatory Requirements; Design Requirements; Fabrication and Assembly Requirements; Testing; Conclusions.	**A/C**

Spain	– Yes, “Evaluation for the approval and validation of transport packages”. PT.IV.28. Rev. 0. 26/03/01. – Technical support emits an assessment report. The assessment report is not sent to applicants. – For approvals/validations of packages: – Background (previous approvals/validations, approval of the country of origin, type of package, IAEA edition, modes of transport) – Report objective – Application (Regulatory basis, documentation supporting the application) – Package description – Assessment (argument on the compliance of the relevant requirements established in the regulations for that type of package) – Conclusions – Procedures applied – References – Annex: – Specifications and conditions for the certificate – Basic drawing of the package – Particular assessment reports: mechanical, thermal, shielding, criticality, quality assurance. – For approvals of shipments: – Background (about the shipment or/and similar shipments approvals in the past) – Report objective – Application (regulatory basis, documentation supporting the application, fundamental data of the shipment: material, package, origin, destiny, itinerary, consignor, carrier, planning of transport) – Assessment (argument on the next relevant points: package, packaging maintenance, handling procedures, compliance of stowage and storage limits, emergency arrangements, particular restriction for the different modes of transport, itinerary, liability assurance, security, justifications and compensatory measures for special arrangement) – Conclusions – Procedures applied – References – Annex: – Specifications and conditions for the approval – Assessment report from the expert Units: mechanical, thermal, shielding, criticality, quality assurance.	**A/C**
Sweden	– No written internal procedures for the preparation of an assessment report – In case when a technical support organization is involved, they usually make a report, for example on criticality safety or any other issue evaluated by them. Not specified structure for the assessment report.	**B/D**
Turkey	No practice	**E**

United Kingdom	– Yes, we call them desk instructions. This is an old term used in the civil service which describes the rule book which tells you how to carry out your job. – We write three assessment reports: QA - Review against specified criteria such as documentation, specifications, quality standards and outstanding issues from audits & inspections etc). Engineering - report based on format of applicants guide. Criticality - standard report format concentrating on regulatory requirements.	**A/C**

6.2.4.6.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	Written internal procedures for the preparation of an assessment report	**6**
B	No written internal procedures for the preparation of an assessment report	**7**
C	There is an competent authority or technical support assessment report	**9**
D	In general no competent authority or technical support assessment report.	**5**
E	No practice	**10**
F	No response	**4**

6.2.4.6.3 SUMMARY AND DISCUSSION

Nearly half of the countries (category A) with assessment practice have written internal procedures for the preparation of the assessment report.
Nine countries (category C) issue in any case a report about the results of their assessment work. Five countries abstain from this practice or they issue an assessment report only in special cases, e.g. for the criticality safety.

An assessment report shall be written to identify and record the verifications performed during assessment and the reasons of the conclusion of the assessment. Moreover, in the case of validation, the competent authority has the option of either performing a separate safety assessment or making use of the assessment already done by the original competent authority, thus limiting the scope and extent of their own assessment. In case it would be useful that a report from the competent authority of the country of origin of the package design is available.

The assessment report should be sent to the applicant because the transparency of the assessment makes it easier for the applicant to understand the technical issues raised by the assessment, and then to improve either the safety justifications or the design itself.

6.2.4.6.4 CONCLUSIONS AND RECOMMENDATIONS

- An assessment report should be written for each appraisal
- This assessment report should be sent to applicants, and to CA, if needed
- The format of the assessment report should be harmonized in all EU countries
- This report should contain at least the information given in Annex 7

6.2.4.7 ITEM: ASSESSMENT TIME ACCORDING TO THE APPROVAL CERTIFICATE TYPE

This item contains the average assessment time between the application receipt and the certificate issue.

6.2.4.7.1 LIST OF PRACTICES

Country	Country specific practice to the above named item		Category of practice
Austria	No response		
Belgium	New design approval	6 months – 2 years	
	Renewal	A few months	
	Extension	A few months	
	Validation	A few months	
	Shipment approval	A few weeks	
	Special arrangement	A few weeks to a few months	
Bulgaria	One month		
Cyprus	No practice		
Czech Republic	New design approval	3 month - 3 years	
	Renewal	2 months	
	Extension	2 months	
	Validation	2 months	
	Shipment approval	3 months	
	Special arrangement	3 months	
Denmark	New design approval	Approximately 4 weeks	
	Special arrangement	Approximately 4 weeks	
Estonia	No practice		
Finland	New design approval	6 months	
	Renewal	3 months	
	Extension	1 month	
	Validation	3 months	
	Shipment approval	1 month	
	Special arrangement	1 month	
France	New design approval	12 months	
	Renewal	6 months	
	Extension	4 months	
	Validation	6 months	
	Shipment approval	4 months	
	Special arrangement	6 months	
Germany	New design approval	from some months to some years	
	Renewal	from some weeks to some months	
	Extension	from some weeks to some months	
	Validation	from some weeks to some months	

	Shipment approval	from some weeks to some months	
	Special arrangement	from some weeks to some months	
Greece	No response		
Hungary	New design approval	6-7 months	
	Renewal	2-3 months	
	Extension	2-3 months	
	Validation	2-3 months	
	Shipment approval	2-3 months	
	Special arrangement	2-3 months	
Ireland	No practice		
Italy	New design approval	1 – 1,5 year	
	Renewal	2 months	
	Extension	6 months	
	Validation	3 months	
	Shipment approval	3 months	
	Special arrangement	6 months	
Latvia	New design approval	40 days	
	Renewal	10 days	
	Extension	10 days	
	Validation	20 days	
	Shipment approval	20 days	
	Special arrangement	20 days	
Lithuania	No practice		
Luxem-bourg	No practice		
Malta	New design approval	Not applicable	
	Renewal	Not applicable	
	Extension	Not applicable	
	Validation	Not applicable	
	Shipment approval	2 days	
	Special arrangement	Not applicable	
The Nether-lands	New design approval	1 or 2 years	
	Renewal	1 year	
	Extension	A few months	
	Validation	1 month	
	Shipment approval	1 month	
	Special arrangement	1 month	
Poland	New design approval	2 months	
	Renewal	1 month	
	Extension	1 month	
	Validation	1 month	
	Shipment approval	1 month	
	Special arrangement	1 month	
Portugal	No response		
Romania	New design approval	90 - 150 days	
	Renewal	30-60 days	
	Extension	30-60 days	

	Validation	30-90 days	
	Shipment approval	10-30 days	
	Special arrangement	20-45 days	
Slovak Republic	No response		
Slovenia	After getting the complete documentation, in all above cases the maximum assessment time is 2 months, the minimum assessment time is a few weeks.		
Spain	New design approval	12 months	
	Renewal	4 months	
	Extension	1 month	
	Validation	3 months	
	Shipment approval	2 months	
	Special arrangement	3 months	
Sweden	New design approval	1-3 years	
	Renewal	1-6 months	
	Extension	1-6 months	
	Validation	1-6 months	
	Shipment approval	(no experience)	
	Special arrangement	1-6 months	
	(This varies very much depending on the complexity of the case. We have no statistical follow-up of the time needed. There are only a handful of Swedish package designs and we seldom receive an application for approval of a new package design. There are years between such applications. Multilateral approvals of foreign package designs are in Sweden usually effected by validation of the original certificate. The handling time varies for a validation from a few weeks when the design is already known in Sweden, up to several years for a new package design where Sweden is the country of origin of design.)		
Turkey	No practice		
United Kingdom	New design approval	See in chapter 6.2.3.1 our standard times. However we always request the applicant gives us a "required by" date and attempt to work with applicants to deliver to a suitable timescale. As a result some applications take a long time - some are very quick. We operate a first applied - first assessed basis but allow applicants to exchange priorities with each other.	
	Renewal		
	Extension		
	Validation		
	Shipment approval		
	Special arrangement		

6.2.4.7.2 SUMMARY AND DISCUSSION

It is noticed that the assessment time for a new design approval takes in average 12 months. An assessment for renewal, extension, validation takes in average 3 months. For special arrangement and shipment the assessment time of the countries is in average 1 up to 2 months.

However these data are only experience feedback of spent assessment times. The assessment time depends mainly on the type and novelty of package design and the kind of demonstrations of the safety proofs of the package design by the applicant in the Design Safety Report. That is why the applicant should know the detailed requirements of the competent authority or technical support regarding the safety proofs and the issue of the DSR (see chapter 6.2.2.4 and 6.2.4.1). It could also be helpful to contact the competent authority or technical support by the applicant before application to present the package design and to discuss the requirements of the safety proofs. In general the time of assessment may not be limited by a fixed data.

The indicated times are average ones; they are only indicative and applicable only when no special difficulty implies delaying the assessment. They include some time necessary to the applicant to provide some complementary justifications to a limited extent.

6.2.4.7.3 CONCLUSIONS AND RECOMMENDATIONS

A time for the assessment can only be a guidance level for the applicant. The real time depends mainly on the type of package design, on the quality and completeness of the safety proofs of the package design by the applicant in the Design Safety Report and eventually on the reactivity of applicant to provide complementary justifications when requested as well as on resources of competent authority and technical support.

Nevertheless, the competent authority should give guidance material to the applicant with its requirements for the issue of the safety proofs. A guideline as recommended in chapter 6.2.4.1.4 and a systematic presentation of the package design by the applicant to the competent authority and its technical support, before performance of tests, could permit to evaluate quickly the difficulties and then decrease assessment time encountered when the tests are already performed and the Design Safety Report, already written.

6.2.4.8 ITEM: DIFFICULTIES ENCOUNTERED SEVERAL TIMES DURING ASSESSMENT

6.2.4.8.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	

Belgium	In the past, we have had some problems with:
	- The use of non-scientific arguments such as “It was already been approved in our country, so there is no problem”,
	- Badly organised Design Safety Reports,
	- Safety reports where it is not always obvious if all requirements are satisfied because of no direct link between requirements and demonstration of the requirements,
	- Poor knowledge of the applicant of the regulations and the guidance of the regulations with wrong interpretations of the requirements as a consequence,
	- The justification of the conservative nature of differences between a model and the reality (geometry, material properties, …) often gives rise to discussion. Some specific problems that we have encountered are:
	  - The evolution of material properties during the thermal test has not been considered properly,
	  - The differential flooding case is not always adequately treated in the criticality analysis.	

Bulgaria	No practice	
Cyprus	No practice	
Czech Republic	- SONS finds this difficulties: A. Incompleteness (Safety Analysis Report contains only statements, not proofs; or references to, not available document) B. Insufficientness (Safety Analysis Report contains calculations made by archaic way of calculation or by codes which was not validated) C. Missing justification (i. e. assessment of arrangement of drop test which will lead to the maximum damage)	
Denmark	No practice	
Estonia	No practice	
Finland	Unknown (undocumented) calculation methods	
France	The most recurrent issues are developed in the feedback experience document (attached).	

Germany	We found any difficulty possible in the different Design Safety Reports.	
Greece	No response	
Hungary	Typical problems are the insufficient justification and the incomplete Design Safety Report.	
Ireland	No practice	
Italy	No response	
Latvia	We haven't real case.	
Lithuania	No practice	
Luxem-bourg	No practice	
Malta	No practice	
The Nether-lands	Difficulties on the tests program	
Poland	No practice	
Portugal	No response	
Romania	Sometimes the report is incomplete, or insufficient. Other times the requirements of TS-R-1 are not fulfilled totally, and modifications are necessary in the design.	
Slovak Republic	No response	
Slovenia	Not applicable	
Spain	The more common problem is to receive incomplete information (not all requirements of the regulations are sufficiently considered). In some occasions the justifications are very general (no focused on the particular requirement).	
Sweden	When we validate foreign certificates we frequently find incomplete criticality assessments. (Worst cases are not covered.) Different parts of the safety report are not always in conformance.	
Turkey	No practice	
United Kingdom	- Incomplete applications; inaccurate applications; commercial sensitivities; late "urgent" applications; validation - how to maintain international validity on renewal; slow applicant response.	

6.2.4.8.2 SUMMARY AND DISCUSSION

The mainly reported difficulties encountered several times during assessment are:

- The use of non-scientific arguments such as “It was already been approved in our country, so there is no problem”,
- Badly organised safety analyse reports,
- Poor knowledge of the regulations or/and the guidance of the regulations with wrong interpretations of the requirements as a consequence,
- Design Safety Report contains only statements without justifications; or references to not available document,
- Design Safety Report contains no justified calculations or no validated codes
- Design Safety Reports where it is not always obvious if all requirements are satisfied because of no direct link between requirements and demonstration of the requirements,
- The justification of the conservative nature of differences between a model and the package design (geometry, material properties, …) often gives rise to discussion. Some specific problems which are encountered are:
    - The evolution of material properties has not been considered properly,
    - The differential flooding case is not always adequately treated in the criticality analysis.
- Missing justification (i. e. justification of orientation of package design during drop test which will lead to the maximum damage)
- Incomplete criticality assessments (worst cases are not covered, no applied justification or justifications not applicable to transported contents)

Regarding the assessment there are mainly problems with the structure of the DSR and the demonstration of safety. The recommendations given in chapter 4.4 should help to remove these problems.

Additionally, a French document called ‘Feedback experience document lists technical difficulties most frequently encountered in Design Safety Reports assessments. These difficulties include some of the preceding difficulties. This document is sent to all applicants so that they take into account its recommendations to improve the Design Safety Reports before their submittal.
This document is periodically up-dated (every year or two years) to take into account the most recent evolutions of the regulations which may raise difficulties, and all new difficulties recorded since the last issue. This feedback experience document could be completed with the feedback experience gained in the other EU countries.

6.2.4.8.3 CONCLUSIONS AND RECOMMENDATIONS

To avoid incomplete Design Safety Reports with insufficient safety proofs the following recommendations could be given:

- See recommendations in chapter 4.4 and 6.2.2.4
- Development of a European feedback experience document which list all encountered difficulties in design safety assessment
- Update of this document periodically (the period should be determined) under review by the DGTREN standing working group
-
- This document should be sent to applicants and used by them for preparing new Design Safety Report.
- Update of an European applicant list
- The content of the “Experience feedback in the appraisal of package design safety” is given in Annex 8.

6.2.5 JOINT CERTIFICATION PRACTICES

This item contains the joint certification practices between EU countries or applicant countries.

6.2.5.1 LIST OF PRACTICES

Country	Country specific practice to the above named item	Category of practice
Austria	No response	**D**
Belgium	Only with the relevant European countries in the validation process of the H(M) package approval for 48X and 48Y cylinders.	**C**
Bulgaria	No practice	**C**
Cyprus	No practice	**C**
Czech Republic	There are not joint certification practices with other EU countries or applicant countries in the past.	**C**
Denmark	No practice	**C**
Estonia	No practice	**C**
Finland	No practice	**C**
France	Appraisal co-operation for a few applications: validation process of the H(M) package approval for 48Y cylinders, Fuel Integrity Project (F.I.P), appraisals for NTL 11, NCS 45, TN 81 packages, Castor S1	**A/B**
Germany	Joint certification practice between France and Germany is currently performed for the NCS-45 package design (for irradiated fuel rods and fuel pellets) and the TN 85 package design (for high level vitrified radioactive waste) and for the H(M)- and H(U)-certificate. NCS 45, TN 81, Castor S1	**A/B**
Greece	No response	**D**
Hungary	Although we do not have joint certification practices with EU countries, the followed practices should be similar, as Hungary joined e.g. to the ADR and RID.	**C**
Ireland	No practice	**C**
Italy	No practice	**C**
Latvia	We haven't such practice with other countries.	**C**
Lithuania	No practice	**C**

Luxem-bourg	No practice	**C**
Malta	No practice	**C**
The Nether-lands	No, but Belgium, Luxembourg and Holland accepted their import licences under some restrictions.	**C**
Poland	No practice	**C**
Portugal	No response	**D**
Romania	Shipment of radioactive materials involving Romanian territory shall comply with requirements of EU regulations regarding shipment of radioactive wastes and substances (i.e. Directives 92/3 EURATOM and 1493/EURATOM), transposed by Romanian regulations. Consequently, the forms required in the 2 EU regulations have to be filled accordingly.	**C**
Slovak Republic	Yes, maybe in the future.	**C**
Slovenia	No practice	**C**
Spain	Spanish authority only has participated in the common European approach for the approval of the 48" cylinders with UF6 (validation of the certificate USA/0592/H(M)-96).	**B**
Sweden	No, but contacts on requirements from case to case.	**C**
Turkey	No practice	**C**
United Kingdom	TN-Gemini, H(U)/H(M), NTL 11, Fuel Integrity Project	**A/B**

6.2.5.2 CATEGORIZATION OF DIFFERENT PRACTICES

Cate-gory	Country specific practice	Number of practices
A	Joint certification practices	**3**
B	Joint certification practice only regarding the H(M) package approval	**4**
C	No joint certification practices	**21**
D	No response	**3**

6.2.5.3 SUMMARY AND DISCUSSION

There is a European joint certification practice regarding the certification of H(U)/H(M) UF_6-package designs. In the case all relevant competent authority's discussed the approval

approach jointly with an industry group organized by WNTI. Four countries (category B) informed about their participation in this field.
For other package designs or projects only UK, France and Germany (category A) gave examples for joint certifications. The examples concern in general casks which will be used in those countries.
The number of joint certifications is very low while a validation is necessary by each country through or into which the consignment is to be transported. In the case of international transport needing a validation, the encountered difficulties in the assessment of the Design Safety Report should be discussed between the competent authority of the original country of the design or shipment and all competent authorities involved in the transport. And in all cases, the competent authority of the original country of the design or shipment should be informed about problems or difficulties encountered in the assessment of the Design Safety Report by the other competent authorities.

A joint certification process should allow competent authorities to compare and discuss their respective conclusions of the assessment. Then, the competent authorities and their technical supports should organize common meetings to exchange information and discuss encountered difficulties during assessment.
For that, the competent authorities should have the same documentations available (same safety design report, …) at any time. Then, the applicant answers to requests for complementary demonstrations should be transmitted to all competent authorities involved in the joint certification.

6.2.5.4 CONCLUSIONS AND RECOMMENDATIONS

In the case where competent authorities decide to perform a joint certification, the recommendations, deduced from the evaluation and the conclusions above, are the following:

- At any time, the competent authorities should have the same documentation available (same safety design report…)
- Reciprocal information meetings should be organized by the competent authorities and their technical supports
- Questions to applicants and applicant answers should be circulated among the relevant competent authorities
- Assessment reports should be exchanged

It can be concluded in general, that – if all the recommendations to support harmonization given in this report are available – joint certification will be much easier.

7 CONCLUSIONS AND RECOMMENDATIONS

The conclusions and recommendations for the European Commission resulting from the detailed analyses of the responses to the questionnaires in item tables are already given under each item table itself (see chapter 6.2) or summarized in the Summary (see chapter 4) for the issues

1. Legal Basis
2. Application and Requested Documents
3. Approval Procedure
4. Safety Assessment Procedure
5. Joint Certification Practices.

In conclusion of these recommendations, the DGTREN standing working group should harmonize practices of EU or applicants countries by developing a harmonized comprehensive guidance material for submittal of application and for assessment and issue of certificate, This material should include:

- a harmonized guidance for certification process,
- a harmonized structure of a Design Safety Report,
- a harmonized structure of an assessment report of a package design
- a harmonized structure of a approval certificate.

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