

Safety Guide 6.4

Documentation to request authorisations for the transport of radioactive material: package approvals and authorisation for shipments

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**Documentation to request authorisations
for the transport of radioactive material:
package approvals and authorisation
for shipments**

Madrid, April 5, 2006

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Published and distributed by:
Consejo de Seguridad Nuclear
Pedro Justo Dorado Dellmans, 11. 28040 - Madrid
<http://www.csn.es>
peticiones@csn.es

Print: Imprenta Fareso, S.A.
Paseo de la Dirección, 5. 28039 Madrid

Legal deposit: M.



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1 Introduction

1.1 Objective

The objective of the present guide is to facilitate the drawing up of the documentation to be submitted along with requests for the authorisation required by the regulations governing the transport of radioactive materials and to establish a uniform format for the submittal of information.

The use of the guide will help to ensure that the information included in the applications is complete and will facilitate completion of the process by the CSN and other competent authorities in the shortest possible time.

1.2 Scope of application

This guide is applicable to applications regarding the following:

- Any package design approval required by the regulations in force:
 - The approval of new package designs.
 - The validation of certificates of approval issued by other countries.
 - The revision of certificates of approval and certificate validations.
- The following transport authorisations:
 - Approval of shipments of packages containing fissile substances, if the sum of the criticality safety indexes (CSI) of the packages included in the shipment exceeds 50.
 - Approval of shipments under special arrangements¹.

¹ The denomination of this type of authorisation varies depending on the regulation on modes of transport, due to differences in the translation into Spanish of the term “special arrangement”: *arreglo especial*, *acuerdo especial* and *autorización especial*. The decision has finally been taken to use the first of these since it is the terminology used in the Spanish version of the IAEA’s transport regulation, which is the basis for international regulations. Furthermore, this same terminology is used by two of the four international regulations, the one governing maritime transport (IMDG Code) and the one governing transport by air (ICAO technical instructions).

2 Definitions

The definitions of the terms and concepts used in the present Guide shall be the same as those used in the editions in force of the following documents:

- Regulation for the safe transport of radioactive material (TS-R-1). International Atomic Energy Agency (IAEA).
- European agreement concerning the international carriage of dangerous goods by road (ADR).
- Regulations concerning the international carriage of dangerous goods by rail (RID).
- Technical Instructions for the safe transport of dangerous goods by air – International Civil Aviation Organisation (ICAO).
- International Maritime Code on the transport of dangerous goods by sea – International Maritime Organisation (IMO).

3 Regulatory requirements

The requirements for approval to be fulfilled by radioactive material packages and shipments are those defined in the different regulations on the transport of hazardous goods: ADR for transport by road, RID for transport by rail, International Maritime Organisation (IMO) IMDG requirements for transport by sea and the technical instructions of the International Civil Aviation Organisation (ICAO) for transport by air.

These regulations are in keeping with the IAEA's Regulation for the safe transport of radioactive material, Safety Requirements TS-R-1.

In accordance with the editions of this regulation in force as of the date of publication of this Guide, approval is required in Spain for the following types of packages:

- Type B(U) and type C packages of Spanish origin.
- Type B(U) packages approved in other countries pursuant to the provisions of the editions of the IAEA Regulation of 1973, 1973 (amended), 1985 and 1985 (amended in 1990).

- Type B(M) packages.
- Packages for the transport of fissile material.
- Packages containing more than 0.1 kg of uranium hexafluoride.

Likewise, authorisation is required for the following shipments:

- Transport of packages containing fissile material, if the sum of the criticality safety indexes (CSI) of the packages included in the shipment exceeds 50.
- Shipments under special arrangements.

According to article 77 of the Regulation governing nuclear and radioactive facilities (Royal Decree 1836/1999, of December 3rd), the Directorate General for Energy² is responsible for the approval and validation of transport package models and for the authorisation of radioactive material shipments, as required by the specific regulations, following the issuing of a mandatory and binding report by the CSN.

4 Documentation to be submitted

4.1 General characteristics

The regulations mentioned in the previous point indicate the information that is to be included in requests for each of the different types of approvals. However, in order to facilitate further the preparation of such applications, three annexes have been drawn up dealing in detail with the information that is to accompany the different requests, depending on whether we are dealing with packages of Spanish origin³ (Annex I), package designs already approved in other countries but also requiring approval in Spain (Annex II) or authorisations for shipments (Annex III).

² As of the date of publication of this Guide: The Directorate General for Energy Policy and Mines of the Ministry of Industry, Tourism and Commerce. (Dirección General de Política Energética y Minas del Ministerio de Industria, Turismo y Comercio)

³ Packages of Spanish origin shall be understood to be those whose design has not previously been approved in any country and that is to be approved for the first time by a competent authority in Spain. The design may originate in part or in full in Spain or not, but for the purposes of this Guide the reference shall be to the country of origin of the design approval.

Likewise, Annex IV defines the procedure to be adhered to for modifications to be made to designs approved in Spain. This action procedure varies depending on whether or not the modifications affect nuclear safety and radiation protection.

It is important to bear in mind that if the application did not include the minimum information required, additional information would be requested and the CSN would not begin to assess the application until such time as this information were made available. Furthermore, the documentation submitted must be updated with respect to the legal and regulatory requirements applicable at the time of issuing of the application.

The documentation is required to include an overall Appendix, or one for each of its sections, listing the documents or references mentioned in the previous text.

It is highly recommended that photographic and video material be provided, especially in the sections describing the packaging and test procedures. It is also important for the drawings and diagrams provided to be clear and legible, such that they may be easily read and interpreted. It is also recommended that summary tables be used, showing in a simple manner the results of the evaluations of the different sections of the package Safety Analysis Report (SAR).

The documentation should be submitted in the Spanish language. Submittal in English would be acceptable, as long as the applicant is not from a country in which Spanish is the official language. The submittal of information in other languages should be agreed on beforehand with the CSN.

For certain applications, such as those indicated below, it is essential that there be previous contact with the CSN and with the other competent authorities in order to present the basic principles of the project and specify to the maximum possible extent the actions to be performed and the specific aspects of the documentation for each particular case.

The time required by the CSN for assessment may vary depending on the type of package and the characteristics of its design, as well as on the characteristics of the transport for which the authorisation is required. For this reason it is highly recommendable that there be previous contacts with the CSN to learn of the periods in which it would be appropriate for the different applications to be submitted. This is especially important in those cases in which longer assessment periods are to be expected, such as the following:

- Approval of packages of Spanish origin, especially those containing fissile materials.
- Validation of certificates of approval issued in other countries for packages containing fissile materials.
- Authorisations for shipments under special arrangements.
- Renewals of or modifications to the aforementioned approvals when not limited to extension of the period of validity.

It is recommended that at least two copies of the documentation be submitted to the Directorate General for Energy Policy and Mines of the Ministry of Industry, Tourism and Commerce (Dirección General de Política Energética y Minas del Ministerio de Industria, Turismo y Comercio).

4.2 Approval of package designs of Spanish origin

In view of the fact that they entail the first assessment of a new package design, these applications normally require a larger quantity of documentation and detailed information, since they are subjected to a complete process of approval. The documentation will include the information listed in Annex I and applicable to the specific design of the package. The non-inclusion of aspects considered to be irrelevant or not applicable to the design will need to be justified.

The documentation required in Annex I is made up of a series of basic licensing documents: package content specifications (CS), packaging specifications (PS), test report (TR), package Safety Analysis Report (SAR) and Quality Assurance Program (QAP) that overall basically coincide with what is identified in certain international standards and guidelines, such as the Safety Analysis Report.

For this approval it will be very important to contact the competent authorities beforehand. In particular, the previous presentation of the programme of tests performed on the packages will be fundamental.

Unless some other period has been established in the certificate of approval to be renewed, such renewal should be applied for at least six weeks prior to the date of expiry. If the authorisation sought includes not only an extension of the period of validity of the certificate

but also the inclusion of modifications, the applicant shall adhere to the “procedure for the modification of previously approved designs”, which is dealt with in Annex IV.

The application for revision of the certificate of approval should list the modifications made to the licensing basis documents. The revised documents may be submitted complete, identified with the corresponding revision number and including an indication of the modifications introduced. However, it is recommended that only the modified pages be presented, with the variations signalled, for the corresponding pages of the previous revision to be replaced. In this case it should be taken into account that the format of the documents originally submitted should allow for such replacement. Each of the pages revised or added should indicate the date of the change and the revision number.

For the renewal of a certificate of approval it is recommendable for the licensing basis documents to be subjected to a process of design review by the applicant. The following shall be taken into account in this review: progress in calculation techniques, the availability of more accurate data on the physical properties of the materials, operating experience of use of the package, the maintenance and inspection history, operating experience with similar packages, changes to design parameters due to modifications, etc.

Whenever significant modifications have occurred, it will also be very important to contact the CSN and other competent authorities beforehand.

4.3 Approval of packages already approved in other countries

Packages developed outside Spain and subject to multilateral approval under the regulations in force should be approved for use in Spain.

For these Spanish approvals, which are necessary as part of the multilateral approval required by the regulations, the process applied is normally one of validation of the certificate of approval of the country of origin, although there is also the possibility of undertaking a complete process of approval if this is considered appropriate, in which case the previous section would be applicable.

In general, this validation implies reliance fundamentally on the original certificate and on the safety analysis on which it is based; consequently, the documentation required for such applications does not need to be as exhaustive as in the case of a complete process of approval. Annex II details the minimum documentation that should accompany such applications.

As in the previous case, for the first validation of a certificate it is to be recommended that there be previous contacts with the Nuclear Safety Council and with the other authorities that are to participate in the process of authorisation. Among other issues, this will serve to confirm whether the process may consist of validating the original certificate or whether, on the contrary, a complete approval will be required, as well as to establish the scope of the documentation to be submitted in each specific case.

In the case of revision of a certificate previously validated in Spain, it should be indicated whether the revision is due to a modification to the design and/or operating conditions of the package or whether it is simply a renewal of the period of validity.

The request for revision should list the modifications made to the design and the package and to the corresponding Safety Analysis Report and other applicable documents. Likewise, the changes occurring in revision of the original certificate with respect to the previous revision shall be clearly identified.

If modifications affecting nuclear safety or radiation protection have been made to the design and/or operating conditions of the package, it will be necessary to attach documentation justifying such modifications.

Validations of certificates issued in the country of origin will normally have a period of validity coinciding with the date of expiry of the original certificate, although such validations may allow this period to be extended under certain conditions.

4.4 Authorisation of shipments

In accordance with the regulations, certain shipments require previous authorisation. Annex III indicates the minimum information that should be included with requests for the authorisation of shipments included within the scope of this guide:

- Transport of packages containing fissile substances, if the sum of the criticality safety indexes (CSI) of the packages included in the shipment exceeds 50.
- Shipments under special arrangements.

This information should be sufficient for insight to be gained into the characteristics of the shipment, to assess compliance with the regulatory requirements and, where

appropriate, to determine whether suitable compensatory measures or restrictions have been taken into account during transport.

In the case of shipments under special arrangements, it is considered essential that there be justification of all the possible alternatives having been contemplated prior to the decision to perform the shipment in this way. Although a case-by-case analysis will be necessary, nuclear safety and radiation protection should be the prevailing issues.

Likewise, it should be demonstrated that the overall degree of safety during transport is at least equivalent to that which would be achieved by satisfying all the applicable requirements included in the regulations.

In general, shipments under special arrangements should cover single and unique dispatches, that is to say, non-repetitive operations to be carried out in the short term. In exceptional cases this type of authorisation would be acceptable only for several shipments to be performed over a limited period and in which the characteristics of the shipment (packaging, content, consignor, destination, itinerary, conditions, etc.) were entirely similar.

In these cases especially, it will be fundamentally important that there be previous contacts with the Nuclear Safety Council and the other authorities participating in the process, in order to confirm the possibility of the shipment being undertaken under special arrangements and to establish the specific aspects of the documentation for each particular case.

4.5 Licensing Fees

The applications covered by this guide shall be subject to the provisions of *Law 14/1999, of May 4th, on rates and public prices for services rendered by the Nuclear Safety Council*, for which reason the applicant shall in all cases include his tax identification number in the data provided, for the purposes of application of the provisions of the said Law.

Annex I Request for package design approval

1 General information

- Name and address of applicant.
- Name or identification of package.
- Name and address of designer.
- Name and address of manufacturer.
- Modes of transport for which the package is to be used and for which approval is requested.
- Schedule foreseen for the manufacturing and use of the first package units.
- Illustration of the package, of a size not exceeding 21 cm by 30 cm, indicating the way in which the package is made up and including a brief description of the packaging, including the materials of which it is made, its gross mass, general external dimensions and appearance.

2 Specifications of the radioactive content of the package (CS)

- Radionuclides.
- Physical and chemical status.
- Maximum total activity (Bq) and/or maximum specific activity (Bq/g).
- Maximum mass of radioactive material.
- Maximum enrichment in the case of fissile material.
- Maximum weight of contents.
- Materials that might undergo chemical, galvanic or other reactions, among them those that might generate gases.

- Heat produced.
- Risks not due to radioactivity.

In the case of fuel (fresh or irradiated), the following shall be included:

- Type of fuel.
- Geometric characteristics.

In the case of irradiated fuel, details of the following shall also be included:

- Maximum degree of burnup.
- Initial enrichment.
- Minimum cooling time.
- Irradiation history, if credit has been given to burnup.
- Status of fuel (acceptance or otherwise of damaged fuel in the package).
- Specific loading positions of damaged fuel in the package, if accepted.
- Loading restrictions in certain positions depending on degree of burnup, enrichment or other parameters.
- Possibility of loading other core components in the package (control rods, neutron poison nozzles, etc.) and loading restrictions.

3 Packaging specifications (PS)

- General description. Basic components.
- General dimensions.
- Weight of packaging and total weight including contents.
- Materials specifications.

- Characteristics of containment system.
- Radiation shielding devices.
- Criticality control systems.
- Heat transfer devices.
- Structural devices, including systems for handling and attachment to the conveyance.
- Package marking.
- Drawings (arrangements of components, assemblies and sub-assemblies and details).
- National and/or international codes and standards applied in the design and manufacturing of the prototypes.

4 Test report (TR)

A complete report shall be submitted on the tests performed to demonstrate compliance with the requirements defined in the regulations for normal and accident transport conditions.

The report shall include a description of the test facilities, the procedure applied in each of the tests and the results obtained.

Likewise, the test specimen shall be described by means of detailed drawings, specifying its dimensions and the construction materials used. In the case of scale models, the scaling factor used shall be specified.

If the radioactive content is simulated, the materials used in its place during the tests shall be described.

It is recommended that photographic and video material on test performance be included.

Where appropriate, the report shall contain the preliminary analyses performed, by modelling, calculation or other methods, to define the specifications of the actual tests,

along with the tests carried out on prototype components or preliminary designs whose results have been used for this same purpose.

It will not be necessary for this information to be repeated in the assessments included in the package Safety Analysis Report, for which reference may be made to the corresponding sections of this test report.

If actual tests are not performed to demonstrate compliance with the requirements, a reference shall be made to the analytical method used, which will be described in the corresponding section of the Safety Analysis Report (SAR).

5 Package safety analysis Report (SAR)

1. Classification of package type and assessment of compliance with general packaging requirements.
2. Structural evaluation.
3. Thermal evaluation.
4. Containment evaluation.
5. Shielding evaluation.
6. Criticality evaluation.
7. Package operations.
8. Acceptance testing and maintenance program.

The Safety Analysis Report shall include a justification of compliance with each of the requirements established in the regulations applicable to the type of package for which approval is sought, and shall also include the procedure governing use of the package and its acceptance testing and maintenance schedule.

Identified below are the most important aspects to be considered in each section of the SAR. This does not mean that they are the only aspects, since the contents may vary depending on the specific characteristics of each design.

A summary table dealing with the following shall be included at the beginning of each section:

- The regulatory requirements applicable to each section of the SAR.
- The paragraphs of the edition in force of the IAEA Regulations on the transport of radioactive materials that include these requirements.
- The corresponding paragraphs of the regulations on modes of transport that are applicable.
- A summary containing conclusions regarding compliance with the requirement.

5.1 Classification of package type and assessment of compliance with the general packaging requirements

The package type shall be justified considering its contents and in accordance with the provisions of the regulations on the transport of hazardous goods in force.

An analysis shall be made of compliance with each of the general packaging requirements defined in the regulations, such as:

- That the package may be handled and transported easily and safely and that it may be duly held down on the conveyance.
- That the external surfaces of the package may be easily decontaminated and that they do not collect or retain water.
- That elements added during transport do not imply any reduction in safety.
- That the efficiency of the sealing devices does not decrease during routing transport.
- The possible chemical and physical effects of the materials, components or structures of the packaging, compatibility – both mutual and with the radioactive contents – and the methods used to prevent significant reactions.
- Behaviour in response to the maximum ambient temperatures and pressures expected under routine transport conditions.

5.2 Structural evaluation

The objective of this section should be to describe and analyse the structural design of the package and of safety significant components and systems and to describe the way in which the package fulfils the regulatory requirements.

Although the main components of the package that have a structural function will already have been described in the document on packaging specifications (PS), it may be necessary for this section of the SAR to include a more detailed description focussing on the structural assessment to be carried out.

The load combinations and factors considered as design criteria shall be described, along with the structural failure modes taken into account (brittle fracture, fatigue, etc.).

The codes and standards used to determine the properties of the materials, design limits or loads and stresses combination methods shall be identified. In the event of deviation from the codes, or if certain components were not covered by such codes, the design criteria used shall be described.

The centre of gravity of the package shall be located.

The codes and standards proposed for the design, manufacturing, assembly, testing, maintenance and use of the package shall be identified.

The mechanical properties of the materials considered in the assessment shall be indicated, in particular in the case of materials to be subjected to high temperatures.

An analysis shall be made of the effects of radiation on the materials (degradation of lids, seals, covers and structural materials).

The structural assessment shall consider fundamentally the mechanical behaviour of the packaging in relation to the testing requirements established by the regulations for normal and accident conditions during transport. It shall also include analysis of the structural performance of the elements of the package designed for lifting or handling, as well as for its attachment to the conveyance.

The structural assessment may be performed by analysis, by testing or by a combination of both. The assessment methods used shall be described and their appropriateness and correct application shall be justified.

If the assessment is performed by testing, a detailed analysis of the most limiting initial conditions and most harmful package orientations shall be carried out or, where appropriate, reference shall be made to the contents of the Test report (TR). The use of computer models to simulate the tests for different package orientations will help to determine those that are most damaging, for their subsequent application in actual tests.

If scale models have been tested, the scaling factor used shall be specified and throughout the assessment the extrapolation of the results to the real model shall be justified.

If the radioactive content is simulated, there should be assurance that this replacement has not affected the test results.

An analysis of the test results shall be performed, justifying compliance with the requirements established by the regulations.

If the assessment is performed by analysis, the methods and calculations used in assessing the package shall be described, in sufficient detail to allow the results to be verified.

Whenever computer analysis is used, including finite elements analysis, the computer programme shall be described and its applicability to the assessment shall be justified.

Regardless of whether it is accomplished by testing or analysis, the assessment shall contemplate both normal transport conditions and those accident conditions that, in accordance with the regulations, are applicable to the type of package. Likewise, the analysis shall be carried out for the different types of contents for which use of the package is foreseen, or there shall be assurance that the content selected is bounding.

Following consideration of the conditions of the mechanical tests, the results obtained in the assessment shall be incorporated as initial conditions for thermal assessment.

5.3 Thermal evaluation

This section of the SAR should describe and analyse aspects relating to the thermal design of the package, under both routine and normal operating conditions and under accident conditions, in order to assure package compliance with the applicable regulatory requirements. As in the case of structural assessment, this analysis may be performed by analysis or testing or by a combination of both.

Although the main components of the package that have a thermal function will already have been described in the basic PS document, it may be necessary for this section of the SAR to include a more detailed description focussing on the thermal assessment to be performed.

The basic criteria of the thermal design and operation of the package shall be described from the thermal point of view, along with the design heat transfer mechanisms expected under routine, normal and accident conditions.

The thermal properties of the materials of the packaging and the specifications of its components shall be included, such that compliance with the safety functions be justified over a range of temperatures considering routine, normal and accident conditions.

The thermal analyses or tests performed shall be described, including a summary of the results. The maximum heat loss considered in the thermal assessment shall be in keeping with the source term assumed in the shielding and containment analyses.

A thermal assessment shall be performed under routine transport conditions in order to demonstrate that there is no significant reduction in the safety conditions of the package, among them degradation of the heat transfer capacity, changes in the properties of the materials affecting the safety function and reduction of the capacity of the package to withstand normal and accident conditions. The maximum internal pressure under these conditions shall be determined.

A thermal assessment shall be performed for normal and accident conditions, in accordance with the acceptance criteria and requirements defined in the regulations. The analysis shall include the temperatures reached by the packaging components of significance. Consideration shall be given to the increases in pressure caused in

the processes of combustion or decomposition of the packaging materials under these conditions.

5.4 Containment evaluation

This section of the SAR should describe and analyse aspects relating to the package containment system, in order to assure that the package fulfils the applicable regulatory requirements under routine, normal operating and accident conditions.

The containment system shall be defined and described, including the specifications of components such as the containment vessel, shielding, covers, closing devices, seals, welds, valves and other sealing structures. Although the main components of the package containment system will already have been described in the basic PS document, it may be necessary for this section of the SAR to include a more detailed description focussing on the assessment of containment to be performed.

Describe the containment penetrations and their sealing methods. Identify the usage specifications for pressure relief systems and valves, along with the methods for protection against non-authorised operations, and describe the leakage retention systems.

The assessment of the containment system under all operating conditions shall be accomplished considering the most limiting package contents from the chemical and physical point of view, as considered in the basic CS document, and taking into account the maximum internal pressures.

The secure closing of the containment system shall be assured by means of a device that prevents unintentional opening or opening as a result of overpressure inside the package. Where appropriate an analysis and justification shall be performed of the tightening torques to be used to maintain containment under normal and accident conditions.

A description shall be included of the leak tests required to demonstrate that the package fulfils the containment requirements, such as tests performed during and following the manufacturing of the packaging, periodic testing and tests prior to each transport operation.

5.5 Shielding evaluation

This section of the SAR should describe and analyse aspects relating to the shielding system of the packaging, the aim being to assure that the dose rate limits required by the regulations will be met under routine, normal and accident conditions.

Although the main components of the package that have shielding functions will already have been described in the basic PS document, it may be necessary for this section of the SAR to include a more detailed description focussing on the assessment of the shielding to be performed.

The characteristics of the design of the package radiation shielding shall be described, considering all the components and systems that allow for compliance with this objective, including dimensions, tolerances, construction materials and the densities of the shielding material for neutrons and gamma radiation.

A description shall be included of the contents and bounding gamma and neutron source terms to be used in the analysis, taking into account any increase in these source terms with respect to time. For packages designed for the transport of irradiated nuclear fuel, consideration shall be given to the degree of burnup of the fuel and its cooldown time.

The maximum radiation dose rates expected under routine, normal and accident conditions shall be defined, in both exclusive use and non-exclusive use conditions. It is recommended that tables be used showing the dose rate values at different points with respect to the package, allowing for comparison with the applicable limits. Likewise, it is recommended that schematic diagrams of the packaging and its components showing these points be submitted.

A general description of the shielding analysis methodology shall be included, the hypotheses applied in analysis shall be detailed and discussed and the results of the analysis shall be included, justifying compliance with the regulatory requirements.

5.6 Criticality evaluation

This section of the SAR, applicable only to packages for fissile material, shall describe and analyse the design of the package and its components and systems of importance to maintain the subcriticality of the package, in isolation and in array, such that compliance

with the regulatory requirements be assured under both routine and normal operating conditions and under accident conditions.

In performing the assessment, use may be made of the recommendations included in Appendix VII of the IAEA Safety Guide TS-G-1.1 (ST-2) [3].

Although the main components having a safety function with respect to the criticality of the package will already have been described in the basic PS document, it may be necessary for this section of the SAR to include a more detailed description focussing on the criticality assessment to be performed.

Firstly, the main characteristics of the design from the point of view of criticality shall be included:

- A detailed description of the elements of the package of significance from the point of view of safety against criticality shall be included. Information shall be included on the system for the confinement of fissile material, neutron absorbing and moderating materials, spacers, etc.
- A summary table shall be provided showing the results of the criticality analysis for isolated packages, for arrays of undamaged packages and for arrays of damaged packages, with respect to the conditions established in the regulations. The table shall include at least the maximum value of the effective multiplication constant (k_{eff}), uncertainty, bias and the number of packages considered in the groups.
- The Criticality Safety Index (CSI) shall be provided, based on the number of packages assessed in the group and showing how this has been calculated.

A detailed description of the methods used to calculate the effective multiplication constant of the package shall be provided, demonstrating compliance with the standards applicable to packages containing fissile material. A description of the computer programme and cross-section library used shall also be included. The key input data for criticality calculations shall be identified. Also included shall be a benchmarking of the calculation method used.

Information shall be provided on the calculation model used. The differences between the actual configuration of the package and that of the model used shall be shown,

along with the differences between the models for normal transport and accident conditions.

Although the contents will already have been described in the basic PS document, it may be necessary for this section of the SAR to describe them in greater detail from the point of view of criticality analysis, including mass, dimension, enrichment, chemical and physical composition, density, humidity and other characteristics of fissile materials of significance for the analysis, justifying their boundary with respect to other possible contents of the package not specifically considered in the analysis.

The properties considered in the models for the packaging materials and contents shall be provided. Consideration shall be given to the differences between routine, normal and accident conditions, especially in the case of materials affecting the criticality design.

The performance of the assessment shall be included for packages in isolation, arrays of undamaged packages and arrays of damaged packages, justifying compliance with the requirements established in the regulations. The analyses shall demonstrate the most reactive configuration in each case.

5.7 Packages operations

This section of the SAR shall describe the operations to be performed for loading and unloading of the package and ensure adequate preparation for its transport. The different steps of each operation should be presented in the same sequence as they are to be performed.

Details of the package handling operations may be included in more exhaustive written procedures based on the operations described in this section of the application, to which reference shall be made. When developing the procedures consideration should be given to the ALARA principle as regards operational exposure to radiations.

The loading operations shall include the inspections, tests and processes for preparation of the package for loading, as well as the inspections to be performed prior to loading to determine that the package is not damaged and ensure the suitable

placing of neutron absorbers or moderators when required and the inspection of sealing gaskets and devices, along with the criteria for their replacement and/or repair where necessary.

The loading operations for the different contents and the way in which the package should be closed shall be described.

The operations for preparation of the package for transport shall contemplate the surveillance of radiation and contamination and, where appropriate, other verifications such as leak testing, measurement of the temperature on the surface of the package and the arrangement of seals.

The instructions to be taken into account by the transport company during reception of the package, its loading, transport and unloading shall be described, such as the surveillance of radiation and contamination, the inspection of seals or the special precautions and controls to be considered in handling and unloading of the packages and instructions on any special operational controls, such as routes, weather conditions, timetable restrictions in transport, etc.

The package opening and content unloading operations shall be described, including the inspections, tests and special preparations necessary for such unloading.

Consideration shall be given also to the preparation of empty packages for transport, including the package inspections, tests and special preparatory measures to ensure that they fulfil the criteria and limits defined in the regulations for this type of packages.

5.8 Acceptance tests and maintenance program

This section shall specify the tests and checks to be performed prior to the first use of each package and the periodic maintenance schedule to which such packages are to be subjected.

It shall include a description of and the acceptance criteria for the tests, among them visual inspections, weld tests, structural, pressure, heat transfer and leak tests and tests on the components and materials of the packaging, such as gaskets, neutron absorbers, insulating material or shielding.

The objective of the acceptance tests shall be to confirm that each package has been manufactured in accordance with the package design specifications analysed in the SAR. There shall be a description of the actions to be taken when the acceptance criteria are not met.

There shall be a description of the maintenance program, both preventive and repair, established to ensure the continuous good condition of the packages. The program shall include periodic tests and inspections, a spares programme and criteria for the replacement and repair of components and sub-systems.

Details of the maintenance process may be included in more exhaustive written procedures based on the operations described in this section of the request, to which there shall be a reference.

Any process that might cause a deterioration of the materials and components of the packaging shall be identified.

6 Quality assurance programme (QAP)

The *Quality assurance programme* developed for the design of the package prototypes, including the test process, shall be included. The development of this programme may be based on the indications included in CSN Safety Guide 6.1 on *Quality assurance in the transport of radioactive substances*.

Annex II Validation of certificates of approval issued by other countries

1 General information

- Name and address of applicant.
- Name or identification of package.
- Application proposal (indicate whether this is the first validation in Spain or whether a previous revision of the original certificate has already been validated in Spain).
- Competent authority issuing the original certificate.
- Modes of transport for which the original certificate approved use of the package.
- Schedule foreseen for first use of the package in Spain.
- If not included in the certificate of the country of origin, an illustration of the package, of a size not exceeding 21 cm by 30 cm, indicating the way in which the package is made up and including a brief description of the packaging, including the materials of which it is made, its gross mass, general external dimensions and appearance.

2 Certificate of approval of country of origin

The certificate shall be submitted in the original language, accompanied by translations into Spanish and English.

3 Description of package

Packaging

- General description: dimensions, weight, basic components and materials specifications.
- Drawings (arrangement of components, assemblies, sub-assemblies and details).

Content

- Radionuclides.

- Physical and chemical status.
- Maximum total activity (Bq) and/or specific activity (Bq/g).
- Mass and maximum enrichment in the case of fissile substances.
- Risks not due to radioactivity.
- In the case of irradiated fuel, details of the following shall also be included:
 - Maximum degree of burnup.
 - Minimum cooling time.

4 Compliance with regulatory requirements

The Safety Analysis Report (SAR) of the original package, or an extract from it, shall be submitted. If the decision is taken not to send the complete SAR, the following information at least shall be considered essential:

- Summary of the test programme and details of the results or alternative demonstration of compliance.
- Package operations.
- Maintenance program.
- Criticality evaluation (for packages containing fissile material).
- For type B(M) packages, details of restrictions and special conditions or operational controls during transport.

Annex III Approval of shipments

1 General information

- Name and address of applicant.
- Name and address of consignor or dispatcher (if different from applicant).
- Name and address of consignee.
- Application proposal.
- Schedule foreseen for transport operation performance.
- Period of time for which the authorisation is requested.

2 Basic transport data

- Radioactive material to be transported.
- Transport mode(s).
- Conveyance.
- Points of origin and destination.
- Foreseen itineraries or routes.
- Packaging model.
- Certificate of approval of package, where applicable.
- Number of shipments foreseen.
- Number of packages per shipment.
- Number of packages per vehicle or conveyance.
- Action procedures for emergencies during transport.

- Liability insurance of nuclear damage.
- Special precautionary measures and administrative or operational controls, if required, and details of their performance.

If storage is foreseen in transit, indicate the following:

- Place.
- Nature of storage.
- Foreseen duration.
- Personnel responsible for custody.

3 Request for authorisation under special arrangements

It is fundamentally important that this type of request include the following, in addition to the data indicated above:

- Clear identification of those aspects in relation to which the transport cannot meet the requirements included in the regulations.
- Justification of the reasons for which transport under special arrangements is considered necessary, with sufficient arguments explaining the absence of other alternatives.
- Special measures that would be adopted to compensate for deviations.
- Authorisation under special arrangements by the country from which the shipment is to leave, where appropriate.

Annex IV Procedure for modification of designs already approved

In the case of packages with a certificate of approval issued in Spain, any modifications to the design of the package (structural integrity, containment, shielding, heat transfer or criticality) or to its operating and maintenance conditions that affects nuclear safety or radiation protection must previously be analysed by the applicant to verify continued compliance with the criteria, standards and conditions on which the approval of the package was based.

If the analysis performed leads to the conclusion that these requirements continue to be met, the modifications may be undertaken, the Nuclear Safety Council being informed of the modifications and the safety analyses performed within the first quarter of each year. Such modifications shall be incorporated in the next process of renewal of the certificate of approval and, if necessary, a revision of the documents on which the request is based (package content specifications, packaging specifications, test report, package SAR and QA programme) shall be issued.

In the case of minor modifications or changes, among them corrections of errors and changes to document or drawing references, the aforementioned basic documents shall be updated in the shorter of the two following periods of time:

- Three years.
- Next renewal of the certificate.

For other modifications not affecting nuclear safety or radiation protection, the basic documents shall be updated in the shorter of the two following periods of time:

- Two years.
- Prior to the next renewal of the certificate.

For this type of modifications, which do not imply revision of the package certificate of approval, the applicant shall define a procedure for their communication to the users to whom the packaging has been supplied.

For modifications deemed, following analysis, to affect nuclear safety or radiation protection, a revision of the certificate of approval of the package shall be requested from the Ministry of Industry, Tourism and Commerce (Ministerio de Industria, Turismo y Comercio), this to be issued prior to the modification's coming into effect.

Bibliography

The following is a list of the most representative documents:

1. Regulations for the safe transport of radioactive material (TS-R-1). 1996 Edition (As amended 2003). International Atomic Energy Agency (IAEA).
2. European agreement concerning the international carriage of dangerous goods by road (ADR). 2005 Edition.
3. Advisory Material for the IAEA Regulation for the Safe Transport of Radioactive Material. Safety Guide TS-G-1.1. International Atomic Energy Agency (IAEA).
4. Guide to an application for UK competent authority approval of radioactive material in transport (IAEA 1996 regulations). DETR Environment Transport Regions Ref: DETR/RMTD/0003, January 2001.
5. Draft Regulatory Guide DG-7003. Standard format and content of Part 71 applications for approval of packaging for radioactive material. December 2003.
6. NRC Regulatory Issue Summary 2004-20. Lessons learned from review of 10 CFR Parts 71 and 72 applications. December 16, 2004.
7. Guideline for the design approval procedure of packages for transport of radioactive material, of special form radioactive material and low dispersible radioactive material –R003– Verkehrsblatt des Bundesministers für Verkehr, Bau- und Wohnungswesen (BMVBW). November 17, 2004.
8. PT.IV.28. Procedimiento técnico sobre la evaluación para la aprobación y convalidación de bultos de transporte (Technical procedure for the approval and validation of transport packages). CSN 26.03.01.
9. PT.IV.41. Procedimiento técnico sobre la evaluación de solicitudes de autorización de transporte de material radiactivo (Technical procedure for the assessment of radioactive material transport authorisation applications). CSN 16.09.03.

The safety guides contain the methods recommended by the CSN from the point of view of nuclear safety and radiation protection, and their objective is to orientate users and facilitate application of the Spanish nuclear regulations. Compliance with these guides is not obligatory and the user may apply methods different from those contained therein, as long as they are duly justified.

Whatever comments and suggestions might improve the content of these guides will be considered in subsequent revisions.

All correspondence should be sent to the Technical Standards Office (Oficina de Normas Técnicas) and requests to the Publications Service (Servicio de Publicaciones) at the following address: Consejo de Seguridad Nuclear, Pedro Justo Dorado Dellmans, 11, 28040 (Madrid).