Office for Nuclear Regulation

Guide to an application for UK competent authority approval of radioactive material in transport

This document was produced when the regulation of the transport of radioactive material was the responsibility of the Department for Transport. On 24 October 2011, responsibility for the regulation of the transport of radioactive material transferred to the Office for Nuclear Regulation.

This document has been superseded by new guidance that was published in April 2016. However some of the information in this guide may still be useful and relevant for applicants, and so the guide will remain on the website for a limited period during which additional guidance may be published.

RADIOACTIVE MATERIALS TRANSPORT DIVISION

GUIDE TO AN APPLICATION FOR UK COMPETENT AUTHORITY APPROVAL OF RADIOACTIVE MATERIAL IN TRANSPORT (IAEA 1996 REGULATIONS)

Ref: DETR/RMTD/0003
January 2001

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DEPARTMENT OF THE ENVIRONMENT, TRANSPORT AND THE REGIONS.
RADIOACTIVE MATERIALS TRANSPORT DIVISION

GUIDE TO AN APPLICATION FOR UK COMPETENT AUTHORITY APPROVAL OF RADIOACTIVE MATERIAL IN TRANSPORT. (IAEA 1996 REGULATIONS)

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This Guide is for applications requiring UK Competent Authority approval. The basis for such approval requires the Applicant to meet the requirements of IAEA Safety Standard Series No. TS-R-1, (ST-1 Revised) "Regulations for the Safe Transport of Radioactive Materials, 1996 Edition" (Revised) and appropriate National Regulations. National Regulations will be subject to change from time to time. Applicants should check that the current issue of this Guide is being used when making an application.

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THE TRANSPORT RADIOLOGICAL ADVISER
RADIOACTIVE MATERIALS TRANSPORT DIVISION
DETR
GREAT MINSTER HOUSE
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January 2001

REVISION SHEET

REVISION NUMBER	REVISION DATE	DESCRIPTION	SIGNATURE

PART I GENERAL INFORMATION

INTRODUCTION

This Guide is designed to 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.
The Competent Authority for the United Kingdom is the Secretary of State for the Environment, Transport and the Regions (DETR). The Radioactive Materials Transport Division (RMTD) of the Department acts on his behalf in these matters.
If the applicant is unclear regarding any questions in this Guide, or requires assistance in interpreting the regulations, RMTD should be contacted for guidance. Enquiries should be addressed to:-

THE TRANSPORT RADIOLOGICAL ADVISER
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Fax No. 020 7944 2187.

GENERAL INFORMATION

1. All relevant information and documentation should be provided to the Competent Authority with the application. All information supplied to the Competent Authority will be treated as Commercial-in-Confidence and will not be disclosed to any other person or organisation without the prior consent, in writing, of the applicant (subject to the provisions of any relevant Freedom of Information statutes). The application should be submitted at least six months before approval is required. Attention is drawn to the fact that applications are generally dealt with in order of receipt. Exceptions to this are that an organisation can, with the agreement of the Competent Authority, rearrange the priority of its own applications. In view of this, applicants should be aware that approval of an application might not be given by the date requested. Alteration in priority listing will not be allowed in the case where the application at the higher priority has had substantial assessment time spent on it. The operation of the priority system is at the discretion of the Competent Authority who reserve the right to alter or amend the system or priority on any application.

2. 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.

3. Packages shall meet the regulatory requirements of UK statutes and regulations. These are generally consistent with the International Atomic Energy Agency (IAEA) Safety Standard Series No TS-R-1 (ST-1 Revised) "Regulations for the Safe Transport of Radioactive Materials, 1996 Edition (Revised)", (termed **the Regulations** - within this Guide).
These regulations are supported by IAEA Safety Standard Series No TS-G-1.1 (ST-2) “Advisory Material for the Regulations for the Safe Transport of Radioactive Material (1996 Edition) (termed **the Advisory Material** - within this Guide).
IAEA references in this Guide, i.e. (IAEA 202), relate to the paragraphs in the Regulations.

4. Most countries have based their regulations on IAEA requirements. In this case, designs having unilateral approval by the United Kingdom Competent Authority should normally be acceptable in those countries. Where this is not the case, or in all cases where multilateral approval is necessary, applicants should take due account of the regulations of the country concerned at the earliest possible time. Advice in this respect may be sought from the Competent Authority of the country(s) concerned or The Transport Radiological Adviser. A list of Member States of IAEA is given in the Regulations. A list of Competent Authorities is given in the IAEA National Competent Authorities List, which is updated annually.

5. Excepted packages, Industrial Packages (IP's), and Type A Packages (provided they do not carry fissile materials), and uranium hexafluoride Packages (carrying less than 0.1kg of uranium hexafluoride), do not require Competent Authority approval. Such packages are self-assessed and certified by the Consignor (designer/manufacturers organisation).
For Freight Containers, to be used as IP-2 and IP-3 Packages, DETR have provided specific guidance material, (see DETR/RMTD/0002 (Freight Containers), July 1999). The document covers both 1985 and 1996 Regulations. The applicant should consult this document for fuller guidance details.
In using these self-assessed/certified packages, it is in the interest of the consignor to comply with all appropriate regulations and codes.
The Competent Authority may require the consignor to present to them the safety case for self-assessed packages. All calculations, analyses, test reports and any other relevant data, which demonstrate that the package meets regulatory requirements, shall be presented.

6. The establishment of Quality Assurance programmes relative to all aspects of transport is a requirement to support and demonstrate continued high levels of transport safety, as well as positively contribute to assuring compliance with the regulations. This not only assures the Competent Authority that the package complies with the regulations during design and manufacture, but also that it continues to comply with the approved design specifications/requirements throughout its entire working life (IAEA 310).
In many situations, the applicant is not necessarily the user. Documentation, which will be issued to the user, to ensure that integrity is not compromised by use in unwarranted situations or deleterious conditions, should be submitted with the DSR.

7. The application should also include a description of the Quality Assurance programmes applicable during design, manufacture, testing, documentation and other phases of transport over which the applicant has control or influence. Where the applicant is not the only envisaged manufacturer, consignor, user or carrier, general recommendations for Quality Assurance in the manufacture, testing, documentation, use, maintenance and inspection of the packages shall be included in the Application (IAEA 310, 803(d) Special Form and Low Dispersible Material, 805(b) uranium hexafluoride packages, 807(i) Type B(U), Type B(M) and Type C packages, 813 Fissile packages).

8. The applicant is reminded that the Competent Authority may choose to monitor the design, manufacture, testing, inspection and maintenance of packaging.
To this end the applicant should give sufficient early information to the Competent Authority regarding manufacture, testing, etc., of package designs, to allow participation, by the Competent Authority, in witnessing tests, carrying out inspections, etc., even before formal application for approval has been made.
Monitoring may also be required during the preparation, documentation, handling and stowage of packages by consignors and carriers, to provide evidence that the regulations are being complied with (IAEA 311).

9. Applicants are reminded that certification, to show that the approved design specification has been fully implemented on all packages, should be available for scrutiny during and/or after manufacture (IAEA 310). All essential records pertaining to design, manufacture, modification and maintenance should be available for scrutiny.

10. Applicants are required to give the names and addresses of all the manufacturers of the packaging to enable the Competent Authority to arrange for inspection during construction, if required (IAEA 310).

11. Applicants are reminded of the requirements of the regulations concerning goods or articles other than radioactive material within the packaging (IAEA 503 to 506 inclusive).

12. The need for marking (IAEA 534 to 540 inclusive), labelling (IAEA 541 to 545 inclusive) and placarding (IAEA 546, 547), in accordance with the regulations, should be considered at the design stage.

13. When special lifting gear is provided, the appropriate requirements of the Docks Regulations, the Factories Act and the Health and Safety at Work etc. Act, together with the relevant regulatory requirements of foreign countries concerned with the shipment, shall be taken into account.

14. Applicants shall apply serial numbers to all packagings manufactured to the approved design and inform the Competent Authority of those numbers (IAEA 819).

15. All data supplied should be in SI units.

16. 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:-
    i) Evidence of validation of the code and operating platform (Q A aspects of the validation, management and use of the code).
    ii) Discussion of benchmark studies between code and tests, where appropriate.
    iii) Evidence of the suitability of the particular application of the code.
    iv) A review of the analysis technique and its appropriateness to the analysis in hand (including any shortcomings and how they are addressed).
    v) An analysis of potential errors and how these errors translate to safety related aspects of the design.
    vi) 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.
    The applicant should note that there is a Regulatory/Quality Assurance requirement to retain all design-related information for the life of the package.
    This paragraph should be read in conjunction with other particular requirements associated with any computer analysis identified elsewhere in this Guide.

17. Renewals. For renewal of an existing certificate, the applicant should give at least 6 weeks notice before the expiry date of the current certificate. However, before applying for a second renewal (a maximum of 6 years), the applicant must have subjected the DSR and all supporting evidence to a Design Review. Such a Design Review shall have been conducted by a competent person within (or independent of) the applicants organisation. The review should give consideration to; advances in calculation techniques; availability of more accurate physical property data; changes in design safety parameters due to modification etc.; package usage; operational experience; maintenance and inspection history; etc. The review documentation should form an integral part of the second renewal application.

PART II PACKAGE DESIGN APPROVAL

1. ADMINISTRATIVE INFORMATION

1.1 State title or acronym by which the package will be identified.

1.2 State name, address, fax/e-mail and telephone number of the organisation and responsible officer who will be the contact for communications for the following:-

1.2.1 Applicant.
1.2.2 Designer.
1.2.3 Manufacturer (principal contractor for each package).

1.3 State the location of the package during manufacture.

1.4 State type of Approval required:-
Type B (U), Type B(M) or Type C, Fissile (IP, Type A, Type B(U), Type B(M) or Type C) (see also PART III), special form radioactive material (see also PART IV), low dispersible radioactive material (see also PART V), uranium hexafluoride package (see also PART VI), Shipment Approval (see also PART VII), Special Arrangement (see also PARTVIII), or Validation (see also PART IX).

1.5 Indicate mode(s) of transport required (road, rail, sea, air, inland waterway), and state if there are any restrictions on the types of vehicles or freight containers to be used (IAEA 833(d)). Should an air transport mode be required then the specific requirements for air transport must be demonstrated as met. (IAEA 576 to 578 and 617 to 619, etc.).

1.6 State the Competent Authority Identification Mark.
The Identification Mark should be as attributed to the design by the Competent Authority. For a general explanation of the Identification Mark make up see IAEA 828.
It should be noted that the UK Competent Authority Identification Mark requires a make-up letter to be associated with the design number, i.e. VRI/Design Number (Make-up Letter)/Type Code. These make-up letters are assigned by RMTD.

1.7 Specify the applicable Quality Assurance programmes (see also PART II paragraph 7) and identify, and provide for, interfaces between the applicant's Quality Assurance programmes, and other Quality Assurance programmes, where the applicant is not expected to be the sole manufacturer, consignor, user or carrier (IAEA 310). The applicant should provide timely notification to RMTD to allow for witness or inspections to take place.

1.8 State the method by which the Competent Authority will be informed of the serial numbers of all packagings manufactured to the approved design (IAEA 819).

1.9 Date by which Approval is required (see PART I paragraph 1).

1.10 Date of Application.

2. SPECIFICATION OF RADIOACTIVE CONTENTS

General:
The information required in these paragraphs identify the nature and maximum content (quantity and type) of radioactive material to be approved. Knowledge of the contents is subsequently used as a measure of radiological risk. For example, liquid contents may introduce a vapour pressure consideration in Maximum Normal Operating Pressure (MNOP) IAEA 228, powder size may influence leakage path considerations in Type B(U), Type B(M) or Type C packages, quantity and type may give rise to considerations of neutron/gamma shielding requirements.

2.1 Describe general nature of Contents, e.g., Irradiated Fuel, Metallurgical Specimens, Radiographic Source, etc.

2.2 Specify:-

2.2.1 Radionuclides.
2.2.2 Physical state.
2.2.3 Chemical composition or state.
2.2.4 Quantity (grams) and enrichment (where applicable).
2.2.5 Maximum total activity (Becquerels) OR maximum specific activity (Becquerels/gram).

2.3 If the A_1/A_2 values for the radionuclides to be carried are not listed in the latest version of Table 1, of the Regulations, show how the values used have been determined (IAEA 402 to 406).

2.4 State nature of radiation's emitted.

2.5 Are there any materials present in the contents or packaging that affect the nature of the radiation emitted either separately or by interaction? If so state the materials and the resultant effects, e.g. the interaction between Beryllium and Americium to produce neutrons.

2.6 Do the daughter products of any isotope present cause additional hazards or problems?

2.7 If irradiated nuclear fuel is to be carried, give details of:-

2.7.1 Maximum rating at end of life.
2.7.2 Maximum irradiation.
2.7.3 Minimum cooling time.
2.7.4 Initial enrichment (where applicable).
2.7.5 Minimum irradiation (where applicable - see PART III).

2.8 What is the maximum heat load (watts) to be carried? Show what reference data has been used to derive the figure.

2.9 State:-

2.9.1 What physical or chemical effects (if any) that normal and/or accident conditions of transport will have on the contents.

2.9.2 The reference to the justification for the physical or chemical effect.

2.10 State whether the proposed contents has any dangerous properties as described in any class covered in the latest Edition of the United Nations Recommendations on the Transport of Dangerous Goods [other than Class 7 (radioactive)], i.e. explosive, pyrophoric, corrosive, inflammable, oxidising etc. and that such properties have been taken into account in the design of the packaging.
It is necessary to take into account the possible formation of products having dangerous properties produced by the interaction of contents with the atmosphere or with water (e.g. in the case of UF_6) (IAEA 109, 309, 507 and 616.).

3. <u>SPECIFICATION OF PACKAGING</u>

General:
The information that is required in these paragraphs allows an appreciation of the package and packaging (as presented for transport), and the design features to be identified. Safety in transport, and hence the protection of persons, property and the environment, is largely achieved by design features such as, containment of the radioactive material, control of external radiation levels, prevention of criticality, prevention of damage caused by heat, etc. The approaches adopted to maximise the protective nature of the package design should be emphasised.
Continuous safety in Transport also relies on the operational procedures specified by the applicant and on the consignors implementation of and compliance with these requirements, at all stages in the transport cycle.

Consideration should be given to through life use and the applicant should specify design intent and ensure that these intentions are given consideration in maintenance and inspection requirements.
The illustration required for the package certificate allows third parties, possibly with less technical background, a ready visual identification of the package in transport.

3.1 Specification.

3.1.1 The applicant should give an outline description of the package along with all necessary specifying documents, and any ancillary equipment, being presented for assessment and the major design features highlighted. The description should include an overview of the package design considerations, with references to design; conditions of use; maintenance; tests; inspections; etc. and how such design intent will be achieved, and continue to be achieved, through life.
The applicant should discuss the criteria for the selection of materials, finishes, treatments and jointing of the package and demonstrate that rigorous consideration has been given to chemical and galvanic compatibility, known deleterious effects, irradiation, etc., commensurate with the intended duty cycle over the design life.
The applicant should provide a statement or supporting evidence that demonstrates that overall design considerations have been satisfied.

3.1.2 State the title, issue, and date of issue either of the Document Reference List or of all documents that are relevant to the Application. This should include all Company standards and references, including British or International standards or similar works of reference.

3.2 Packaging Make-up.

3.2.1 Give the following information as applicable.

COMPONENT	TITLE	DRAWING LIST No. and ISSUE	DESIGN IDENTIFICATION	OVERALL SIZES	WEIGHT	HOW MANY UNITS PER PACKAGE
Package Assembly						
Outer						
Inter - mediate						
Inner						
Inner - most						

[The above listed components are examples. Add or delete as necessary]

3.2.2 Total weight of the packaging.
3.2.3 Gross weight (including contents).
3.2.4 Design life.

3.3 Drawings.

3.3.1 State the numbers, issue status, and date of issue of all drawings relating to the packaging.
Where there are more than three drawings to any Packaging Assembly, a Drawing List with all the drawings, their respective issues and dates should be provided. The Drawing List itself must be numbered, with an issue status and date of issue and date. Changes to drawings will necessitate raising the issue of Drawings and Drawing List.

Changes to drawings must be accomplished within the applicants drawing control system and any changed drawing must reference/identify either the change on the drawing or reference to the documentation under which the change was made. Copies of such changes should be made available on request.

3.3.2 Provide a reproducible illustration, not larger than 180 mm x 200 mm, showing the make-up of the package.

3.4 State what method or device is used to provide evidence that the package has not been opened during the transport operation (IAEA 635).

4. TRANSPORT OPERATIONS

General:
The transport operation encompasses more than just the period when the package is in carriage within the public domain. Transport comprises all operations and conditions associated with, and involved in, the preparation, consigning, loading, carriage (including in-transit storage), unloading, and receipt at final destination. The applicant should consider all operations associated with the transport operation.
Contents preparation and package handling forms an important functional role in safety and the applicant must provide sufficient detailed information to ensure that design intent is preserved by users, consignors and consignees (IAEA 555, 561)
As well as package handling there is also a requirement to securely stow the package (IAEA 564, 606). The Applicant should give due consideration to how this is to be achieved, and how the forces imposed on the package, during routine conditions of transport, will be accommodated in a safe manner.
It is recommended that such information be presented in comprehensive packing and handling procedure documents within, or as a supplement to, the DSR.

4.1 Handling.

4.1.1 Identify and discuss all package attachments that can be used for handling and securing in transport either the package or its components (IAEA 564, 606, 612, 636).

4.1.2 Give details of any special lifting equipment required, together with maximum and safe working loads. State how any special lifting equipment requirements are advised to Consignors/Operators. Additional indelible markings on the package, adjacent to the handling/lifting features, may be used to ensure that design intent is observed.

4.1.3 Show, by analysis or test, that any lifting attachments on the package will not fail in normal use. Include a minimum snatch factor of 100%, unless there are valid and justifiable reasons for a lower factor (IAEA 607).

4.1.4 If the integrity of the handling system (and its subsequent reactions on the package) is to be evaluated by analysis, identify and discuss the basic loading conditions. The applicant may present this loading data in a convenient tabular form.
Normal asymmetries of loading must be addressed and the worst case loading used in subsequent analysis. For example, in a rigid, redundant, lift system, it is unlikely that all supports will be effective through life (if normal tolerances, wear, corrosion, or clearances are assumed). The applicant should consider such cases.

4.1.5 Identify the criteria, codes or standards used to determine design limits, load combinations, allowable stresses, fatigue life, etc.
If the applicant wishes to define allowable stresses, without reference to appropriate standards or codes, then the applicant must bear in mind that:
i) The package is subjected to dynamic loading, and
ii) Co-existing stresses invariably result from the loading.
The applicant must ensure that allowable stress is less than Yield Stress or 0.2% Proof Stress.

4.1.6 Consider the effects of fatigue loading, at local details, on handling features over the design life of the feature. The applicant should consider that all lifting and handling operations are enhanced by the snatch factor and be analytically demonstrated to have a minimum fatigue life compatible with the design life of the handling feature. The applicant should provide references from which Stress Concentration Factors have been derived for the local structural detail under consideration.

4.1.7 Identify, justify, and discuss any analysis simplifications.

4.1.8 Show how any possible feature of the package, that could possibly be used for lifting, have been designed to act as a lifting point or is removed or is otherwise rendered incapable of being used as a lifting point (IAEA 608). Additional indelible markings on the package, adjacent to the handling/lifting features, may be used to ensure that design intent is maintained.

4.1.9 Provide verifiable evidence, which demonstrates that the overall conclusion of the evaluation has achieved the requirement of the criteria, code, or standard.
One method of presenting verification of the design intent is to tabulate the results of $^{\text{Actual stress}}/_{\text{Allowable stress}}$ from the analysis of structural details to demonstrate that the requirements of the code or standard have been met.

4.2 Tie-down (or Retention) system.

General:
The information required in these paragraphs provide assurance that the package can be properly secured on a conveyance (IAEA 564, 606), under routine conditions of transport (IAEA 106) without impairment of integrity. Tie-down (retention) loads, due to accelerations encountered in routine conditions of transport, are defined in the Advisory Material, Appendix V.
A quantitative envelope definition of the magnitude of modal package accelerations, representative of routine conditions of transport, has been agreed, by IAEA Member States. These are shown in the Advisory Material, Table A.V-1. These acceleration values are acceptable to the UK Competent Authority and agreed by other Competent Authorities as acceptable values for approved packages over which Member States have no knowledge of transport modal infrastructure. These accelerations represent a design basis for assessing the package structural attachment forces. The acceleration factors are presumed to act simultaneously, in worst combination.
It should be noted that for vertical accelerations the values quoted in the Advisory Material, Table AV-1, are absolute values. The effect of gravity has to be allowed for.
For some specific packages some Competent Authorities and modal transport organisations allow alternative definitions of routine conditions of transport. The Advisory Material, Table AV-2, identifies some of these values. It should be noted that in some instances the effect of gravity may have been included.
For applicants wishing to use these alternatives they should be agreed with the UK Competent Authority, (and those Competent Authorities who may have to validate the approval).
The package structural reactions from routine transport induced loading, from the tie-down (or retention) system, are generally accommodated by attachments on the package. The applicant must ensure that such reactions do not compromise the ability of the package to meet its regulatory requirements over the design life, having given consideration to wear, corrosion, etc. One approach to preserving such design intent is to demonstrate (by calculation) that package attachment loading response, on structural details, remains within the elastic response of the material, i.e.< Yield or 0.2% Proof Stress.
There is a requirement (IAEA 612) to ensure, under routine conditions of transport, that securing systems remain effective. One method of compliance is for the applicant to demonstrate, by a fatigue analysis, that fatigue life has been considered at the package attachment. The applicant should note that fatigue damage is a local phenomenon and any analysis carried out must consider any local stress concentration effect.

4.2.1 Identify all attachments that are a structural part of the package and can be used as a tie-down (or retention system), for securing the package in transport (IAEA 636), and the response of such systems under normal and accident conditions of transport.
If, under normal or accident conditions, failure of any attachment (or any engineered "weak link" should occur), show that the integrity of the package (in terms of containment, shielding, leak-tightness, criticality safety, heat rejection criteria etc.) is unimpaired.

4.2.2 Discuss and justify the overall tie-down (or retention) system.

4.2.3 Identify, justify and discuss the basic loading conditions and present these loading data in a convenient tabular form. Reference basic data inputs generated from other specialist or design groups.
Normal asymmetries of loading must be addressed and the worst case loading used in subsequent analysis. For example, in a rigid, redundant, tie-down (or retention) system it is unlikely that all supports will be effective through life if normal tolerances, clearances, corrosion or wear are assumed The applicant should consider such cases.

4.2.4 For the UK Competent Authority the minimum values of acceleration to be applied as quasi-static forces, applied simultaneously, to the centre of mass of the package, are as given in the Advisory Material, Table A.V-1.
Should the applicant wish to propose alternative acceleration values then these should be discussed, and justified.

4.2.5 Identify the criteria, codes or standards used to determine design limits, load combinations, allowable stresses, etc.
If the applicant wishes to define allowable stresses, without reference to appropriate standards or codes, then the applicant must bear in mind that:-
i) The package is subjected to dynamic loading,
ii) Co-existing stresses invariably result from the loading.
Identify conservatism in the choice of allowable stress and justify their use.

4.2.6 Identify, justify, and discuss any analysis simplifications.

4.2.7 Show that during transport (routine, normal, and accident conditions) stresses in the package attachments will not effect the integrity of the package nor impair its ability to meet the requirements of the Regulations.
Demonstrate that consideration has been given to local fatigue damage of attachment features used for either a combination of package support and tie-down (or retention), or tie-down (retention).
In assessing fatigue-loading consequences, the applicant should provide references from which Stress Concentration Factors have been derived for the local structural detail under consideration.
Data on a fatigue cycle for road transport can be found in the latest version of AECP (TCSC) 1006. This document is published by AEA Technology plc, Harwell, Didcot OX11 0RA. In applying the data to other transport modes, the applicant should provide reasoned arguments for the choice of:-
i) the appropriate cycle;
ii) the appropriateness of the approach to a particular design or mode of transport.
Alternative data may also be used and justified by applicants to support a fatigue analysis.

4.2.9 Provide verifiable evidence, which demonstrates that the overall conclusion of the evaluation has achieved the requirement of the criteria, code, or standard, for both strength and fatigue.
One method of presenting verification of the design intent, is to tabulate the results of $^{\text{Actual stress}}/_{\text{Allowable stress}}$ from analysis of structural details to demonstrate that the requirements of the code or standard have been met.

4.3 Stowage Provisions.

4.3.1 Provide a calculation to determine the maximum heat flux for the range of contents to be carried. If the package average surface heat flux exceeds 15W/m^2 then state and justify the stowage criteria (IAEA 565).

4.3.2 State what instructions will be issued with regard to stowage during transport.

4.4 Action Required by Consignor Before Each Shipment.

4.4.1 Detail any specific instructions on package preparation, including filling and closure, and inspection or test procedures for verification of leak-tightness standard, which are to be carried out by the Consignor prior to each shipment (IAEA 502).

4.4.2 Is the package to be despatched before thermal equilibrium conditions are reached? If so, give details.

4.5 Action Required During Shipment.

4.5.1 Detail any operational controls that are necessary to ensure the safety of the package during transport e.g. loading, trans-shipment and unloading, storage, stowage, handling, transport, special stowage provisions, venting etc., and state how these are to be effected (IAEA 555). Alternatively, confirm that no such controls are required.

4.6 Emergency Instructions.
State the emergency arrangements or instructions required for this package design. (IAEA 308, 309, 555).
There must always be Emergency Arrangements. This question must be answered. A nil response is not acceptable.

4.7 Exclusive Use Conditions.
State whether transport of the package is to be made under Exclusive Use Conditions and give the reasons (IAEA 221, 530 to 532, 572, 578, 652).

5 TESTING

General:
Section VII of the Regulations identifies the preparation and testing for all packages (IAEA 713 to 737 as appropriate) requiring, either self-assessment or Competent Authority approval, as demonstration of compliance with Regulations.

5.1 Regulatory Compliance Testing of Package Design.

5.1.1 State whether the evidence for compliance with the regulatory test requirements is from actual tests, extrapolation from other designs, calculation or by reasoned argument (IAEA 701).

5.1.2 Provide evidence and/or justification to support the case for compliance with regulatory requirements. Attach copies of test reports and any reference documents. Where testing reports are supplemented by photographic evidence, the photographs should be of high quality and capable of producing high quality copies from the report by normal copying means (Xerox, etc.).

5.2 Performance Tests Before First Shipment.

Detail any performance tests that have been or will be carried out on the following prior to first use (as appropriate) (IAEA 501(a and b), and, if fissile 501(c)):-

5.2.1 Containment System.
- i) Pressurisation.
- ii) Leak-tightness.

5.2.2 Radiation Shield.
5.2.3 Thermal Shield.
5.2.4 Heat dissipation characteristics - normal conditions.
5.2.5 The Confinement System. (see Part III).
5.2.6 Presence of Neutron Poisons. (See Part III).

6. DESIGN

General:
Package designs can be demonstrated compliant by reference to previous satisfactory demonstrations of similar features, performance testing or by calculation (IAEA 701).
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.
If computer analysis is to be undertaken e.g. finite element codes, then the applicants should refer to Part I, paragraph 16, for a fuller description of the Competent Authority general requirements for supporting such undertakings.
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. Reference may be made to paragraph 3.3, if relevant.
b) Identify and discuss differences between the geometric models and the package specification in paragraph 3. Show that these differences are conservative or justify the use of any non-conservative assumptions.
c) Provide the results of scoping and sensitivity studies, where appropriate.
d) Describe the basic calculational method, referencing any appropriate documentation.
e) Any other requirements specified in the following paragraphs.

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

6.1 Structural Evaluation.

General:
The requirement to present a structural analysis depends upon the package design. All Type B(U), Type B(M), Type C, uranium hexafluoride, and fissile (Industrial and Type A) packages are required to demonstrate integrity under routine, normal & accident conditions of transport.
If the applicant carries out a structural evaluation by analysis, then the applicant should refer to Part I, paragraph 16 and paragraph 6 General: (above) for Competent Authority general and specific requirements for analytic demonstration of compliance.
In the particular situation where a thermal stress structural evaluation is undertaken the applicant should discuss how any errors in deriving the thermal field are quantified and how they are conservatively catered for in the subsequent structural analysis of thermal stress.
Identify the principal structural members or systems that are essential to the safe operation of the package. Highlight their location on appropriate sketches and discuss the structural design and performance requirements
Identify the location, load combinations, and any other factors that serve as design criteria for the structural evaluation. A sketch may be used to identify location. Sketches should be in sufficient detail to allow assessment of the analysis at the required location and point of interest. Loading cases considered should be identified on the sketch.

For each of these criteria state:-
a) The allowable stress for ductile failure.
b) How other structural failure modes (e.g. brittle fracture, fatigue, buckling,) are considered.
If different design criteria apply to different parts or different conditions, appropriate values for each case should be stated.
Identify all codes and standards used to determine design limits, load combinations, mechanical properties, allowable stresses, etc.
List and reference all the material mechanical properties used in the structural evaluation i.e. Yield, Ultimate, Modulus, etc.
For materials subject to elevated temperatures, the appropriate property should be used.
Basic data inputs generated from other specialist groups should be identified and referenced.
Identify the Centre of Gravity of the package and any other C of G used in the analysis.
Consideration should be given to whether repeated combined loading (mechanical and thermal) may cause fatigue failure and how these are addressed.
Provide verifiable evidence that demonstrates that the combined effects of pressure, mechanical loads, thermal gradients etc., have been considered and meet the overall performance requirements and design criteria of the evaluation.

6.2 Radiation Shielding (including neutron absorbers, if applicable).

General:
The applicant should demonstrate that due consideration has been given to the regulatory requirement of meeting shielding dose rate criteria under routine, normal and accident conditions of transport. For example, in some package designs, there is a requirement for additional hydrogenous neutron shielding to be provided. The applicant should take due care in the selection and placement of such materials to ensure that under, for instance, fire transients any volatile gases given off by decomposition, etc. are given consideration.
If the applicant carries out a shielding evaluation by analysis, then the applicant should refer to Part I, paragraph 16 and paragraph 6 General: (above) for Competent Authority general and specific requirements for analytic demonstration of compliance.
Identify, justify, and discuss the shielding design intent/considerations and the criteria adopted in the shielding evaluation. Discussion should also be provided on specific areas of the shielding analysis i.e. build-up, multiplication, interaction, tolerances, neutron dose, seal dose.
State the assumed package configuration in the post-test condition, with particular reference to the consequences of loss of shielding, giving due consideration to degradation by time, irradiation, mechanical and thermal damage etc., and discuss the implications of these assumptions on the evaluation.
Signify whether such assumed damage has been inferred from actual tests, by analysis or reasoned argument.
Identify, in tabular form (together with tolerances), the major outputs of the evaluation and reference where these are to be used by other specialist design groups.
Provide verifiable evidence that demonstrates that the overall conclusion of the evaluation has satisfied the shielding criteria.

6.2.1 Show, by means of an appropriate diagram, the position and physical size of the radioactive source in relation to the external surface of the package.

6.2.2 Specify the material and thickness of the radiation shielding components.

6.2.3 Specify the melting point of the materials.

6.2.4 Show what the maximum radiation levels will be, when the package contains the maximum intended activity for the radionuclide(s) to be carried (IAEA 530 to 532, 572(a), 574, 578 as appropriate):-
a) At the seal positions.
b) On each of the external surfaces of the package.
c) At one metre from these surfaces.

6.2.5 Show how the components forming the radiation shielding are securely closed by a positive fastening device that cannot be opened unintentionally or by pressure developed in the package (IAEA 645).

6.2.6 Show that if the package was subjected to the tests detailed in IAEA 719 to 724 and, in the case of packages carrying liquids and gases IAEA 725, that the loss of shielding integrity would result in no more than a 20% increase in the radiation level measured or calculated at the surface of the package before the tests (IAEA 646(b)).

6.2.7 Show that the requirements relating to post accident radiation levels is met (IAEA 656 (b), (ii), (i)).

6.2.8 For Type C packages, show that the requirements relating to post accident radiation levels are met (IAEA 669 (b), (i)).

6.3 Containment System.

General:
Containment systems (IAEA 213) are required to retain their effectiveness over the life of the package. The applicant must demonstrate that during and after the normal conditions of transport tests (IAEA 719 to 724) that the containment system remains acceptable i.e. without loss or dispersal of contents.
The applicant should:-
Identify, justify and discuss the containment system considerations and criteria adopted.
Tabulate loading conditions for both normal transport and accident conditions against which containment will operate and reference their source.
State the methods, analysis, or tests by which containment criteria are demonstrated.
If computer analysis is to be undertaken e.g. finite element codes, then the applicant should refer to Part I, paragraph 16 and paragraph 6 General: (above) for Competent Authority general and specific requirements for analytic demonstration of compliance.
Provide verifiable evidence that demonstrates that the overall conclusion has satisfied the containment criteria.

6.3.1 Nominate the items(s) of the packaging forming the containment system. Show how the containment system can be securely closed by a positive fastening device that cannot be opened unintentionally or by pressure developed in the package (IAEA 639).

6.3.2 Is any item approved as Special Form Radioactive Material ? (IAEA 239, 602, 604 and 640). If so, state the Competent Authority Special Form Identification Number.

6.3.3 If the containment system forms a separate unit of the package, explain how the system is sealed and closed at each stage. Show how the system is capable of being securely closed by a positive fastening device independent of any other part of the packaging (IAEA 641).

6.3.4 Show that when the package is at equilibrium the containment system will retain its contents under the reduction of ambient pressure to 60kPa (0.60 kg/cm^2) (IAEA 643). For packages transported by air show that the containment system will retain its contents under the reduction of ambient pressure to 5kPa (IAEA 619).
The applicant should note that the ICAO regulation requires a pressure difference of 95kPa to be applied across the package.

6.3.5 For Type B (U), Type B(M) and Type C packages, with activity greater than 10^5 A_2 (IAEA 657 and 670), show that the containment system will not rupture if subjected to test specified in IAEA 730 (enhanced immersion test). This test is not preceded by any other test.

6.3.6 State whether or not compliance with permitted activity release limit depends upon filters or a mechanical cooling system (IAEA 658).

6.3.7 State whether the package is fitted with a pressure relief system from the containment system (IAEA 659). Show that release, under the tests specified in IAEA 719 to 724 and 726 to 729, meet the regulatory requirements.

6.3.8 Show that the levels of strains in the containment system, with the system at MNOP, will not attain values which would compromise the ability of the package to meet the requirements of the Regulations when subjected to the tests specified in IAEA 719 to 724 and 726 to 729.

6.3.9 State whether the internal pressure inside the containment system exceeds 700 kPa (gauge) under MNOP conditions (IAEA 661).

6.4 Leak-tightness.

General:
Discuss the design intent and considerations adopted to assure leak-tightness of the package.
The Type B(U), Type B(M) and Type C leak-tightness standard required is $10^{-6}A_2$ / hour for normal conditions of transport (IAEA 719 to 724) and A_2 / week for accident conditions of transport (IAEA 726 to 734) tests. This is generally achieved by the use of a testable seal.
The applicant should bear in mind the required temperature range (-40° to + 70°C) (IAEA 637) of the seal material and provide evidence that the seal materials proposed are able to functionally meet the low temperature performance requirement (IAEA 719 to 724 and IAEA 726 to 734).
Through life compression set (elastomers) or creep (metallic), mechanical degradation, and thermal ageing, etc. should be taken into account in selecting appropriate material.
Evidence must be produced to demonstrate that the regulatory requirements are met.
Identify, justify, and discuss basic data inputs.
Leak-tightness may be demonstrated by test or calculation.
If leak-tightness is to be demonstrated by test, the applicant should identify how the long-term affects of seal ageing (on leak-tightness) are to be incorporated into the tests, for routine, normal and accident conditions.
If leak-tightness is to be demonstrated by computer analysis e.g. finite element codes, then the applicants should refer to Part I, paragraph 16 and paragraph 6 General: (above) for Competent Authority general and specific requirements for analytic demonstration of compliance.
If leak-tightness is to be demonstrated by hand calculation, provide sufficient information to allow independent verification and assessment to be undertaken, if necessary.
Show that there is a minimum 10% seal compression maintained throughout the testing sequence.
If a figure <10% is used this should be justified and agreed with the UK Competent Authority.
Evidence should be presented which demonstrates that any leak-tightness test equipment, used operationally, has sufficient sensitivity to meet the criteria adopted.
Provide verifiable evidence that demonstrates that the overall conclusion has satisfied the design intent or criteria.
Compliance with package leak-tightness requirements may be demonstrated either by measurement of the radioactive content release rate or by separate tests, using a tracer fluid, or by any other method.
If direct measurement is used, the applicant should provide details of the equipment used, the test procedure, and the conversion of the results to MNOP and accident conditions.
If a separate test is used, with a tracer gas, the applicant should provided the following information, with justification:-
a) Inventory of radioactive materials which can escape through a leak, viz. gaseous, liquid (including dissolved solids) and fine particulate. Such inventories are required for normal operation and accident conditions.
b) Allowable leakage rates for normal and accident conditions, based on the activity concentration of the fluid with leakage potential (in terms of A_2 /unit volume).

c) Specification of test to demonstrate the achievement of the most restrictive of a) or b) above, with details of test and the correlation between test and operational conditions (normal and accident conditions).
If any other method is used, provide full details of the method, with justification.

6.4.1 When carrying the maximum contents, with the containment system at MNOP, show how the design meets the requirements of IAEA 656, 659 and 666 (for Type B(M) packages) or IAEA 669 (for Type C packages), as appropriate, in respect of leak-tightness requirements.
For the A_1/A_2, value(s) use either that shown in the latest version of Table 1 of the Regulations or as established in Part II paragraph 2.3.

6.4.2 If leak-tightness performance is dependent upon special procedures for filling and closure, state what these are and how these procedures will be notified to consignors.

6.5 Thermal Considerations.

General:
The applicant may demonstrate regulatory compliance by analysis, test, or reasoned argument.
The applicant should note that thermal testing, using scale models, is unacceptable.
For applicants wishing to demonstrate thermal performance by test, the package presented must represent the damaged condition imposed by the normal (IAEA 719 to 724), and accident (IAEA 727 (a), or (c) and (b), as appropriate) conditions of transport tests.
For Type C packages, the package presented must represent the damaged condition imposed by the tests specified (IAEA 734). The applicant should note that the duration of the enhanced thermal test (IAEA 736) is 60 minutes.
The Competent Authority should be given early warning of such testing to allow review of the facilities identified for the test, and for agreement to be reached as to their acceptability.
If computer analysis is to be undertaken e.g. finite element codes, then the applicants should refer to Part I, paragraph 16 and paragraph 6 General: (above) for Competent Authority general and specific requirements for analytic demonstration of compliance.
Give particular discussion to specific areas of the analysis e.g. thermal radiation, etc. and how the analysis technique caters for these.
Identify, justify, and discuss analysis assumptions
Where other specialists require the analysis output, the applicant should discuss how any error is quantified, for example, errors in temperature fields may influence thermal distortions at seal faces, internal pressure, etc.
Provide evidence that consideration has been given to the thermal performance of the package to ensure that under MNOP and maximum temperature/ pressure/ deformation (normal and accident conditions of transport) integrity of the package is maintained.
Identify, justify, and discuss the criteria adopted in the evaluation.
State, reference and justify the assumed mechanical condition of the package before the thermal test and discuss rigorously the implications of these assumptions on the package thermal characteristics.
The use of combustible or non-combustible organic materials within some package designs can lead to degradation and the production of gaseous releases. Such items should be identified and any assumptions made with respect to performance and overall integrity, justified, and discussed.
The applicant should note that following the test no artificial cooling is permitted. Any combustion of materials of the package shall be permitted to proceed naturally.
Identify, in tabular form, the major thermal/pressure outputs (and tolerances on their values) of the evaluation and reference where these outputs are used by other specialist design groups.
Where temperature gradients are structurally significant, these should be identified, referenced, and included as databases for subsequent structural analysis.
Provide verifiable evidence that demonstrates that the overall conclusion of the evaluation has satisfied the design intent or criteria.

6.5.1 Temperature Range.

i) Indicate what ambient temperature condition has been assumed for purposes of design during normal transport of the package (IAEA 664).

ii) State what package design temperature limits have been taken with regard to the selection of materials for components and contents (IAEA 637). For air transport the temperature limits are as IAEA 618.

6.5.2 Insolation.

i) State what insolation data has been adopted (IAEA 654 or 665).

ii) Specify any means of intercepting solar radiation. Show what effect this has on the packaging and contents.

iii) Provide a calculation for the daily heat input to the package due to insolation and justify the value of solar absorptivity used in the insolation calculation. The sensitivity, or otherwise, of solar absorptivity values, due to the effects of decontamination fluids, transport grime, oxidation, time, etc. on painted or plated surfaces, should be taken into account.

6.5.3 Temperatures of Packagings and Contents. Conditions in the Package.

Show what the maximum and minimum temperature(s) will be in safety significant components of the packaging and contents (assume maximum and minimum heat load of contents to give the worst effects) under the following circumstances:-

i) Prior to shipment, assuming equilibrium heat conditions, but without insolation (IAEA 502(d)).

ii) During normal transport, but assuming the additional effect of insolation and wind chill as appropriate.

iii) During and after thermal test conditions, include the effects of insolation and extremes of ambient temperature as appropriate.

For Type B (U) or Type B(M) packages, there is a requirement to address the thermal characteristics of the package after mechanical tests (IAEA 727). Identify whether the damage considered has been inferred from actual tests, by analysis or by reasoned argument, and justify the choice.

For Type C packages, enhanced thermal test (IAEA and36) and a burial test (IAEA 668) are specified. Acceptance criteria (IAEA 668, 669(b)) must be met during and after the tests (IAEA 668, 734).

6.5.4 Surface Temperature. Determine the maximum temperature that any accessible surface of the package will reach, in the shade, under normal conditions of transport (IAEA 652, 662).

6.5.5 Low Temperature Effects.

i) Show that the package containment system is unimpaired if it is subjected to a temperature of -40^{o}C under normal conditions of transport (IAEA 637, 664).

ii) State whether any part of the packaging is vulnerable to the risk of brittle fracture or any other low temperature effect (including hardening of elastomer seals) and demonstrate the effects upon the packaging with respect to shielding and containment integrity and (if applicable) criticality safety (IAEA 637, 664).

6.5.6 Thermal Protective Shield.

If the Type B (U) or Type B(M) packaging includes thermal protection, show that this will remain effective under the requirements of IAEA 655, i.e. if subjected to the specified tests or under conditions not simulated in the tests e.g. by ripping, cutting, skidding, abrasion, or rough handling.

6.5.7 Primary Heat Transfer Medium (PHTM).

If the containment system includes a liquid primary heat transfer medium state:-

i) Volume of PHTM at closure.

ii) Ullage under closure conditions.

iii) Ullage under normal transport conditions (ambient -40^{o}C to +38^{o}C).

iv) Ullage during and after accident conditions.

v) How design ullage is ensured at closure.

6.6 Pressure Considerations.

General:
The requirements of these paragraphs are to demonstrate that, under MNOP, normal and accident conditions tests, the level of strain in the containment system would not attain values which would adversely affect the package in such a way that it would fail to meet regulatory requirements. Applicants should note that the effects of both internal and external differential pressure may require demonstration. Applicants may demonstrate compliance by test or analysis (see paragraph 6 General: (above)).

6.6.1 Show what the maximum pressure will be within each successive enclosure of the Containment System under the following circumstances:-
i) Prior to shipment assuming equilibrium temperature conditions.
ii) During normal transport (MNOP) (IAEA 228, 660, 661).
iii) During and subsequent to accident conditions (IAEA 660).
Where applicable, include the effects of vapour pressure arising from a liquid within the system, the evolution of gas from corrosion and radiolysis of the contents or primary heat transfer medium, the desorption of soluble gas in the primary heat transfer medium, and the release of entrapped gases or vapours from one enclosure to another.

6.6.2 State measures to mitigate the effects of corrosion and radiolysis. Justify, by provision of relevant experimental or analytical results, and any assumptions made with respect to these effects upon pressure.

6.6.3 Give the material specification(s) of the structural components of the containment system and state the minimum yield and ultimate strength(s) at the relevant material temperatures applying in circumstances detailed in sub-sections 6.5.3 (i) to (iii).

6.6.4 Show that requirements, with respect to Maximum Normal Operating Pressure and strength of the components of the containment system, meet the criteria selected in paragraph 6.1.

6.6.5 For Type B (U) or Type B(M) packages, containing more than 10^5 A_2, and Type C packages, the enhanced immersion test (IAEA 730) must demonstrate that the containment envelope maintains integrity. Analytical demonstration is acceptable.

6.7 Impact Evaluation.

General:
The applicant should bear in mind that the impact response of a package (fissile, Type B(U), Type B(M) or Type (C) may have considerable influence on other considerations, e.g. shielding, thermal response, containment, criticality, etc.
Identify the criteria that will be used to demonstrate package performance compliance for impact evaluation.
The following points should be borne in mind by the applicant in choosing the option(s) which support the package design:-
The Regulations are explicit that consideration must be given to demonstrating impact response when the package receives maximum ("worst") damage. Unless the package is of very simple design it is unlikely that the applicant could justify that a single impact attitude maximises package damage simultaneously to containment, shielding, criticality, or thermal design features.

6.7.1 Comparison to Similar Packages. The comparison must demonstrate by discussion and reference to drawings or sketches that the applicants package is, in all respects, better than, or equal to, the package previously approved. The applicant must show that the "new" package, or design feature, can meet all the regulatory performance requirements.

The following information should be provided in support of this option:-
a) Detail drawings or sketches showing all dimensions, materials, and configuration of both packages.
b) Weight and form of the components of both packages.
The comparison should demonstrate and provide evidence:-
i) That the packages will have similar response to the specified tests and that the interaction of the components of "approved" and "new" package responses "trade through".
ii) That the forces acting on all vital systems and components of the applicants package are equal to, or less than, the tested package and have sufficient structural integrity.
iii) That the "new" package will meet all the regulatory requirements.

6.7.2 Prototype Testing. Describe the test method, procedures and target used. Prior to physical manufacture and/or test, the applicant must notify RMTD that such manufacture and/or tests are to be carried out. Sufficient notice shall be given of the intended manufacture and/or test(s) for RMTD to arrange to witness such manufacture and/or test(s), at their discretion. The notification of such manufacture and/or test(s) must be accompanied by detailed manufacture and/or test procedures and Quality Assurance documentation to allow RMTD to review fully such documents, prior to manufacture and/or testing. A test Quality Plan (for both manufacture and testing) should be submitted, identifying responsible persons/organisations for each element of the proposed test.
Indicate the package orientation at the time of impact. If the package tested is not identical in all respects to the package described in the Application explain and justify the differences and show that these differences would not affect the test results or components/system interactions. Describe and discuss any substitutions made and show that these substitutions would not affect the test results or interactions.
Indicate in a quantitative manner the damage (internally and externally) caused by the impact and the results and consequences of any measurements made.
Provide photographic, and/or video (or similar) evidence of the damaged package identifying the location and nature of damage (initial impact, secondary impact, etc.).
Show or demonstrate that the overall conclusion has satisfied all the performance criteria.

6.7.3 Model Testing. Describe the model completely and provide detailed drawings that show dimensions and materials of construction.
Prior to physical manufacture and/or test, the applicant must notify RMTD that such manufacture and/or tests are to be carried out. Sufficient notice shall be given of the intended manufacture and/or test(s) for RMTD to arrange to witness such manufacture and/or test(s), at their discretion. The notification of such manufacture and/or test(s) must be accompanied by detailed manufacture and/or test procedures and Quality Assurance documentation to allow RMTD to fully review such documents, prior to manufacture and/or testing. A test Quality Plan (for both manufacture and testing) should be submitted, identifying responsible persons/ organisations for each element of the proposed test.
Highlight deviations between model and Full-Scale package. For example, one aspect of geometric scaling is the effect of physical scaling of welds. Welds, especially if they are involved in the area of high local damage, require correlation to defect sizes specified in, for instance, Full-Scale production non-destructive examination (NDE) on the package. Discuss such issues.
Specify tolerances to which the model is fabricated/constructed and compare these with the Full-Scale package.
Rigorously discuss and justify any differences between the model and the Full-Scale package (material properties, strain hardening modulus, etc.).
State the scale factor and describe in detail the laws of similitude used (time scale, density, impact velocity, kinetic energy, max./min. tolerance effects, etc.).
The applicant should note that models at less than one quarter scale are unacceptable to RMTD.

Some applicants choose to instrument (strain gauges, accelerometers, etc.) their tests. In such cases, the applicant should give a detailed discussion of what such outputs signify and how such outputs are to be used to infer Full-Scale response. The applicant will be expected to show, by integration of accelerometer signals, that velocity and displacement output traces are within expectation.
Historic experience with instrumented model packages has shown that a high level of redundancy and diversity of instrumentation is necessary for a meaningful "set" of test outputs to be collected.
The applicant should show that the model tests would give conservative results for peak g-forces, maximum deformation, and dissipated energy.
For the actual model tests, provide all the information in 6.7.2 above.
Correlate the damage done to the model with the damage which would have been done to a Full-Scale package.
Show or demonstrate that the package has satisfied all the performance criteria.

6.7.4 Analysis. There is a wide variation between applicants in the level of complexity used to infer impact response. Analysis can range from simple hand-calculation "flow-stress" approaches (to define quasi-static force/displacement behaviour) to those of full 3-D large displacement finite element codes, where package structure is fully defined and detailed.
For hand -calculation approaches the applicant should provide adequate discussion, use sketches and free body force diagrams, where appropriate. For equations used in the analysis, either the source should be referenced, or the derivation included.
Such analysis should show how all the kinetic energy would be dissipated, which local deformations and dynamic forces would occur during impact and their consequences on package integrity.
If computer analysis is to be undertaken, then the applicants should refer to Part I, paragraph 16 and paragraph 6 General: (above) for Competent Authority general and specific requirements for analytic demonstration of compliance.
The currently available commercial codes require significant user background knowledge, judgement and experience to be displayed in their use.
In the presentation of impact assessment, by finite element analysis, produce evidence that material behaviour has been fully characterised. Where supplementary test-work has been conducted, to underwrite particular aspects of the input analysis parameters, these supplementary documents should be presented.
In some impact attitudes, friction between "target" and package can have a significant effect on impact response. Evidence that such sensitivities have been considered should be presented.
It is unlikely that the analysis output, from such code assessments, would be acceptable to (and endorsed by) RMTD, without substantial evidence being provided. Such evidence would include validation testing, etc., to give confidence in the predicted results.
Nevertheless, these analytical approaches can serve a useful function, as a design tool, at the design phase of the package

6.8 Type B(M) Packages only (IAEA 665).

6.8.1 Specify those prescriptions of IAEA 637, 653, 654 and 657 to 664 with which the package design does not conform (IAEA 810a).

6.8.2 Give the reasons for non-compliance.

6.8.3 Specify and justify the operational controls to compensate for non-compliance (IAEA 810b).

6.8.4 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 666).

6.8.5 Where transport is restricted to the UK, an ambient temperature range of -10^{o}C to +26^{o}C and half the insolation data values of IAEA Table XI may be assumed. Such a package must be classified as 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.

6.9 Type B(U) and Type B(M) Packages.

6.9.1 Confirm that the package meets the General Design requirements (IAEA 606 to 616)

6.9.2 Confirm that the package meets Type A requirements (IAEA 633 to 635, 638, 642, 644, 647 to 649, and, if carried by air, IAEA 617 to 619).

6.9.3 State which component is marked with the Trefoil Symbol. Describe the method of marking to show that it is resistant to fire and water (IAEA 539).

7. QUALITY ASSURANCE

7.1 The applicant should:-

7.1.1 Demonstrate that effective and adequate Quality Assurance programmes are specified and established for those aspects of the design, manufacture, testing, documentation, use, maintenance and inspection of packages, transport, storage in transit for which the applicant is responsible.

7.1.2 Specify what other Quality Assurance programmes or Quality Assurance arrangements are applicable for covering those aspects of transport for which the applicant is not directly responsible.
This may cover multiple manufacturers and users of packages and may be satisfied by appropriate reference to an acceptable international or national Quality Assurance standard.

7.1.3 Provide documentary evidence, by a system of design reviews, or similar methods, that the design specification has been implemented and is being achieved.

7.1.4 Quality Assurance programmes shall be consistent with the hazard inherent in the radioactive contents. The level of Quality Assurance applied to design, testing, manufacture etc., shall be commensurate with the safety significance of items or components contributing to the necessary integrity of the packaging.
Aspects requiring design verification or review shall be identified and documented. (This could typically be recorded in a Design Quality Plan derived from the applicants Quality Assurance Programme).

7.2 Quality Control in Manufacture and Construction.

7.2.1 Detail any tests or examinations not specifically mentioned in the Quality Assurance programme that have been or will be carried out on the constructional methods and materials regarding:-
i) Containment System.
ii) Radiation Shielding.
iii) Insulation and Thermal Shielding (Heat Transfer Characteristics) to ensure compliance with design specification.

7.2.2 Give results, or state when these will be available.
These tests or examinations may be called up on a Quality Plan which is a document derived from the Quality Assurance Programme (extended if necessary) setting out the specific quality practices, resources and activities relevant to the approved design (IAEA 310).

7.3 Maintenance.
Detailed schedules of proposals for turn-round and periodic inspection and maintenance shall be supplied with the application. Any Quality Assurance arrangements for maintenance and servicing which are, or could be, different from those previously stated (Part II paragraph 1.7, and paragraphs 7.1 and 7.2) should be declared (IAEA 310).

7.4 Control of Use and Care of Packages.
Address subsequent control, use, and care of the package to ensure continued compliance with the design intent and regulatory requirements. These should be specifically addressed within the Quality Assurance programmes/specifications called up in sub-paragraph 7.1.1 or 7.1.2.
The applicants, and others, Quality Assurance systems may be audited by RMTD in the course of its Compliance Assurance activities. RMTD will, at its discretion, accept Quality Assurance programmes based on recognised international or national Quality Assurance standards such as BS ISO 9000 series, BS 5882, Safety Series No. 50-C/SG-QA. If traceability, to a recognised Quality Assurance Standard, is not claimed, the Competent Authority will assess the adequacy of the declared Quality Assurance programme/s to the provisions of IAEA the Advisory Material Appendix IV.

PART III ADDITIONAL DESIGN INFORMATION REQUIRED FOR FISSILE MATERIAL

1. INTRODUCTION

1.1 The information to be provided in this section must demonstrate compliance with each requirement of IAEA 671-682 .The sub-criticality of the individual package in isolation and of arrays of packages, must be demonstrated by experiment, calculation or reasoned argument and detailed in the relevant paragraphs below. References may be made to the appropriate paragraphs, figures or tables in specialist criticality Safety Documents.

1.2 The applicant should use this Part for all new or revised Criticality submissions for Approval under the 1996 Regulations, including those made under paragraphs 816 and 817 (Grandfather Provisions).

1.3 Changes to existing approvals requiring assessment of fissile aspects only or of fissile aspects with some minor mechanical assessment should be clearly marked: "FISSILE PRIORITY".

1.4 Where variations in internal furniture give rise to package design variants (Part II paragraph 3.2), the basis of compliance of each variant must be addressed.

2. EXCEPTED MATERIAL

2.1 State whether or not the package is exempt (under IAEA 672) from the requirements of IAEA 673-682 inclusive and, if so, on what grounds.
(In this case, the remaining sections 3 to 9 of this Part are not applicable.)

3. IRRADIATION HISTORY

3.1 Has credit for the irradiation history of the fissile material been taken in the determination of sub-criticality ?

3.2 If so, provide evidence that the parameters affecting sub-criticality can be adequately determined from the irradiation history and that this is known. Detail the measurement(s) which have been or will be carried out, prior to shipment, in order to confirm the conservatism of the isotopic composition used in the determination of sub-criticality (IAEA 674 (b)).

3.3 If not, at what point in the irradiation history is the neutron multiplication of the material at a maximum? Confirm that this assumption has been made in the calculations of sub-criticality. (IAEA 674(a))

4. NEUTRON POISONS

4.1 Detail any performance tests, or analysis, which have been or will be carried out, prior to first use of the package, in order to confirm the presence and distribution of any neutron poisons necessary to comply with the requirements of IAEA 671 (IAEA 501 (c)).

4.2 Reference the proposals for maintenance to confirm the continued effectiveness of these poisons.

5. ASSESSMENT OF ARRAYS OF PACKAGES UNDER NORMAL CONDITIONS.

5.1 State the maximum fissile loading for each of the radioactive contents described in paragraph 2 of Part II of this Guide, together with limiting values of other physical parameters of relevance to criticality safety (IAEA 673 is relevant)

5.2 State the quantity and nature of any moderating material to be found within the containment system of the package as it is designed to be presented for transport. If appropriate, references may be made to other parts of this Guide. (IAEA 673 is relevant)

5.3 State either the value of moderation-to-fissile atomic ratio(s) derived from paragraphs 5.1 and 5.2, or, if more appropriate, state any explicit or implied limitations of these ratios arising from the model used in 5.4 and 5.5 below. (IAEA 673 is relevant)

5.4 Provide dimensional sketches of the geometric models used in the assessment. Reference may be made to the information provided in paragraph 3.3 of Part II of this Guide if relevant.

5.5 Identify the materials of each region of the model, stating material densities and isotopic compositions. Discuss the neutronic significance of each with reference to the calculations. The results of scoping and/or sensitivity studies should be provided where appropriate. (IAEA 673 is relevant)

5.6 Identify and discuss differences between the geometry and material specification of paragraphs 5.4 and 5.5 above and the package specification in paragraph 3 of Part II of this Guide. Show that these are conservative or justify the use of any non-conservative assumption. (IAEA 673 is relevant)

5.7 Describe the basic calculational method, referencing any appropriate documentation. If appropriate, include representative input/output data from computer calculations.

5.8 Discuss the results of the calculations and justify the margin of sub-criticality.

6. ASSESSMENT OF ARRAYS OF DAMAGED PACKAGES

6.1 State the evidence for compliance with the regulatory test requirements of IAEA 682(b) whether from actual tests, comparison with other designs, calculation or reasoned argument. Reference supporting documents.

6.2 Describe the state of the damaged package following the tests prescribed in IAEA 682(b).

6.3 Discuss the effects of each of the contingencies in IAEA 671(a) (i) to (iv) and (vi) in terms of the damaged state of the package.

6.4 State the evidence for this damage whether from actual tests, extrapolation from other designs, calculation or reasoned argument.

6.5 Provide dimensional sketches of the geometric models used in the assessment.

6.6 Identify the materials of each region of the model(s) used to represent the array of damaged packages giving material densities and isotopic compositions. Discuss the neutronic significance of each with reference to the calculation. The results of scoping or sensitivity studies should be provided where appropriate. (Details are only required in respect of differences from paragraph 5.5).

6.7 Consider, where appropriate, the effect of partial (differential) flooding of the package (IAEA 671(a)(i)).

6.8 State and justify the differences between the model(s) defined in paragraphs 6.5 and 6.6, and the package as specified in paragraph 6.2. Show that these differences are conservative or justify the use of any non-conservative assumptions.

6.9 Discuss the effect of water at varying densities between packages (IAEA 671(a)(v) and 682(a)).

6.10 Describe the basic calculational method where this differs from that of paragraph 5.7, referencing any additional documentation.

6.11 Discuss the results of the calculation and justify the margin of sub-criticality.

7. CRITICALITY SAFETY INDEX FOR NUCLEAR CRITICALITY CONTROL

7.1 What are the two numbers 'N' (IAEA 681 and 682) and the corresponding Criticality Safety Index (IAEA 528) ?

8. ASSESSMENT OF THE SINGLE PACKAGE IN ISOLATION

8.1 Identify the confinement system as defined by IAEA 209

8.2 If water in-leakage or out-leakage to the extent specified in IAEA 677 is not being assumed to take place, detail the special features on the basis of which the assumption has been set aside.

8.3 Describe the most reactive state of the package in terms of the assessed damage (under IAEA 679), water in-leakage/out-leakage (under IAEA 677), the arrangement of fissile material (under IAEA 679), and the assumed reflection (IAEA 678). (Reference may be made to paragraphs 5 or 6 above). If the confinement system is released from the package as a result of the tests the assessment should be based on the most reactive condition, either the confinement system surrounded by the packaging surrounded by water, or the confinement system surrounded by water.

8.4 Provide dimensional sketches of the geometric models used.

8.5 Identify the materials of each region of the model giving material densities and isotopic compositions. Discuss the neutronic significance of each with reference to the calculations. The results of scoping and/or sensitivity studies should be provided where appropriate. (Reference may be made to paragraphs 5.5 and 5.6 above).

8.6 State and justify the differences between the model as specified in paragraphs 8.5 and 8.6, and the assessed state of the package in paragraph 8.4. Show that these are conservative or justify the use of any non-conservative assumptions.

8.7 Describe the basic calculational method where this differs from that of paragraphs 5.7 or 6.10. Reference any additional documentation.

8.8 Discuss the results of the calculation and justify the margin of sub-criticality.

If air transport is allowed (see answer to Part II section 1.5) then questions 8.9 to 8.12 must be addressed.

8.9 Describe the condition of the package following the enhanced tests for air transport specified in IAEA 734 (IAEA 680(a)).

8.10 State the evidence for this damage whether from actual tests, extrapolation from other designs, calculation or reasoned argument.

8.11 Given the condition of the package as described in paragraph 8.9 provide justification, based on calculation or reasoned argument, that the requirements of IAEA 680(a) are met. If the tests specified in IAEA 734 have not been carried out (or simulated) then demonstrate that the package contents surrounded by 20cm of water is sub-critical (it should be assumed that poisons built into the packaging may become detached; the condition of the contents should be consistent with the tests in IAEA 734 - i.e. credit may be taken for material properties such as LDM; no additional moderation of the contents should be considered).

8.12 If water ingress was not considered as described in paragraph 8.2 state the evidence that water ingress will be prevented following the enhanced tests for air transport specified in IAEA 734 (IAEA 680(b)). Otherwise provide an assessment based on the potential for full water ingress, the condition of the package being as in paragraph 8.3

9. VALIDATION OF CALCULATIONS

9.1 Describe briefly the bench mark experiments relevant to the assessments in paragraphs 5, 6 and 8 (References should be provided for fuller information).

9.2 Outline and discuss the relevant neutronic differences and similarities between the experimental assemblies and the package(s) in paragraphs 5, 6 and 8.

9.3 Outline and discuss the relevant differences and similarities between the calculational model used for the bench mark experiments and the models used in paragraphs 5, 6 and 8. Show that the bench mark experiment is appropriate.

10. SPECIAL ARRANGEMENT TRANSPORT OPERATIONS

10.1 If approval is sought for a Special Arrangement Transport Operation, questions 6 and 6.1 of Part VI of this Guide may be answered here in respect of nuclear criticality safety.

11. NUCLEAR MATTER TRANSPORT CERTIFICATES

11.1 By reason of international conventions and the terms of the Nuclear Installations Act 1965, a carrier of nuclear matter, other than excepted matters, must have a Nuclear Matter Transport Certificate in respect of potential third party liability claims. The certificate shall contain the particulars as stated in paragraph 3 of the Nuclear Installations (Insurance Certificate) Regulations 1965 SI 1965 No 1823 as amended by SI 1969 No 64. There is no specific requirement that the certificate should accompany the relevant consignment on a journey, but it should be available for inspection by port authorities, if required. A certificate is not required where the carriage in question is wholly within the territorial limits of the United Kingdom.

PART IV SPECIAL FORM RADIOACTIVE MATERIAL APPROVAL

INTRODUCTION

The information requested here is for "new" applications for special form radioactive material (IAEA 239) and for the "renewal" of existing approvals. It should be noted by the applicant that Competent Authority approval certificates are up-issued at each renewal, or re-issue, and invalidate all previous issues of the approval.

When a renewal approval is requested, the applicant should provide a documentary trail that encompasses previous versions of an existing approval, including unambiguous reference to drawing numbers and issues that have been historically approved by the Competent Authority, if there is a requirement to maintain special form radioactive material approval for previous versions.

The specification of contents (paragraph 3.) requires the applicant to identify the design basis for the product.

1. ADMINISTRATIVE INFORMATION

1.1 Applicant's name, address, fax/e-mail, and telephone number, including name of the responsible officer who will be the contact for communications.

1.2 State the Competent Authority Identification Mark. This should be either:-

1.2.1 Obtained from the Competent Authority for the new special form radioactive material or new capsule application.

1.2.2 The same for the special form radioactive material or capsules which have previously been approved.

1.3 Special form radioactive material Title/Applicants Reference.

1.4 State whether already approved for other contents and if so, what are those contents (the radionuclides and quantities).

1.5 Specify the applicable Quality Assurance programme(s) and whether it/they are already approved for this design, or similar design(s).

1.6 Date by which approval is required. (See PART I, paragraph 1).

1.7 Date of Application.

2. SPECIFICATION OF SPECIAL FORM RADIOACTIVE MATERIAL

2.1 State the title and issue and/or date of issue either of the document reference list or of all documents that are relevant to the application. This should include all company standards and references including British, or international standards, or similar works of reference.

2.2 State the specification of the special form radioactive material. The specification should include the applicable design basis to be realised for the special form radioactive material. All materials of manufacture should be included in this specification.

2.3 State the Quality Assurance programmes or Quality Assurance specification established for design, manufacture, testing, use, documentation, maintenance and inspection of special form radioactive material.

2.4 Specify the drawings and submit one copy of each. If there are more than three drawings then supply a drawing list that indicates the issue number of each drawing. The drawing list itself must be numbered, with an issue status and issue date.

2.5 Unless this appears on the drawings, specify the ordering or manufacturing specifications including reference to applicable national or international standards.

3. SPECIFICATION OF CONTENTS

3.1 Specify the radionuclide(s) and maximum activity in Becquerels.

3.2 Specify the form of the contents.

3.3 Specify the nature of emitted radiation(s).

3.4 Specify and justify any design basis to be realised for the special form radioactive material or capsule.

3.5 Specify the means of removing moisture from the contents prior to sealing a capsule.

3.6 State whether exposure to temperature change within the range -40^{o}C to +70^{o}C will cause a change in physical state and the effect on the integrity of the special form radioactive material or capsule.

3.7 Confirm that where the special form radioactive material is a sealed capsule that external irradiation does not take place after encapsulation.

3.8 Where the special form radioactive material is a capsule:

3.8.1 Specify the gases present and their pressure at the time of encapsulation.

3.8.2 Specify whether gas evolution occurs during use

3.8.3 Quantify any such gas evolution time rate (at STP conditions).

3.9 Specify the total heat output.

3.10 State whether the proposed contents have any dangerous properties other than Class 7 (radioactive), i.e. explosive, pyrophoric, corrosive, inflammable, oxidising etc.
If "yes", has this take into account in the design specification. It is also necessary to take into account the possible formation of products having dangerous properties produced by interaction of contents with the atmosphere or with water (IAEA 109, 309, 507).

3.11 Specify the chemical compounds present at time of despatch.

4. DEMONSTRATION OF REGULATORY COMPLIANCE (IAEA 704, 713 to 715).

4.1 Describe the special form radioactive material as tested.

4.2 Demonstrate or justify to the Competent Authority (by calculation, test or reasoned argument) that the design of special form radioactive material or capsule meets the design basis identified in paragraph 2.2 or 3.4 above.

4.3 Demonstrate or justify to the Competent Authority (by calculation, test, or reasoned argument) that under conditions appropriate to the Test Requirements (IAEA 705 to 709) containment integrity is maintained.

4.4 If testing is carried out give detailed information on the condition of the test specimen following subjection to the tests as specified below (a separate specimen can be used for each test:-

4.4.1 Impact Test (IAEA 705 or 709(a))

4.4.2 Percussion Test (IAEA 706 or 709(a))

4.4.3 Bending Test (IAEA 707)

4.4.4 Heat Test (IAEA 708 or 709(b)).

For the Impact Test (IAEA 705), Percussion Test (IAEA 706) or the alternative ISO Impact Class 4 Test (IAEA 709(a)), justify that the test arrangement is such as to cause maximum damage.

4.5 Specify the leak test method(s) used giving measured results where required (IAEA 710 and 711(a)) as appropriate or of any other method used (IAEA 711(b))
If a leaching assessment leakage test is undertaken justify that after applying all scaling considerations that the capsule, carrying rated activity, will meet the acceptance requirements of IAEA 603(c)**.**

4.6 Provide photographs of tested specimen in sufficient detail to reveal any damage.

PART V LOW DISPERSIBLE RADIOACTIVE MATERIAL APPROVAL

INTRODUCTION

The information requested here is for "new" applications and for "renewal" applications for approval of low dispersible radioactive material (IAEA 225). The applicant should note that Competent Authority approval certificates are up-issued at each renewal, or re-issue, and invalidate previous issues of the approval. The approval will quote the current assembly drawing number and issue status, at the time of re-issue.

When a renewal approval is requested, the applicant should provide a documentary trail that encompasses previous versions of an existing approval, including unambiguous reference to drawing numbers and issues that have been historically approved by the Competent Authority, if there is a requirement to maintain low dispersible radioactive material approval for previous versions.

The specification of contents (paragraph 3.) requires the applicant to identify the design basis for the product.

1. ADMINISTRATIVE INFORMATION

1.1 Applicant's name, address, fax/e-mail, and telephone number, including name of the responsible officer who will be the contact for communications.

1.2 State the Competent Authority Identification Mark. This should be either:-

1.2.1 Obtained from the Competent Authority for the new low dispersible radioactive material, or capsule, application.

1.2.2 The same for low dispersible radioactive material, or capsule, which have previously been approved.

1.3 Low dispersible radioactive material Title/Applicants Reference.

1.4 Specify the applicable Quality Assurance programme(s) and whether it/they are already approved for this design, or similar design(s).

1.5 Date by which approval is required. (See PART I, paragraph 1).

1.6 Date of Application.

2. SPECIFICATION OF LOW DISPERSIBLE RADIOACTIVE MATERIAL

2.1 State the title and issue and/or date of issue either of the document reference list or of all documents that are relevant to the application. This should include all company standards and references including British, or international standards, or similar works of reference.

2.2 State the specification of the low dispersible radioactive material. The specification should include the applicable design basis to be realised for the low dispersible radioactive material. All materials of manufacture should be included in this specification.

2.4 2.3 State the Quality Assurance programmes or Quality Assurance specification established for design, manufacture, testing, use, documentation, maintenance and inspection of low dispersible radioactive material.

2.4 Specify the drawings and submit one copy of each. If there are more than three drawings then supply a drawing list that indicates the issue number of each drawing. The drawing list itself must be numbered, with an issue status and issue date.

2.5 Unless this appears on the drawings, specify the ordering or manufacturing specifications including reference to applicable national or international standard.

3. SPECIFICATION OF CONTENTS

3.1 Specify the radionuclide(s) and maximum activity in Becquerels.

3.2 Specify the form of the contents. Only solid materials are acceptable.

3.3 Specify the nature of emitted radiation(s).

3.4 Specify and justify any design basis to be realised for the low dispersible radioactive material or capsule.

3.5 If a capsule, specify the means of removing moisture from the contents before sealing.

3.6 State whether exposure to temperature change within the range -40^{o}C to +70^{o}C will cause a change in physical state and the effect on the integrity of the low dispersible radioactive material or capsule.

3.7 Confirm that where the low dispersible radioactive material is a sealed capsule, that external irradiation does not take place after encapsulation.

3.8 Where the low dispersible radioactive material is a capsule:

3.8.3 3.8.1 Specify the gases present and their pressure at the time of encapsulation.

3.8.2 Specify whether gas evolution occurs during use

3.8.3 Quantify any such gas evolution time rate (at STP conditions).

3.9 Specify the total heat output.

3.10 State whether the proposed contents have any dangerous properties other than Class 7 (radioactive), i.e. explosive, pyrophoric, corrosive, inflammable, oxidising etc.
If "yes", has this take into account in the design specification. It is also necessary to take into account the possible formation of products having dangerous properties produced by interaction of contents with the atmosphere or with water (IAEA 109, 309, 507).

4. DEMONSTRATION OF REGULATORY COMPLIANCE (IAEA 701, 712).

4.1 Describe the low dispersible radioactive material as tested. If only a representative sample of the material is to be tested, justify that the results obtained can be reliably scaled up. Confirm that the tested material will be representative of the low dispersible radioactive material that will be transported.

4.2 Demonstrate or justify to the Competent Authority (by calculation, test or reasoned argument) that the design of low dispersible radioactive material, or capsule, meets the design basis identified in paragraph 3 above.

4.3 Demonstrate or justify to the Competent Authority (by calculation, test, or reasoned argument) that under conditions appropriate to the Test Requirements (IAEA 736 and 737) the low dispersible radioactive material meets the requirement of IAEA 605 (b) and (c).

4.4 If testing is carried out give detailed information on the condition of the test specimen following subjection to the tests as specified below (a separate specimen can be used for each test):-

4.4.1 Impact Test (IAEA 737)

4.4.2 Enhanced Thermal Test (IAEA 736).

4.5 Identify and discuss how the impact and thermal test arrangements will capture all airborne release of gaseous and/or particulate form and show that this release meets the requirements of IAEA 605(b).
Give detailed information of the reproducibility of the test arrangement measurements.

4.6 Show that the test specimen(s) meet the requirement of IAEA 605(C) following the impact and enhanced thermal test and after being subjected to the leach test specified in IAEA 703.

PART VI ADDITIONAL INFORMATION REQUIRED FOR URANIUM HEXAFLUORIDE PACKAGE APPROVAL

INTRODUCTION

The design basis for the package should meet the requirements of IAEA 629. The information requested is for the approval of packages containing 0.1 kg or more of uranium hexafluoride.

1. In addition to the applicable requirements of Parts II and III of this Guide, the following demonstration of regulatory compliance is required (IAEA 718, 722 and 728).

1.1 Describe the uranium hexafluoride package as tested.

1.2 Demonstrate or justify to the Competent Authority (by calculation, test, or reasoned argument) that under conditions appropriate to the Test Requirements (IAEA 718, 722 and 728) the uranium hexafluoride package meets the requirement of IAEA 630 (a), (b) and (c).

1.3 Give detailed information on the condition of the test specimen(s) following subjection to the tests as specified below:-

1.3.1 Pressure Test (IAEA 718)

1.3.2 Free Drop Test (IAEA 722)

1.3.3 Thermal Test (IAEA 728).

1.4 Confirm that the post-test results for:-

1.4.1 The pressure test results meet the requirement of IAEA 630(a).

1.4.2 The free drop test results meet the requirement of IAEA 630(b).

1.4.3 The thermal test results meet the requirement of IAEA 630(c).

2. H(M) Approval only (IAEA 632).

2.1 Specify and justify the standard(s) used to qualify the package design (IAEA 632(a)).

2.2 Confirm that the structural test pressure detailed in IAEA 718 is equal to, or greater than, 1.4MPa and less than 2.8MPa (IAEA 632(b)).

2.3 Confirm that if the package does not meet the requirement of IAEA 630(c), then it contains 9000kg or more of uranium hexafluoride IAEA 632(c)).

PART VII SHIPMENT APPROVAL.

INTRODUCTION
Except as allowed in IAEA 821, Multilateral Shipment Approval is required for the following (IAEA 820}:-
Type B(M) not conforming to the requirements of paragraph 637 or packages designed to allow controlled intermittent venting.
Type B(M) packages containing radioactive materials with an activity greater than :-
3×10^3 A_1 or 3×10^3 A_2, as appropriate, or 1000 TBq, whichever is the lower.
Fissile packages, if the sum of the Criticality Safety Indexes of the packages exceeds 50 (as provided in IAEA 566)
Radiation protection programmes for shipments by special use vessels according to IAEA 575.

1. ADMINISTRATIVE INFORMATION
The following questions marked * need not be answered if this application accompanies a Package Design Approval Application (PART II). If a combined Package Design and Shipment Approval is required this should be clearly stated.

1.1 State name, address, fax/e-mail and telephone number of organisation and officer who will be the contact for communications for the following:-

1.1.1 * Applicant.

1.1.2 Consignor (if not Applicant).

1.1.3 Originator of Shipment.

1.1.4 Consignee.

1.2 State:-

1.2.1 The actual radioactive contents.

1.2.2 The expected modes of transport.

1.2.3 The type of conveyance.

1.2.4 The probable or proposed route (IAEA 822(b))**.**

1.3 State if there are any restrictions on the modes of transport, type of conveyance or freight container to be used and any route instructions (IAEA 832(e)).

1.4 State:-

1.4.1 Any special precautions and special administrative and operational controls which may be required.

1.4.2 How these controls are to be put into effect (IAEA 822(c)).

1.5 In the case of Exclusive Use give details of any special vehicle or freight container that will be used to comply with IAEA 572.

1.6 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.

1.7 * State the Competent Authority Identification mark. This should be either:-

1.7.1 The same for designs which have previously been approved.

1.7.2 Obtained from the Competent Authority for new design applications.

1.8 Specify the Quality Assurance arrangements or programmes that will apply. (See also Part II paragraph 1.7).

1.9 Specify the Emergency Arrangements.

1.10 Consignment details.

1.10.1 Specify the number of packages per load.

1.10.2 Specify the number of loads per consignment.

1.11 For each transit store, specify the following:-

1.11.1 The place.

1.11.2 The nature of the storage place.

1.11.3 The expected duration.

1.11.4 The person who will be responsible for custody.

1.12 Date(s) of intended shipment(s). (See PART I paragraph 1).

1.13 For what period is shipment required (IAEA 822(a)).

1.14 Date of Application.

PART VIII SPECIAL ARRANGEMENT TRANSPORT OPERATION APPROVAL

INTRODUCTION

This part to be completed when a package design does not satisfy all the applicable requirements of the regulations and therefore is subject to paragraph 824 to 826 of the IAEA Regulations. The application should be accompanied by completed Part II and Part III (as applicable).
It is in the interest of the applicant to demonstrate that all alternative options have been fully explored and that all documentary evidence is presented to justify the reason for the Special Arrangement application. Such applications should only be sought on a short-term basis or to cover minor shortfalls in some regulatory requirement.

1. ADMINISTRATIVE INFORMATION.

1.1 Provide name, address, fax/e-mail and telephone number of organisation and officer who will be the contact for communications for the following:

1.1.1 Applicant.
1.1.2 Designer (if other than applicant).
1.1.3 Manufacturer.
1.1.4 Consignor.
1.1.5 Originator of shipment.
1.1.6 Consignee.

2. State:-

2.1 The actual radioactive contents.

2.2 The mode of transport.

2.3 The type of conveyance.

2.4 The probable or proposed route (IAEA 822(b)).

3. State if there are any restrictions on the mode of transport, types of conveyance or freight container to be used (IAEA 831(e)).

4. Specify:-

4.1 The number of packages per conveyance.

4.2 The number of conveyances per consignment.

5. State the Competent Authority Identification Mark. This should be either:-

5.1 The same for designs which have previously been approved.

5.2 Obtained from the Competent Authority for new design applications.

6. State in which respects, and justify, the reasons why the consignment cannot be made in full accordance with the applicable requirements of the regulations. Reference the relevant sections of this Guide (IAEA 825(a)).

6.1 Identify and justify what 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)).

6.2 Specify the Quality Assurance arrangements/programmes that apply and will be referenced on the Certificate.

6.3 Specify the Emergency Arrangements. A nil response is unacceptable.

7. If it is intended to store the consignment temporarily at any point during transit specify:-

7.1 The place.

7.2 The nature of the storage place.

7.3 The expected duration.

7.4 Who will be responsible for custody.

8. State date(s) of intended shipment(s). (See PART I section 1).

9. State date of Application.

PART IX APPLICATION FOR UK APPROVAL OF DESIGNS OF FOREIGN ORIGIN BY VALIDATION OR INDEPENDENT CERTIFICATION AS PART OF A MULTILATERAL CHAIN

1. ADMINISTRATIVE INFORMATION

1.1 State the name, address, fax/e-mail and telephone number of the organisation and officer who will be the contact point for communication for the following:-

1.1.1 Foreign Competent Authority.
1.1.2 Consignor (if not the Applicant).
1.1.3 Carrier(s).
1.1.4 Consignee.

1.2 The documents which must be submitted to the UK Competent Authority in support of an application for UK validation of an approval certificate issued by a foreign Competent Authority or for UK approval by independent certification are as follows:-

1.2.1 The approval certificate itself.

1.2.2 Either i) extracts from the original DSR, or,
ii) a new DSR.

The extracts from option i) should be as submitted to the Competent Authority of the country of original approval.

For option ii), the DSR should follow the format identified in the relevant parts of the Guide.

The DSR must include: -
i) All drawings.
ii) Summary test results, or details of alternative demonstrations of compliance.
iii) Material specifications, if not given on the drawings.
iv) References to quality assurance programmes applicable within the jurisdiction of UK Competent Authority.
v) References to the emergency response procedures applicable whilst the package or consignment is in the UK.
vi) For package designs and shipments involving fissile materials, appropriate safety information on the means of establishing compliance with the regulatory criticality safety provisions.
vii) For approvals under special arrangements, detail the reasons for special arrangement and compensatory safety measures that demonstrate regulatory standards of safety are attained.
viii) For Type B(M) packages, details of operational controls, specific to transport in the UK.

1.2.3 The following documents should be available before submission and supplied on request.
i) Full test reports.
ii) Details of the applicable Quality Assurance programmes.
iii) Details of the Emergency Response arrangements.

1.2.4 For shipment approval, it is not necessary to include the additional items under section 1.2.2, if these have previously been submitted for UK approval.
However, shipment approval from the country of origin must be available.
Provide any necessary additional details of operational controls specific to transport in the UK.
Provide the information in Part IV section 2 of this Guide.

1.3 Submit all documents in English. Time delays may result in seeking translation within the UK.

1.4 State the date by which Approval is required.

1.5 Give the date of Application. This should be at least 3 months in advance of the date given in 1.4 above.

PART X MODIFICATION PROCEDURE FOR EXISTING DESIGNS

1. INTRODUCTION

The object of this procedure is to establish a system whereby modifications can be classified according to their effect upon safety of the package design. The procedure is intended to help prevent inadvertent invalidation of certificates due to alterations of package designs made without Competent Authority knowledge and to allow alterations having no effect on safety to proceed with minimum administrative delay.

Proposed modifications to existing approved designs are subject to competent authority approval and shall be submitted for consideration under one of the categories shown in paragraph 4.

In view of the minor nature of amendments and many concessions, and the fact that concessions in particular may be numerous in the manufacture of large items, the need for formal prior competent authority approval may be waived in some cases, in the interests of expediency. In all cases where prior competent authority approval is not sought, copies of the amendment /concession documentation must be submitted to the competent authority following internal approval. A decision not to apply for prior competent authority approval for amendments and concessions is at the risk of the consignor. Applicants are advised to discuss the need for approval with the competent authority for all but the most minor cases to avoid the risk of non-compliance with the terms of approval.

When the modifications have been approved by the Competent Authority, the documentation will be updated in accordance with paragraph 4 below. This arrangement may also be used to cover changes to the safety report, involving operating procedures, or assessment methods etc where no change to the hardware is involved.

2. ADMINISTRATIVE INFORMATION

2.1 State package title and Competent Authority identification mark.

2.2 State name, address, fax/e-mail and telephone number of the organisation and officer who will be the contact for communications for the following:-

2.2.1 Applicant.

2.2.2 Designer (if other than Applicant).

2.2.3 The location where the package may be seen during modification.

2.3 State category of proposed modification i.e. CATEGORY A, B, C, AMENDMENT OR CONCESSION.

2.4 State method by which the Competent Authority will be informed of the serial numbers of modified packages.

2.5 Expiry date of current Certificate.

2.6 Date by which modification is requested (See PART I paragraph 1).

2.7 Date of Application.

3. MODIFICATION

3.1 Briefly describe the proposed modification and the necessity for the change on a Modification Sheet (see paragraph 3.6)

3.2 Justify that the proposed modification preserves the original design intent.

3.3 Identify the parts of the original application affected: state paragraph references and provide editorial details.

3.4 Justify the choice of the selected category.

3.5 The Competent Authority reserves the right to reclassify the modification category proposed by the Applicant.

3.6 The Modification Sheet should contain, as a minimum, the information outlined below:-

a) Reference Number.
b) Competent Authority Design Number.
c) Applicants Safety Document Reference.
d) Drawing Reference.
e) Subject.
f) Modification Category proposed and justification.
g) Detail of proposed Modification.
h) Applicants Name.
i) Signature of Responsible Officer and Date.
j) Space for Competent Authority comments and signature.
Sufficient space (50mm x 30mm minimum), must appear on the Modification Sheet for the Competent Authority Authorisation Stamp.

4. GUIDE TO MODIFICATION CATEGORIES

4.1 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 or 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.

4.2 CATEGORY B:

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

If approval is granted, the Modification Sheet (see paragraph3.6) 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.

4.3 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 (see paragraph 3.6) 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.

4.4 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 (see PART I paragraph 2) other than in iii) below. The following examples fall within this category.

i) Changes in reference document numbering systems (provided they do not change the scope of the reference).
ii) Changes in drawing numbers resulting from the Applicants own internal organisational 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 in order to rectify an indisputable error and for which the 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.

4.5 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.