



## Guidance for Package Approvals in the United Kingdom

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### 1 Abstract

Approval is required under the transport regulations for a wide range of package designs and operations, and applications for competent authority approval and validation are received from many sources, both in the United Kingdom and overseas.

To assist package designers and applicants for approval, and to promote consistency in applications and their assessment, the UK Department for Transport issues guidance on the interpretation of the transport regulations and the requirements of an application for approval and its supporting safety case.

The general guidance document, known as the "Guide to an Application for UK Competent Authority Approval of Radioactive Material in Transport", has been issued for many years and updated to encompass the provisions of each successive edition of the IAEA transport regulations. The Guide has been referred to in a number of international fora, including PATRAM, and was cited as a "Good Practice" in the report of the IAEA TRANSAS Appraisal of the UK in 2002.

Specialist guides include the Guide to the Suitability of Elastomeric Seal Materials, which is the subject of a separate paper in this conference, and the Guide to the Approval of Freight Containers as Types IP-2 and IP-3 Packages.

This paper discusses the guidance material and summarises the administrative and technical information required in support of applications for approval of package designs, special form and low dispersible radioactive materials, shipments, special arrangements, modifications and validations.

### 2 Introduction

Competent authority approval is required under the IAEA transport regulations [1] for a range of package designs, special form and low dispersible radioactive material designs, special arrangements and certain shipments. In the United Kingdom, the Department for Transport, DfT, is the competent authority responsible for these approvals, and receives several hundred applications per year from transport operators throughout the world.

In the interests of common safety standards it is important that a consistent approach be maintained to the assessment and approval of applications from all operators, and for applicants to have clear guidance on what is acceptable to the competent authority. The transport regulations [1] and their supporting guidance material [2] lay down very clear requirements for package safety, although there is scope for interpretation, particularly in design methodology and the approach to compliance. As discussed in the IAEA publication "Compliance Assurance for the Safe Transport of Radioactive Material" [3] it is the responsibility of individual applicants to develop their safety cases to achieve compliant designs and operating regimes, and the approving authority, for its part, is encouraged to ensure that applicant organisations are clear as to what is acceptable. The DfT encourages applicants to discuss their proposals in advance of submission, to ensure that requirements are clearly understood and to avoid unnecessary delays and expense due to misunderstandings.

As part of its policy of informing applicants of the requirements and expectations, the DfT issues a number of guidance documents covering both specialist and general topics. Specialist guides include the Guide to the Suitability of Elastomeric Seal Materials, which is the subject of a separate paper in this conference [4], and the Guide to the Approval of Freight Containers as Types IP-2 and IP-3 Packages [5].

The DfT's general guide which applies to all applications is the "Guide to an Application for UK Competent Authority Approval of Radioactive Material in Transport" [6], commonly known as "The Applicants' Guide", or "The Guide", and this is the subject of this paper.

The Applicants' Guide has two main purposes. First, as mentioned above, it provides prospective applicants with information on the requirements for demonstration to the competent authority of compliance with the transport regulations, including some specific technical guidance, and second, it presents a format for the presentation of the safety case information to cover all requirements of the regulations. This also offers the benefit to the assessors that safety cases from different applicants are presented in a uniform style, thus easing the task of ensuring that all necessary items are covered. The Guide also includes an application procedure for approval of modifications during the currency of an approval certificate.

The Guide has a long history, having been issued for the 1973 edition of the IAEA Regulations and updated to cover each successive edition. It has been the subject of a number of papers by both the competent authority [7], and industry [8] and was cited as a "good practice" in the IAEA's TRANSAS mission to the UK in 2002 [9].

### **3 The Structure and Contents of The Guide**

The Guide contains information relating to all types of application that are normally likely to be made to the competent authority. It is separated into parts so that the applicant need only refer to the specific parts relevant to the type of application being prepared. The following sections summarise the several parts of The Guide:

#### **4 Part I General Information**

The General Information part of The Guide begins by confirming the confidentiality of all information supplied in connection with an application, subject to statutory requirements, and advises on timely submission to ensure approval by the required date. Applications are normally dealt with in order of receipt, although applicants may re-arrange priorities subject to assessments not having been started or substantially progressed. The format of The Guide is to be followed and all items covered unless shown not to be applicable. Packages are required to meet the UK statutory requirements, which are generally consistent with the IAEA regulations and the supporting advisory material. Applicants are advised to take account of any multilateral approval and other requirements in other countries likely to be involved in the subject of the application.

The guide only covers applications for competent authority approval, hence excepted packages, industrial packages, Type A packages and other self-certified items are excluded, although the user is advised that the competent authority may request sight of the safety cases of such items.

The importance of quality assurance in all aspects of transport is stated, to ensure a high level of transport safety and compliance with the regulations, particularly where the applicant is not necessarily the user of the package. Under the regulations, quality assurance programmes are required for design, manufacture, testing, documentation and use of the package, and the applicant must include in the application appropriate quality assurance recommendations for other organisations who may use, maintain or inspect the package.

The competent authority may wish to monitor any aspects of the production and use of a package including design, manufacture, testing and maintenance, and applicants are advised to give sufficient early information to enable inspectors to witness tests and carry out inspections. This will frequently be necessary before the formal application for approval is made. Certification or other evidence that a manufactured item meets the approved design specification is required and should be available for scrutiny. The names and locations of manufacturers should be provided to allow inspections to be made if required.

The General Information section also reminds the applicant of the regulatory requirements concerning the inclusion of other, non-radioactive, goods in packages, and the need for marking, labelling and placarding, which should be considered at the design stage, together with any special lifting gear, which would be subject to health and safety legislation of the countries in which it is to be used. The need to apply serial numbers and to inform the competent authority of these is also pointed out.

Computer analysis in design and verification is generally acceptable provided the procedures are shown to be reliable and conservative, and applicants using this method are asked to ensure that they have adequate evidence of validation, benchmarking and suitability to the application, together with an analysis of the effects of potential errors, and evidence of the competence of those engaged in the use of computer techniques.

Approval certificates are normally issued for a period of three years, but may be renewed upon application, allowing at least six weeks before expiry, if there are no changes to the safety case or the approval requirements. Applicants are expected to review their designs regularly, however, and evidence of a design review, addressing advances in techniques and availability of more accurate information, and any adjustments resulting from experience and/or changes of requirements etc., is required after a maximum of six years of use.

## **5 Part II Package Design Approval**

This is by far the largest part of The Guide, and it covers the requirements for an application for approval of a package design, separated into sections dealing with the several aspects of the design.

Part II begins with a section on "Administrative Information", including such requirements as the applicant's details, the type of approval required, the competent authority identification mark and the modes of transport required.

The first technical information required concerns the "Specification of the Radioactive Contents". Full information on the contents is required to enable the nature of the hazard to be assessed. The general nature of the materials is to be given, e.g. irradiated fuel, radiographic sources etc., followed by specific information on the radionuclides, the physical and chemical states, the quantity and the total activity. For isotopes whose  $A_1$  and  $A_2$  values are not included in the regulations, the method of determination is to be given. The nature of radiation emitted and any materials that affect the emitted radiation are to be identified, as well as any hazards due to daughter products. The maximum heat load to be carried and any effects on the contents due to normal and accident conditions of transport are to be stated with justification. Finally, any other dangerous properties of the contents are to be stated, and for irradiated nuclear fuel, the properties and irradiation history.

"Specification of Packaging" requires information on the design features that ensure that the principal requirements of the packaging are fulfilled, namely containment, control of radiation levels, prevention of criticality and prevention of heat damage. Thus an outline description of the package, including weights, is required along with any drawings, specification documents, and procedures for manufacture, inspection and maintenance. A tabular presentation of information relating to the design features and documents relating to each component of the packaging make up is encouraged.

"Transport Operations" include all those items associated with the preparation, consigning, loading, carriage, unloading and receipt of the package, and the provisions for these items are required in the application. Details of handling attachments, and special lifting equipment, with analytical or test evidence that lifting attachments will not fail in normal use are required. This includes the effects of fatigue, snatch loading and stress concentrations. Features not intended to be used for lifting must be protected from attempts at such use by removal, or other effective means.

Considerable attention is paid to the integrity of tie-down (or retention) systems. The transport regulations specify that "packages shall be securely stowed", and specific guidance on acceleration values to be allowed for to ensure international acceptability is given in the advisory material. These figures are acceptable to the UK competent authority. As far as package design approval is concerned, it is the tie-down attachment point to the package itself that is assessed, and crucially, if this attachment point should fail under excessive loading as in an accident, then the protective function of the package must not be compromised.

Also under "Transport Operations" the applicant is asked to supply details of heat output and to provide stowage instructions in the event of a high surface heat flux. Actions required both before and during shipment, and any need for exclusive use conditions are to be stated. Emergency arrangements or instructions are required for all package designs.

"Testing" is an integral part of all package design safety cases and applicants are asked to state the basis of their evidence for compliance with the regulatory test requirements. This may include actual tests, extrapolation, calculation or reasoned argument. Evidence to support the case is required, including relevant test reports and photographs. Performance tests before the first shipment, as required by the regulations, must be reported or specified as appropriate.

The section on "Design" begins with guidance on the use of analytical techniques to justify integrity under normal and accident conditions. Calculations should be explained using sketches, discussion and references, and

computer analyses, such as finite element analysis, should include a detailed description of the models used with any simplifying features and deviations from the package design. Scoping and sensitivity studies should be reported. Where thermal structural evaluation is carried out, then full details of the thermal model, with discussion of errors and simplifications are to be given. All structural evaluations should take account of material properties (at the appropriate temperatures) and failure modes, and full references to codes and standards or other sources should be quoted.

The adequacy of radiation shielding must be demonstrated under all regulatory conditions. Consideration is to be given to the effects of impact and fire conditions on the position and properties of the shielding material, including, for example, any volatilisation of hydrogenous neutron shielding components. Attention is required to sensitive areas of the package, such as seals, and to degradation by mechanical and thermal damage and by ageing. The position and physical size of shielding material is to be indicated in relation to the package as a whole. The maximum radiation levels are to be given at appropriate points in relation to the package to enable regulatory data, such as transport index and radiation levels following accidents, to be determined, for the maximum approved contents.

Applicants are required to nominate the items of the packaging forming the containment system and to show how the regulatory requirements for the integrity and robustness of the containment system are fulfilled. If special form radioactive material is to be carried, then its competent authority identification number is to be given.

Leak tightness of the containment system has to be demonstrable to the standards prescribed in the regulations, and this is normally achieved by means of a testable seal to verify the actual standard of leak tightness at each loading. The required temperature ranges of operation are to be addressed and suitable seal materials chosen. Compression set, creep, mechanical degradation, thermal ageing and any other means of deterioration are to be taken into account, so that a minimum of 10% effective seal compression is maintained throughout the transport operation, including accidents. Leaktightness standards may be demonstrated by calculation, computer analysis or by test, taking account of standardised leak rates and the concentration of radioactive material in the escaping medium to ensure that the permitted leakage limits under normal and accident conditions are not exceeded. Applicants should apply all tests and justifications to a package containing the maximum inventory and under maximum normal operating pressure.

Compliance with thermal requirements may be demonstrated by test, analysis or reasoned argument, although scale model tests are not acceptable for this purpose. Notable provisions are that prior damage from the regulatory impact events must be incorporated into the thermal assessment, and no artificial cooling is permitted following the thermal test. On the broader matter of thermal performance, applicants are asked to indicate the temperature limits for package operation and to calculate the effects of insolation and to identify any means of intercepting solar radiation. The temperatures reached by the package under regulatory conditions are to be determined taking account of the maximum and minimum heat loading. The effects of low temperatures on the containment system and on the susceptibility of the packaging materials to brittle fracture are to be considered. If the containment system includes a liquid primary heat transfer medium, the ullage must be defined and shown to be adequate under all regulatory transport conditions.

The effects of pressure on the package, including pressure caused by corrosion or radiolysis are to be assessed under all conditions, to show that the containment system does not experience unacceptable strain so as to threaten its effectiveness. Effects are to be given in relation to the mechanical properties of the materials.

The evaluation of impact performance is one of the most important aspects of a package safety case, as the impact response may affect all safety features of design, e.g. shielding, thermal response, containment and criticality. Impact evaluation may be by means of comparison with similar approved package designs, prototype testing, model testing, analysis or reasoned argument or a combination of these. If a comparison is being made, then the applicant must show by reference to drawings and design data that the subject package is at least as good as that previously approved. For prototype or model testing, the test methods should be described and the test orientations discussed to demonstrate that the most damaging attitude has been selected. For all but the most simple designs, a number of tests in different attitudes is likely to be required. For model testing, the model must be shown to be representative of the package design, and any deviations explained and justified. Test models of less than one quarter scale are not normally acceptable. Particular attention is to be paid to the scaling of welds. Where test models are to be instrumented, the significance of the outputs should be discussed. Test quality plans should be produced for all test programmes, and the Department should be advised in advance of the manufacture

of test items and the conduct of tests to enable arrangements to be made to witness operations. Analytical evaluation may involve relatively simple hand calculations or more sophisticated computer numerical analysis. In all cases the methods should be fully discussed and justified, materials should be fully characterised and, particularly where complex computer codes are used, the techniques must be validated by comparison of the results with known practical behaviour. Commercially available computer codes require significant user knowledge and experience, and evidence of this is required by the competent authority assessors.

Finally in the Design section, the applicant is required to confirm that the general and Type A requirements are met and, for Type B(M) packages, to state the Type B(U) requirements that are not met and to specify the compensating operational controls.

The final section in Part II refers to "Quality Assurance". Applicants are required to demonstrate the adequacy of quality assurance programmes for all stages of a package's life from design, through manufacture and inspection to use, maintenance and storage. The applicant has to show that the quality assurance arrangements of all parties involved in the package are acceptable and consistent with the hazards inherent in the transport of radioactive materials.

## **6 Part III Additional Design Information Required for Fissile Material**

This part specifies the information required in support of a safety case for transport of fissile material. Where the package is fissile excepted, the applicant is asked to state the grounds for this so that further provisions are not applicable.

Credit for the irradiation history of the fissile material may be taken in the determination of sub-criticality, in which case evidence, including appropriate measurements, are required to demonstrate that the parameters affecting sub-criticality can be determined from the irradiation history. Otherwise the state of maximum neutron multiplication must be assumed. Information is next required on the presence and maintenance of any neutron poisons.

A full assessment is required of arrays of packages under normal and damaged conditions, including the maximum fissile loading and the quantity and nature of moderating materials. Full details of the materials in the package, including dimensional sketches should be submitted together with details of analytical methods. The evidence for compliance with regulatory test requirements is to be given, including the state of damaged packages and the effect of flooding. Similarly the single package in isolation must be assessed including the effects of damage due to impact, fire and immersion. Where air transport is allowed, the effects of the enhanced tests must be given. All calculations are required to be validated and benchmarked, and any relevant differences between experimental assemblies, or calculation models, and the package are to be discussed and justified.

## **7 Parts IV and V Special Form and Low Dispersible Radioactive Materials**

These two parts describe the information to be provided in support of special form and low dispersible radioactive materials respectively. As well as the appropriate administrative information, specifications should include design descriptions and calculations, drawings, manufacturing specifications and quality assurance programmes applicable to all stages in the life of the materials.

The contents specification is to include the nuclides and the maximum activity, the heat output, the form of the materials and the nature of the radiations emitted, the means of removing moisture before sealing and confirmation that the materials are not irradiated after encapsulation. Any gases in the material or emitted during use are to be defined and their effects accounted for as well as any other (non-radioactive) dangerous properties.

A full demonstration of regulatory compliance is required, including the required mechanical and thermal tests, and the post-test measurements to ensure compliance with the regulatory indispersibility requirements.

## **8 Part VI Additional Information Required for Uranium Hexafluoride Package Approval**

This is a short part of the Guide to cover the specific regulatory requirements for packages containing UF<sub>6</sub>. Information is required on the performance of the package under the pressure, free drop and thermal tests, as well as confirmation of the specific conditions relating to test pressures and contents.

## **9 Part VII Shipment Approval**

Multilateral shipment approval is required for a range of package types as specified in the regulations, and this part of the guide is designed to specify the information to be given to enable the acceptability of a shipment to be assessed. Information required includes the actual radioactive contents of the package and the number of packages and consignments, the expected modes of transport, the proposed route and dates, and any restrictions or precautions applying to the transport operation. Details relating to exclusive use conditions and controls for criticality safety are required. Emergency arrangements, quality assurance programmes and transit storage arrangements are also to be given.

## **10 Part VIII Special Arrangement Transport Operation Approval**

Special arrangement approval is permitted under the regulations where it is not practicable for all regulatory provisions to be met, but where the applicant can show that compensatory safety measures are in place. Part VIII is to be used in addition to Parts II and III as applicable, to explain why the consignment cannot be made fully in accordance with the applicable requirements, and to describe and justify the compensatory arrangements.

## **11 Part IX Application for UK Approval of Designs of Foreign Origin by Validation or Independent Certification as Part of a Multilateral Chain**

Certain designs of foreign origin are required to be validated as specified in the regulations, and sufficient information is required to enable the UK competent authority to assess the acceptability of the package for transport in UK territory. The principal items required are the approval certificate itself, and extracts from the original design safety report (or a new design safety report) including drawings, summary test reports and specifications, references to quality assurance and emergency arrangements, criticality safety arrangements (where applicable), reasons for special arrangements (where applicable), and specific operational controls for Type B(M) packages. Full details of test reports, and of quality assurance and emergency response arrangements should be available to be provided to the competent authority on request.

## **12 Part X Modification Procedure for Existing Designs**

The UK competent authority operates a modification procedure to enable applicants to apply for approval of modifications to an existing design without having to resubmit a complete safety case. Applications are submitted on a single sheet, accompanied by appropriate supporting documentation. Modifications are categorised according to their effect on package safety as follows:

**CATEGORY A:** Major change to the package and/or the package design application directly affecting the assessed package safety, i.e. structural integrity, containment, shielding, heat transfer or criticality. All supporting documentation must be submitted. If approval is granted a revised certificate of approval will be issued before the modification may be put into effect.

**CATEGORY B:** Significant change to the package and/or the package design application not primarily affecting the assessed package safety. If approval is granted, the modification sheet will be endorsed and returned to the applicant to be attached to the certificate. Applicant's documentation is to be updated within six months or prior to next renewal of the certificate, if sooner.

**CATEGORY C:** Minor change to the package and/or the package design application not primarily affecting the assessed package safety. This is treated in a similar way to a Category B modification except that the time limit for updating the applicant's documentation is one year or prior to the next renewal of the certificate.

**AMENDMENT:** Minor change to documentation having no design or safety significance, e.g. numbering system changes and minor or obvious corrections. Documentation is to be updated in the same timescale as for Category C modifications.

**CONCESSION:** An authorisation to use a package which deviates from drawing or specification, in some respect which does not affect integrity or safety, and which it is not intended to introduce systematically to all packages. The requirement for a concession may be recognised during manufacture, maintenance or in service. A

concession does not entail the amendment of the DSR. Documentation is to be updated in the same timescale as for Category C modifications.

(In view of the minor nature of amendments and many concessions, the need of formal prior competent authority approval may be waived in some cases in the interest of expediency, although any decision not to seek approval is at the consignor's risk. Further information is given in the introduction to Part X of The Guide.)

### **13 Concluding Remarks**

The Guide to Applications issued by the Department for Transport presents comprehensive guidance to applicants for competent authority approval of designs and shipments, as required by the IAEA transport regulations. It also includes a procedure for the approval of modifications. It identifies the information required in an application and includes, where appropriate, information on the standards expected by the competent authority to ensure regulatory compliance.

This paper has given a summary of The Guide, its structure and the requirements specified within it. It is not a complete account of The Guide, however, and potential applicants to the Department for Transport for approval of a package design are recommended to consult the document in full before preparing their application. The Guide is to be found on the Department for Transport website at [www.dft.gov.uk](http://www.dft.gov.uk), in the Shipping and Ports section, together with other papers on transport of radioactive material. The Department also encourages applicants to consult with its assessment staff before submitting large or complex applications, or if they are in doubt about what is required.

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