



ONR GUIDE			
<b>GUIDANCE FOR APPLICATIONS FOR UK COMPETENT AUTHORITY APPROVAL</b>			
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Applications for Competent Authority approval should be sent to:

[class7@onr.gov.uk](mailto:class7@onr.gov.uk)

or

Office for Nuclear Regulation  
Transport Permissioning  
4NG Redgrave Court  
Merton Road  
Bootle  
Merseyside  
L20 7HS

## 1. GENERAL INFORMATION

- 1.1 The Office for Nuclear Regulation (ONR) is the GB Competent Authority (CA) for the civil inland surface transport of Class 7 (radioactive material) dangerous goods. This statutory duty is given to ONR through The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (CDG). These regulations transpose into UK law the international standards ADR<sup>1</sup> and RID<sup>2</sup> for transport of dangerous goods by road and rail, which in turn are based on the IAEA Regulations for the Safe Transport of Radioactive Material (currently SSR-6). Similar regulations apply in Northern Ireland, where the CA for civilian road transport of Class 7 dangerous goods is the Department of the Environment Northern Ireland.
- 1.2 There are also international requirements based on SSR-6 applicable to sea and air transport namely the International Maritime Dangerous Goods Code and the International Civil Aviation Organisation's Technical Instructions for the Safe Transport of Dangerous Goods by Air. These are implemented in the UK by The Merchant Shipping Act, The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations, The Air Navigation Order and The Air Navigation (Dangerous Goods) Regulations. The CAs for these modes of transport (of civilian Class 7 dangerous goods in the UK) are the Secretary of State for Transport including the Maritime and Coastguard Agency (for transport in UK waters) and the Civil Aviation Authority (for air transport).
- 1.3 The purpose of the above regulations is to ensure the safety of the transport of radioactive materials. The regulations apply a graded approach, and the aspects of radioactive materials transport involving the higher hazards are regulated by a permissioning regime in which certain designs and activities require prior CA approval. As well as being the CA for inland transport in GB, ONR also provides advice to and, for this permissioning regime (involving design approvals), acts on behalf of the other civilian UK CAs and agencies mentioned above.
- 1.4 The purpose of this document, the Applicants Guide, is to provide guidance to organisations applying to ONR for CA approval for new designs, renewal of existing approvals, validation of overseas approvals or modifications to approved designs. The approach taken in this document varies from that in previous versions of the Guide in that much more emphasis is given to how an application should justify safety. Furthermore unlike previous versions, the document does not attempt to reproduce the requirements of the IAEA regulations. These requirements are set out clearly in SSR-6, and there is supporting guidance in SSG-26 and schedules of regulatory provisions in SSG-33.
- 1.5 Accordingly applicants seeking CA approvals should be familiar with the IAEA requirements, and how they are implemented through ADR and RID, and where appropriate, the International Maritime Dangerous Goods Code and the International Civil Aviation Organisation's Technical Instructions for the Safe Transport of Dangerous Goods by Air.
- 1.6 This document is set at a high level and does not prescribe detailed technical guidance; it is the dutyholder's responsibility to decide how specific safety and legal requirements of transport packages and packagings should be substantiated. ONR

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<sup>1</sup> European Agreement concerning the International Carriage of Dangerous Goods by Road, issued by the United Nations Economic Commission for Europe, Committee on Inland Transport

<sup>2</sup> Regulations concerning the International Carriage of Dangerous Goods by Rail, Appendix C of the Convention concerning International Carriage by Rail, issued by the Intergovernmental Organisation for International Carriage by Rail

expects relevant technical / safety standards and good practices to be used. However ONR publishes on its website various sources of internal technical guidance to inspectors. The scope of these documents is being broadened to cover the safety of the transport of radioactive materials, and so will provide a supplementary source of guidance for applicants in due course.

- 1.7 In April 2014 ONR introduced a policy of charging to cover the costs of its work necessary to grant CA approvals. This is in accordance with Regulation 27 of CDG (2009), which allows the CA to charge a fee where a person has asked the CA to perform one of its functions, such as issuing an approval. The fee must be reasonable for the work performed; in other words it must depend on the amount of work done to satisfy a particular request. It covers the cost of assessing the application and also undertaking any associated inspections, eg of testing procedures, manufacturing methods, or management systems (upon which the CA approval is contingent).
- 1.8 To ensure that the fees charged are reasonable, ONR has reviewed its assessment processes to ensure they are efficient, proportionate and targeted. It is also clearly to the advantage of the applicant to make high quality submissions that have been independently reviewed; this is particularly true for renewal applications. Not only is the approval likely to be granted sooner, but the fees charged should be lower. ONR sometimes uses Technical Support Contractor (TSC) resource to assist its assessment of applications, and the associated costs will also be passed on to the applicant.
- 1.9 As the fees depend directly on the amount of work undertaken, ONR does not have set fees for each type of application. The fees charged for similar types of approval can vary over a broad range. Nevertheless, some information on indicative charges is provided in Table 2 (paragraph 6.7), and further information is presented in the Impact Assessment that was undertaken before the introduction of charging (available on the ONR website<sup>3</sup>).

## **2. APPLICATIONS FOR COMPETENT AUTHORITY APPROVAL**

- 2.1 ONR considers it desirable for there to be some engagement with the applicant before a submission is made, and this is particularly important if the safety case is novel or complex. Should the applicant request this, it gives ONR the opportunity to provide early advice, clarify any general expectations, witness tests, inspect manufacturing eg of prototypes, assess any key technical supporting documents that may be available, and start to gain familiarity with the important elements of the developing safety case. However ONR must remain independent of the process of developing the safety case, which is the applicant's responsibility. Accordingly, any advice given by ONR will be in general terms eg to clarify a design safety principle, and without any guarantee that it will make the case acceptable when it is formally assessed.
- 2.2 The term 'safety case' is used in this guidance to refer inclusively to the totality of the documentation that demonstrates the safety of a design / operation and its compliance with the regulations. The term simply means all the information submitted in an application (with the possible exception of some administrative details) together with any supporting reports or reference material. In the regulations, safety means "an acceptable level of control of the radiation, criticality and thermal hazards to persons property and the environment that are associated with the transport of radioactive material" (SSR-6 paragraph 101).
- 2.3 Applications for CA approval should be sent to the address on page 2. The application should preferably be submitted in electronic form; SI units should be used; and the application should be in English to avoid delays and additional charges. With electronic

<sup>3</sup> <http://www.onr.org.uk/transport/rmt-final-stage-ia.pdf>

submissions, it will be helpful if informative file and folder names are used (or at least if an index to these is provided). Applications should be prepared using a process that consistently produces safety cases that are of a good quality, fit for purpose and useable. Guidance on the qualities of safety cases is provided below (paragraph 2.35 onwards).

- 2.4 All those involved in the various aspects of the preparation of safety cases should be suitably competent, including any contractors involved in the work. Preparation of safety cases involves more than carrying out assessments and analyses and writing the constituent documents. The detailed information in these documents needs to be checked and verified; there then should be an independent review of the complete safety case by someone not involved in its preparation; and finally the safety case should be approved by a person in a position of appropriate responsibility in the applicant's or design authority's organisation.

### Contents of Applications

- 2.5 Applications for CA approval should address all the applicable requirements of the regulations for the types of design / application and the modes of transport requested. Applicants should be aware that although the regulations contain sections or chapters setting out design requirements, there are other sections on general provisions and requirements, eg on management systems. Applicants may find SSG-33, which contains schedules of regulatory provisions, useful in this respect. The regulations require certain information relating to the safety case to be presented on certificates of approval (CoA), and if this information is coherently provided in the submission, with evidence of its adequacy, this may expedite the processing of the application.
- 2.6 The application should include a 'route map' showing where in the submission compliance with the requirements of the regulations has been demonstrated. To do this, it should include a list of all the paragraph numbers of the regulations relevant to the design etc and mode of transport in question, and cross reference these to the submission documentation (see also paragraph 2.38).
- 2.7 For renewals of existing approvals, applicants are strongly encouraged to include a design review in their application; further details are discussed in Section 4.
- 2.8 The fundamental question to be addressed in a submission is whether a design / consignment is safe, ie compliant with the regulations. The submission therefore should describe the aspects of the design and operations that ensure safety, ie answer the question: how is it safe; what makes it safe? It can also be helpful if the submission considers safety margins, and addresses the question: how safe is it? An effective submission answers these questions simply and succinctly, and supports all claims by adequate arguments and evidence.

### Structure of Applications

- 2.9 Generally for applications for approval of new designs, shipments or consignments, or where the safety case has been rewritten, the application should be divided into two parts.
- Part 1 provides information, including as appropriate the description of the design and the safety limits on operation. Part 1 should explain why the design and its operation are safe. It should summarise and make reference to the detailed evidence in Part 2 that substantiates the claims made in Part 1.
  - Part 2 contains the technical analysis and justification demonstrating compliance with the regulations, ie the substantiation of the design.

- 2.10 This tiered approach is similar to that for the European PDSR<sup>4</sup>, and is appropriate for most applications, not just package designs. A possible exception may be for separate shipment approvals of individual packages, where only Part 1 would be required if the design of the package had been fully substantiated in other documentation, to which Part 1 would need to refer, to explain and justify the claims made.
- 2.11 Applicants are encouraged to follow this two tiered approach (ONR applies the European PDSR as a benchmark standard during its assessments, and IAEA is incorporating it into its guidance). This approach is optional for renewal applications, where there may be little change to the original safety submission. Renewal applications should include a proportionate design review report (paragraph 4.2) and a route map to the regulations (paragraph 2.6).

### **Application Part 1**

- 2.12 Part 1 should:
- a) contain general and administrative information, including as appropriate
    - i) name of design of package / material
    - ii) contact details of applicant, design authority etc
    - iii) CA identification mark<sup>5</sup>
    - iv) type of approval requested, and the regulations under which the application is being made
    - v) modes of transport and any restrictions on the types of vehicles or freight containers
    - vi) whether the design has been approved by the CA of another country
    - vii) details of manufacturers, should the CA wish to inspect
    - viii) information relating to packaging serial numbers
    - ix) the requested date for the Approval (state any strategic or timing factors that may be useful to ONR in prioritising the approval work);
  - b) for shipment approvals (including special arrangements) provide details as appropriate of:
    - i) the consignor, originator of shipment, consignee, conveyance, packages per load, loads per conveyance
    - ii) the probable or proposed route
    - iii) the place, nature, duration of any transit storage, and person responsible for custody
    - iv) intended dates of shipments or requested duration of approval;

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<sup>4</sup> produced by the European Association of Competent Authorities, see <http://euraca.eu>

<sup>5</sup> For new designs the CA may have pre-allocated ranges of numbers to design authorities. Any make-up letter following the design number is assigned by the CA.

- c) provide a full engineering description and specification of the design of the package / material;
  - d) specify the contents including any restrictions on the radioactive contents;
  - e) describe the intended use, and any operational and maintenance requirements, demonstrating their adequacy for the intended use;
  - f) provide details of contingency and emergency arrangements, demonstrating their adequacy;
  - g) provide details of the relevant management system(s) covering all aspects of design, manufacture and use, showing that these arrangements will ensure that the requirements of the safety case will be adequately implemented;
  - h) for design approvals, provide an overview of the safety case – ie the main design principles and safety performance characteristics, summarising and making reference to the detailed evidence (Part 2) that substantiates these claims;
  - i) include a ‘route map’ showing where in the submission compliance with the requirements of the regulations has been demonstrated (paragraph 2.6); and
  - j) for renewal applications, provide a design review (see Section 4).
- 2.13 The information, claims and arguments in Part 1 should answer the question ‘what makes it safe?’. As indicated above, Part 1 should explain why the design and its operation are safe, summarising and linking to the detailed evidence that substantiates these claims in Part 2 (or possibly, for certain shipment approvals, in other documents eg relating to the package design approval).
- 2.14 So that the safety case is clear and intelligible, the description and substantiation of the design should identify and present sufficient details of the design features and components that have an effect on:
- the containment of radioactive materials (eg seals, flask lid / body assembly);
  - the control of external radiation levels (eg shielding and associated support structures);
  - thermal performance (eg internal heat generation and heat removal);
  - preventing criticality (eg neutron absorbers and associated support structures); and
  - the impact and structural performance (eg shock absorbers, lifting / securing features).
- 2.15 Where appropriate, the operational limits of these safety-significant design features and components may be specified to enable these limits to be compared (in Part 2) with claimed performance; this comparison allows the margins to loss of safe performance to be established for each design feature or component.
- 2.16 The description of the management system should justify how the requirements identified within the safety case will be implemented effectively. These requirements should be collated and clearly presented in the safety case, so they are visible to users of the design. The means of implementation considered should include:
- administrative and operational limits and controls to ensure the design / material is used safely at all times;
  - the required examination, inspection, maintenance and testing regimes justified in or assumed by the safety case;

- the procedures and instructions that need to be followed, eg for operation, handling and maintenance;
- supervision of operations, qualification and training of staff, and other safety management requirements; and
- inputs to radiological protection programmes and emergency planning.

## Application Part 2

- 2.17 Part 2 of the application should contain the technical analyses, the detailed evidence to support the demonstration that:
- the design is compliant with the requirements and performance standards of the regulations; and
  - the components of the design will meet their safety performance requirements and provide the necessary safety functions during routine, normal and accident conditions of transport, as defined in the regulations.
- 2.18 In other words, Part 2 should answer the question 'is it safe?'. Where appropriate it should also determine the safety margins for the safety-significant design features and components by comparing claimed performance with the safety limits prescribed in each regulatory requirement (ie answer the question 'how safe is it?'). It should show that these safety margins are greater than the uncertainties associated with the results predicted by the analyses.
- 2.19 Depending on the type of application, Part 2 should provide the detailed technical analyses to demonstrate: the containment of radioactivity; the control of radiation levels; the prevention of criticality; and the prevention of damage caused by heat (both to internal components and externally to the design). It may also be appropriate to provide an underpinning structural analysis of the mechanical behaviour of components and features of the design.
- 2.20 The purpose and conclusion of each analysis section or report should be stated explicitly, in terms of what specific aspects of equipment safety it is justifying. This makes it easier to follow the safety justification arguments in the submission as a whole, and facilitates consistency between the higher level parts of the submission and their supporting analysis sections. (See also the comment in paragraph 2.3 about informative file / folder names for electronic submissions.)
- 2.21 The regulations allow for the substantiation of the design (ie the demonstration that it meets the performance standards in the regulations) to be made by physical testing, calculation or reasoned argument. A combination of all three is often used, with the results of physical testing being interpreted by calculation and reasoned argument. This is especially so for mechanical performance testing; demonstration of the adequacy of shielding is often done by calculation but may also involve or be based on physical measurements; criticality safety justifications are more likely to be entirely by calculation. Computational techniques can vary from bespoke hand-calculations to the use of powerful computer codes involving mathematical models such as finite element or Monte Carlo. It is important not to overlook the significance of reasoned argument, which often provides the cohesion in design substantiations. The applicant may wish to refer to the guidance on Section VII of SSR-6 that is provided in SSG-26.

### *Physical testing*

- 2.22 Physical testing may be on prototypes or scale models (with the test parameters suitably adjusted). It may be permissible to use the results from previous tests or from tests on similar designs, if these can be sufficiently justified (ie shown to be valid for the design in question). The items being tested should be representative of and



simulate as closely as practicable the materials and packagings for which the design approval is sought. Any differences between the items tested and those described and specified in the application should be explained and justified. Tests and experiments may also be necessary to underpin the validation and verification of any mathematical models being used to substantiate the design.

- 2.23 Prior to physical manufacture and/or test of models or prototypes, the applicant should notify ONR that such manufacture and/or test is to be carried out. Sufficient notice should be given to enable ONR to arrange to witness the manufacture and/or test(s), at its discretion. The notification should be accompanied by detailed manufacture and/or test procedures and control documentation, and allow sufficient time for ONR to review these documents, prior to manufacture and/or testing. A test Quality Plan should also be submitted, identifying responsible persons / organisations for each element of the proposed test. Such matters may be raised with ONR during early engagement (see paragraphs 2.1 and 6.4).

### *Mathematical modelling*

- 2.24 Complex modelling software is becoming increasingly accessible and easy to use, with the accompanying danger of misuse by inadequately trained analysts (even simple codes can be misapplied by the untrained); the mathematical modelling section of the analysis report serves as the confidence test of the competence of the analyst (although ONR may also request some objective evidence of this competence).
- 2.25 Accordingly, analysis reports should demonstrate that all mathematical models used have been validated and verified. Definitions of validation and verification are provided on the National Agency for Finite Element Methods and Standards (NAFEMS) website<sup>6</sup> as follows (these definitions are equally applicable to criticality and shielding codes):
- Validation: the process of determining the degree to which a model is an accurate representation of the real world from the perspective of the intended uses of the model.
  - Verification: the process of determining that a computational model accurately represents the underlying mathematical model and its solution.
- 2.26 So validation means explaining why the model used in the analysis is an adequate simulation of the 'real world' problem, ie it should answer the question: 'why is this model the right one for solving this problem?' So, this part of the submission should:
- Describe and justify the assumptions and simplifications used to produce the model, for example: why certain features of the design can be excluded from the model, and why the included features are modelled the way they are.
  - Demonstrate that the output of the model accords with reality, for example by benchmarking against test data.
- 2.27 A simple, bounding model based on pessimistic assumptions may be considered an acceptable simulation, provided the assumptions do not make the implementation of the design impracticable.
- 2.28 Model verification answers the question 'is the model error-free?' and confirms that particularly for complex codes they have been used correctly by analysts who are competent to use them. So this part of the analysis report should:

<sup>6</sup> [http://www.nafems.org/downloads/working\\_groups/amwg/4pp\\_nafems\\_asme\\_vv.pdf](http://www.nafems.org/downloads/working_groups/amwg/4pp_nafems_asme_vv.pdf)

- For new, bespoke models, demonstrate that the governing mathematical equations and calculational methods have been correctly formulated and implemented.
- For well-established codes, demonstrate that the code has been correctly installed and tested.

2.29 This part of the analysis report should also demonstrate that accurate and appropriate physical and material property data have been used, especially for novel designs and materials, and that the model has used 'as-built' design data.

#### *Test cases and results*

2.30 A sufficient number of tests and calculational cases need to be performed and presented so that the questions 'is it safe?' and where appropriate 'how safe is it?' can be answered for the safety-significant design features and components. These should be performed for all the prescribed regulatory conditions, including the cases for which the prescribed challenges are to be applied individually as well as for when the challenges are to be applied successively, eg a 9 m drop followed by a 30 minute 800 °C fire. In the latter case, the potential for a challenge making the package more vulnerable to a following challenge should be addressed.

2.31 The validity of presented calculational results should be established by:

- demonstrating that the initial results confirm modelling assumptions (eg for elastic behaviour, temperature range for material data, meshing refinement etc);
- performing enough sensitivity cases to cover uncertainties (eg range of applied challenges, gaps opening/closing, slap-down angle, directional variations in thicknesses available for shielding or neutron absorption etc);
- undertaking (and presenting evidence of) internal quality assurance checks and independent peer review; and
- undertaking 'sanity checks' and eliminating 'loose ends' by resolving / explaining any aberrant or unexpected behaviour.

#### *Managing analysis by third-party contractors*

2.32 When the analysis in a submission has been undertaken by a third-party contractor to the applicant, the regulator may have to interact with this contractor as well as the applicant. The GB CA has historically interacted with the range of applicants' third-party contractors, including manufacturers, suppliers, material test laboratories, design authorities and analysis specialists. In many respects, the analysis specialist contractor is no different from any other contractor in that interactions required between ONR and the contractor are governed by the same principles, which include the following:

- The liability for the application is on the applicant and they are responsible for ensuring (and assuring the CA) that their contractor is suitably competent for the services being provided, and that the deliverables from the contractor are fit for purpose.
- Evidence of the contractor's competence and compliance with applicable standards should be made available to the CA, as well as the results of any audit carried out by the applicant on the contractor.
- The CA may require access to the contractor to establish the contractor's suitability or for technical discussions regarding the deliverable; in this case the applicant's contract with the contractor must be flexible enough to allow for this.
- CA access to the contractor with regard to the submission will be arranged by and through the applicant.

## Desirable Qualities of Applications

### 2.33 Submissions should:

- describe the safety-significant design features and components of the design / consignment (ie those which have an effect on safety) and their safety function;
- describe the safety limits or constraints on these safety-significant design features and components, why they are needed and how they are derived;
- justify claimed safe performance using appropriate and validated analysis methods;
- keep the arguments simple – even if analysis is complex; and
- provide consistency between the higher level safety report (eg Part 1) and the supporting documentation / evidence.

### 2.34 Submissions should avoid:

- presenting unnecessary information, but be focussed on quality and clarity, not quantity;
- leaving 'loose ends' / gaps in arguments – this casts doubt on the applicant's quality assurance and makes the regulator ask: 'what else is wrong?';
- using the CA as a peer reviewer – applicants should do their own internal quality checks and independent reviews; and
- being incomplete or having unresolved issues – any analysis and contractual conflicts should be resolved before formal submission to the regulator (notwithstanding any early engagement).

### 2.35 The desirable qualities of safety cases may be considered under eight headings as follows.

#### *Intelligible*

2.36 The application, and safety case it contains, should be intelligible and structured logically to meet the needs of those who will use it. There should be a sufficient description of the design and/or operation, and all descriptions and terms should be easy to understand by the key users. All arguments should be cogent and be developed coherently. All references and supporting information should be identified and be easily accessible. There should be a clear trail from claims through the arguments to the evidence that fully supports the conclusions, together with commitments to any future actions. Operational requirements, including maintenance, etc should be clearly defined.

#### *Valid*

2.37 The application should be valid. It should accurately represent the intended design and manufacture, and the operational and managerial aspects. It should reflect changes that have arisen from previous modifications, revised operating methods, operating experience, examination and test results, different analytical methods, renewal reviews and any other appropriate trigger.

#### *Complete*

2.38 The safety case should be complete and contain the information necessary to show that the design, shipment and associated operations will be adequately safe and will be so over the period for which the safety case is valid, ie they will continue to meet all the applicable regulations (explaining why any regulations are considered to be not applicable). There should be reference out from the safety case to important supporting work. For package designs, the safety case should substantiate the design

of the packaging for the authorized radioactive contents, including the internal components, materials, furniture etc that are necessary for the packaging to perform the safety functions.

### *Evidential*

- 2.39 The safety case should be evidential. The arguments developed in the safety case should be supported with verifiable and relevant evidence (ie documented, measurable, etc). This should encompass the following:
- Identification of key assumptions and the basis for these.
  - The degree of sensitivity to key assumptions (sensitivity studies may be needed for key data assumptions).
  - The link between engineering and safety provisions should be demonstrated.
  - Claims relating to the integrity or performance of engineered components should be justified in the engineering substantiation part of the application. The necessary understanding of the behaviour of novel aspects of the design should be established from appropriate research and development.
  - The analytical methods used to substantiate safety, including any computer code analyses, should be shown to be fit for purpose with adequate verification and validation. If a limit on the validity of an approach exists, evidence should be provided to show that the approach is used within the valid region; the use of inferred or extrapolated information needs to be carefully substantiated.
  - Where safety is demonstrated using claims based on previous experience, sufficient evidence should be presented to show that it is relevant to the current application.

### *Robust*

- 2.40 The safety case should be robust. It should demonstrate that the design conforms to good engineering practice, sound safety principles and the requirements of the regulations, including appropriate conservatism where there is uncertainty, and adequate safety margins.

### *Integrated*

- 2.41 The safety case should be integrated. The various parts of the application should be internally consistent. Operational assumptions and controls, and those needed for shipment, should be identified and substantiated.

### *Balanced*

- 2.42 The safety case should present a balanced account, taking into consideration the level of knowledge and understanding. Areas of relative uncertainty should be identified, not just strengths and claimed conservatisms. Limitations or potential areas for improvement in the design or operation should be explained clearly and openly (eg in the summary or main conclusions of the safety case).

### *Forward looking*

- 2.43 The safety case should be forward looking and demonstrate that the proposed design will remain safe throughout a defined life-time, taking account of the effects of ageing and degradation. It should identify the important aspects of operation and management that need to be implemented to maintain safety, including maintenance, inspection and testing regimes, and operational limits and conditions. It should identify any potential modifications / improvements along with the timescale for their implementation. It may also be desirable to consider the impact of known, future changes to the regulations.

### 3. VALIDATIONS

- 3.1 Multilateral approval is required for certain designs and shipments, especially those of higher radiological hazard and for all fissile materials. The first approval is by the CA of the country of origin and then subsequent approvals are issued by the CAs of the countries through or into which the shipment is made. Multilateral approvals may be granted by these subsequent countries either by a new CoA or by the validation of the original CoA if no additional controls or restrictions are to be applied.
- 3.2 Regarding the form of the validating document, the regulations state that validation may take the form of an endorsement on the original certificate or the issuance of a separate endorsement, annex, supplement, etc. ONR takes advantage of this flexibility allowed by the regulations and uses a number of formats for the different types of validation. However if ONR finds that it needs to impose additional controls or restrictions to those stated on the original certificate, then ONR will issue a GB CoA.
- 3.3 For validations of CoAs for fissile package designs and shipments, a format similar to a CoA is followed except the original CA identification mark is retained rather than assigning a GB mark. These are referred to as Validations rather than CoAs, to avoid confusion.
- 3.4 For the situation where a fissile package being transported by ship enters a UK port but the package does not come ashore, ONR issues a validation that it refers to as a **Transit Approval**. This document is in the form of a letter from ONR.
- 3.5 Designs requiring only unilateral approval but originating outside the European countries contracting to ADR and RID require further endorsement or approval by the first such country reached before they can be transported within this region. ONR may validate these by countersigning the original certificate, following a proportionate degree of assessment.
- 3.6 Applications to ONR for CA validation should include the information described in 'Application Part 1' above, and should include an English translation as necessary. A copy of the overseas Approval Certificate must be provided. It is particularly useful to provide a route map (paragraph 2.6) cross-referencing the submission to the regulations if the format of the overseas safety case is different to one from the UK. Where appropriate the design substantiation (as described under Application Part 2) should also be provided (especially if this is available in electronic form).

### 4. RENEWALS AND EXTENSIONS

#### *Renewals*

- 4.1 CoAs are granted for a period of up to five years, at the discretion of ONR. If it is intended that the design will be used, or shipments made, after the certificate expiry date, an application for renewal must be made.
- 4.2 Applications for renewal should include the documentation to justify safety (ie the safety case) over the renewal period, and a periodic design review report. Where there have been relatively few or only minor changes, the periodic design review report may in effect become part of the safety case for the renewal period, with the existing safety documentation. In this case the revisions to the existing safety case documentation will be limited and mostly administrative, and the justification of any changes will be presented in the periodic design review report.
- 4.3 Alternatively, if significant changes to the safety case are necessary, or to consolidate the accumulated effects of changes over a number of renewals, it may be appropriate

to submit a new revision of the safety case, with the periodic design review report as a separate document detailing and explaining the changes that have been made.

- 4.4 In either case the periodic design review report will be an important focus of the ONR assessment of the submission, and facilitate this assessment. It should lead to an earlier response and lower charges, if applicable. Renewal applications should also include a route map (paragraph 2.6). The periodic design review should be systematic and comprehensive, but also proportionate in depth taking account of the potential hazards. It should be conducted by a competent person(s), and be subjected to an independent peer review.
- 4.5 The periodic design review should give consideration to the impact of the following on the safety of the design and its operation:
- changes in relevant standards, regulations, criteria and methodologies (including possible changes in the circumstances or ranges for which they are valid);
  - changes in technology (eg research findings, inspection techniques) or in knowledge (eg operational experience, physical property data);
  - the continuing adequacy of the management system for design, manufacture, maintenance and repair of packaging, and the preparation, consigning, loading, carriage including in-transit storage, unloading and receipt;
  - changes in design safety parameters due to modifications;
  - revised operating methods;
  - changes in use of the design;
  - operational experience, including any incidents;
  - maintenance and inspection arrangements and history;
  - the effects of ageing, degradation and obsolescence on components' ability to deliver their safety function;
  - the erosion of safety margins, and confirmation they will remain adequate for the renewal period;
  - the continuing accessibility of information underpinning the safety case eg in relation to test data, manufacturing records and operational information;
  - the continuing availability of appropriate spare parts via the supply chain;
  - the status of any issues remaining from previous design reviews; and
  - any other aspects considered relevant by the reviewer(s).
- 4.6 The periodic design review should be forward looking, giving consideration to life-limiting aspects of the design, and in particular identifying any ageing and 'cliff-edge' effects. It should also identify any desirable modifications or improvements to the design or operation, and the timescale for their implementation. It should give consideration to known, future changes to the regulations.

### *Extensions*

- 4.7 ONR may issue an extension to an existing approval as an interim measure to enable a transport package / material design to continue to be used for strategic safety and security reasons by extending the current approval period, provided ONR is satisfied with its continuing safety. This would not normally be because a renewal application had been made with insufficient time before the certificate expiry date (see paragraph 6.7, Table 2 for indicative timescales needed for assessment of applications). Extensions can be granted because the normal five year life of an Approval is not a statutory requirement but is at the discretion of the CA.
- 4.8 Infrequently, ONR may consider issuing an extension without an application for a full renewal having been made, although there must still be a valid safety case. This may be when a package / material design needs to be used for a short period beyond the

current expiry date of the approval, to ensure strategic safety / security benefits, before being permanently taken out of service.

- 4.9 The reissue of the existing Approval document with a revised expiry date (of no more than 12 months) is the normal means by which ONR will grant an extension.
- 4.10 As processing an extension will utilise assessment resource, which may be better spent on the renewal application itself, it is ONR policy to issue extensions only in exceptional circumstances eg to allow the urgent transport of essential medical supplies or for other strategically important reasons, where it is judged by ONR to be safe to do so.

## 5. MODIFICATIONS

- 5.1 Any proposed changes (ie modification) to information in an application that has received CA approval, or that could affect the safety of a design, its compliance with the regulations, the safety of its operation or the relevant management systems need to be done in a controlled manner, and the modification is likely to need prior CA approval. For a modification process to be efficient and effective, it needs to include a system for categorising proposed modifications by their safety significance.

### Modification Categories

- 5.2 Proposed modifications should be categorised by whether they impact on safety provisions and how significant the impact would be if the modification was inadequately conceived or executed.
- 5.3 A proposed modification is considered to **impact on safety provisions** if it affects any aspect of the design, operation, maintenance or relevant aspects of the management system, which are necessary to ensure delivery of a safety function (eg relating to structural integrity, containment, external contamination, shielding, heat transfer, criticality etc). Changes to management systems previously assessed as adequate by ONR in relation to the design may be made without further ONR approval provided the alteration falls within the change control procedures set out in the management systems.
- 5.4 The modification is considered to be **significant** if, should it be inadequately conceived or executed, it could lead to the design or operation etc becoming non-compliant with the regulations.
- 5.5 Modifications should be categorised A, B or C according to the above and as shown in the following table.

**Table 1:** Categories of modifications

Impact on Safety Provisions	Significant	Category of Modification
YES	YES	A
YES	NO	B
NO	YES	B
NO	NO	C

- 5.6 Category A and Category B modifications could impact on safety provisions and/or compliance with the regulations, and therefore require CA approval by ONR before the modification can be put into effect. Category C modifications could not impact on

safety provisions or compliance with the regulations and so these can be self-assessed and authorised by the applicant / design authority.

- 5.7 Category A and Category B modifications are approved by ONR either by the issuing of a revised CoA, (particularly if a change in information on the CoA is necessitated) or by endorsement of the Modification Sheet (see paragraph 5.17). If the latter route is followed, the endorsed Modification Sheet should be attached to the existing CoA, and details of the modification and its justification should be consolidated within the applicant's safety documentation prior to the next renewal of the CoA or as specified by ONR.
- 5.8 It is also expected that the cumulative impact of all modifications (A to C) on the safety of a design and its operation should be reviewed at each renewal (ie considered in the periodic design review report) and reflected in the revised safety case covering the renewal period.
- 5.9 For modifications requiring CA approval, if an applicant has a robust, independent safety assessment process as part of its modification procedure, ONR is willing to consider requests to take this into consideration when determining the extent of the ONR assessment. This should expedite the modification approval process and may shorten timescales for approval.
- 5.10 Although Category C modifications do not require prior approval by the CA, copies of documents detailing the modification and its internal authorisation should be supplied to ONR following this authorisation. Determining a modification as Category C is at the risk of the applicant, and applicants may wish to discuss the proposed categorisation with ONR if there is any uncertainty over a particular proposal, to reduce any risk of becoming non-compliant and possibly attracting enforcement action.

#### *Amendments and concessions*

- 5.11 Previous versions of the Applicants Guide considered 'amendments' and 'concessions'. These types of changes should be categorised according to the principles discussed above, and managed in the same manner as other modifications.
- 5.12 For example, amendments are changes to documentation relating to the applicant's existing approval. If an amendment could not affect safety or compliance with the regulations it would be a Category C modification. Category C amendments may be as follows:
- Changes in document reference numbering systems (provided they do not change the scope of the reference).
  - Changes in drawing numbers resulting from the applicant's own internal organisational requirements (provided they do not change the detail of the drawing(s)).
  - 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.
- 5.13 The term concession is sometimes used to denote the authorisation of the continued use of a package / material which has deviated from the design specification in some respect, and where there is no intention to introduce the change systematically. As indicated above, such concessions should be treated no differently to other modifications, and need to be categorised, justified and if necessary approved by the CA.
- 5.14 The requirement for concessions may arise during manufacture, if items are produced out of tolerance. The design authority will need to decide whether to grant a



concession to allow the items to be retained for eventual use and for manufacturing to continue, at commercial risk and in accordance with the management system. Before the manufactured package / material can be put into use it will be necessary to assess the cumulative effect of concessions against the modification categorisation scheme described above. Unless the design authority is satisfied that the cumulative effect could not impact on safety provisions or compliance with the regulations (ie is equivalent to a Category C modification) it would be necessary to aggregate the concessions into a modification, and submit it to the CA for approval in line with the normal modification process.

### **Application for the Approval of a Modification**

5.15 Applications to ONR for approval of Category A and Category B modifications should :

- contain general and administrative information, including as appropriate
  - name of design of package / material
  - contact details of applicant, design authority etc
  - the CA identification mark, and expiry date of current approval
  - the category of the proposed modification
  - information on where the modification will be undertaken, should the CA wish to observe
  - information relating to packaging serial numbers
  - the requested date for the approval;
- describe the proposed modification and the reasons for the change;
- identify the parts of the original application affected, eg state paragraph references;
- justify the categorisation of the modification;
- describe the arrangements for ensuring the likelihood of inadequately conceiving or executing the modification will be minimised;
- demonstrate that the modified design / operation / management system will be compliant with the regulations, properly implemented, and remain safe.

5.16 Applications should include a Modification Sheet, which should summarise the information required in paragraph 5.15. For complex modifications, the Modification Sheet will need to be supported by either a revised safety case or by justification reports amending the existing safety case.

5.17 The Modification Sheet should include the following information:

- applicant's name;
- reference number and title / subject of the modification;
- the CA identification mark;
- existing safety documentation title / reference numbers;
- existing drawing(s) title / reference numbers;
- proposed category of modification;
- justification of the modification category;
- details of the proposed modification;
- compliance / safety justification of the modification or reference to revised safety case / justification reports;
- signature of applicant's responsible officer(s) and date.

5.18 The Modification Sheet should include space for ONR comments and signature.

## 6. APPROVAL PROCESS

- 6.1 On receipt of an application, ONR will carry out a preliminary check (a Q0 check) on the submission to confirm that it is complete and as expected. The assessment team of ONR inspectors (a Project Inspector and appropriate technical assessors) for the work will be assigned and the assessment work programmed.
- 6.2 On confirmation that the application is complete, the assessment team will hold an initial meeting (the 'pre-job brief'), and following this meeting ONR will contact the applicant to inform them of the planned 'Q1' date. This is the date when ONR will send a consolidated list of questions to the applicant. These questions may be subdivided into Tier 1 and 2 (not to be confused with any tiers or parts of the safety case).
- 6.3 Tier 1 questions will need to be resolved before an approval is granted. Tier 2 questions, whilst being safety-related, are not considered essential to the safety case, and it would be disproportionate to withhold the permissioning on these alone. They can therefore be addressed in a longer timeframe, subject to the provision of an adequate improvement / implementation plan agreed with ONR.
- 6.4 Engagement with ONR during the assessment phase is expected. ONR will raise any points for clarification and preliminary questions on the submission, and attempt to resolve these before the end of the assessment. This makes the assessment process more efficient and effective by providing a chance to clear up matters at an early stage, and assists transparency by avoiding surprises. Any initial findings that are addressed in this manner, along with how they were resolved (other than those which turn out to be simple clarification), will be recorded within the Q1 question set that is sent to the applicant at the end of the assessment phase, so that a complete record exists. For new designs or novel, complex or potentially difficult applications, the applicant is encouraged to engage with ONR at an early stage, before the application is made, to present and discuss the options being considered and the outline of the safety case.
- 6.5 The expectation is that the applicant will respond to the Q1 questions within six weeks. If a longer period is required eg to address significant shortfalls in a submission, this should be agreed with ONR. Once all the Q1 questions have been cleared, ONR will prepare a draft approval, and normally send it to the applicant for a factual accuracy check, allowing five working days for comment. ONR will then carry out the final stages of its approval process, complete its records and issue the Approval to the applicant.
- 6.6 If there are substantial problems with a submission it may be more efficient for the application to be withdrawn and resubmitted when the problems have been resolved. ONR may reject an application if it considers that the resolution of any remaining issues is unlikely within a reasonable timescale.
- 6.7 The time required for the approval process can vary even for similar 'Types' as it is determined by a number of factors. Indicative planning assumptions and approximate costs have been developed based on the experience to date (see Table 2). These factors include:
- the quality of the applicant's submission;
  - the type of approval;
  - the novelty or complexity of the design and/or its safety substantiation;
  - whether the design has been previously assessed and approved by ONR;
  - for renewals, whether a periodic design review report has been provided;
  - the agreed work scope and the depth of assessment required as warranted by its significance; and
  - the time taken to resolve issues with the submission.

**Table 2:** Indicative timescales and costs to process applications for Competent Authority approval

Type of Application	Typical Time for Approval (months)	Indicative Cost (£k)
New package design (fissile)	up to 12	200
New package design (non-fissile)	10	150
Validation (Type B(M) / fissile package)	4 – 6	70
Renewal / Cat. A modification	4 – 6	90
Fissile-excepted material	4 – 6	60
Category B modification	up to 3	5 – 50
Special Form (renewal – new design)	2 – 3	10 – 20
Shipment approval	2 – 3	20
Transit approval	2	10
Non-European Type B(U) validation	2	5

- 6.8 Applications are generally dealt with in order of receipt although strategic priorities are also taken into account. An applicant may request ONR to rearrange the priority of its applications although this is not advisable if ONR has already expended substantial assessment time on an application to be given reduced priority. ONR will provide quarterly updates on progress including the latest Q1 date.
- 6.9 During the package approval process ONR will issue 'Q1' questions based on our assessment findings. If following issue of these questions, or any further ONR assessment findings relating to the applicant's responses to the 'Q1' questions, there is a period of nil response / inaction by the applicant for a period of 12 months, ONR may then write to the applicant giving notice that if we do not receive any correspondence within a further 4 weeks, the application will be formally closed and removed from the ONR database. This would not preclude the applicant reinvigorating the application at a later date but this would need to be submitted as a new application.
- 6.10 ONR sometimes uses TSCs to provide additional assessment resource to support assessors working on design approvals in the areas of engineering, shielding and criticality. The TSC usually assesses the design substantiation reports and provides a report on its findings to ONR assessors. Using the TSC report, ONR assessors decide whether they need to carry out any additional assessment of the submission themselves in order to make a regulatory decision in their technical area.
- 6.11 The TSC's assessment findings may be fed into the Q1 question set that is sent to the applicant, and the TSC may assist ONR in reviewing the applicant's responses to the Q1 questions. All regulatory decisions and the use of TSC's assessment findings are ONR's responsibility. The applicant's agreement will be obtained before any of their proprietary information is passed to a TSC.
- 6.12 ONR generally publishes details of its Project Assessment Reports<sup>7</sup> (PAR) on its website, subject to security or proprietary requirements. For radioactive materials transport approvals ONR will send a redacted version of the PAR intended for publication to the applicant for a factual accuracy check, requesting suggestions for further redactions, to be supplied normally within 10 working days.

<sup>7</sup> A Project Assessment Report summarises the output of the assessment process and provides the basis of the regulatory decision.