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| ONR Guidance Document  Guidance for Applications for UK Competent Authority Approval |



ONR Guidance Document

Guidance for Applications for UK Competent Authority Approval

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| 0 | (April 2016): This document replaces the ‘Applicants Guide’ previously issued by DfT |
| 1 | (July 2016): paragraph 6.9 added to describe the process following a period of inactivity of 12 months. |
| 2 | (June 2019): update in accordance with current legal requirements and process changes. |
| 3 | (Sept 2019): removal of costing guidance due to changes in ONR charging process. |
| 4 | (Oct 2023): general update, expectations regarding Human Factors assessment, inclusion of guidance for special arrangements and guidance on expected duration of assessment by ONR |

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# Introduction

## Purpose

1. This document provides guidance to organisations applying to the Office for Nuclear Regulation (ONR) for Competent Authority (CA) approval for new designs, renewal of existing approvals, validation of overseas approvals, modifications to approved designs or an approval under special arrangement.

## Scope and Applicability

1. This document does not prescribe detailed technical guidance; it is the dutyholder’s responsibility to decide how it substantiates the specific safety and legal requirements of transport packages and packaging. ONR expects the applicant to use relevant technical standards, safety standards and good practices. However, ONR publishes on its website various sources of internal technical guidance to inspectors that provide a supplementary source of guidance for applicants.

## Definitions

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| Term/Acronym | Description |
| ACoP | Approved Code of Practice |
| ADN | Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | Agreement concerning the International Carriage of Dangerous Goods by Road |
| CA | Competent Authority |
| CDG | Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations |
| CoA | Certificate of Approval |
| DNSR | Defence Nuclear Safety Regulator |
| GB | Great Britain |
| IAEA | International Atomic Energy Agency |
| ICAO TI | Technical Instructions for the Safe Transport of Dangerous Goods by Air |
| IMDG | International Maritime Dangerous Goods Code |
| IRR17 | Ionising Radiations Regulations 2017 |
| MCA | Maritime and Coastguard Agency |
| MOD | Ministry of Defence |
| ONR | Office for Nuclear Regulation |
| PAR | Project Assessment Report |
| PDSR | Package Design Safety Report |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| SSG-26 | Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material |
| SSG-33 | Schedules of Provisions of the IAEA Regulations for the Safe Transport of Radioactive Material |
| SSG-66 | Format and Content of the Package Design Safety Report for the Transport of Radioactive Material |
| SSR-6 | Regulations for the Safe Transport of Radioactive Material |
| TSC | Technical Support Contract |
| UK | United Kingdom |

# General Information

1. The ONR is the Great Britain (GB) CA for the civil transport of Class 7 (radioactive material) dangerous goods by road, rail and inland waterways. The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG), which are nuclear regulations under The Energy Act 2013 for Class 7 dangerous goods, gives ONR this statutory duty. CDG transposes into GB law the international standards ADR [1] and RID [2] for transport of dangerous goods by road and rail, which in turn are based on the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material (currently SSR-6) [3]. The IAEA Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (SSG-26) [4] supports SSR-6.
2. Similar regulations apply in Northern Ireland, where the CA for civil road transport of Class 7 dangerous goods is the Department of Agriculture, Environment and Rural Affairs Northern Ireland.
3. There are also international requirements based on SSR-6 applicable to sea and air transport namely the International Maritime Dangerous Goods Code (IMDG) [5] and the International Civil Aviation Organisation’s Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI) [6]. 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 British registered ships anywhere in the world) and the Civil Aviation Authority (for air transport).
4. Transport of radioactive material by road, rail and inland waterway in Great Britain must also be in accordance with The Ionising Radiations Regulations 2017 (IRR17) [7]. These regulations are supported by a specific Approved Code of Practice (ACoP) and guidance [8].
5. The purpose of the above regulations is to ensure the safe transport of radioactive materials. The regulations apply a graded approach whereby radioactive materials presenting higher hazards are regulated by a permissioning regime in which certain designs and activities require prior CA approval. In addition to its role as the CA for inland surface transport in GB, ONR also provides advice on this permissioning regime (involving design approvals) on behalf of the other civilian UK CAs and agencies mentioned above. Therefore, applicants should direct all applications for competent authority approval to the ONR following this guidance.
6. This document reflects that the legal duty is to adhere to the modal specific requirements (References 1 to 4). ONR considers SSR-6 and SSG-26 to be relevant good practice and applicants should use these to provide additional guidance on the interpretation or expectations of the modal requirements.
7. Applicants seeking CA approvals should be familiar with how ADR and RID implements the IAEA requirements, and where appropriate, IMDG and ICAO TI.
8. This document may refer to SSR-6 or SSG-26 text as in most cases it is common between all modes of transport, but duty holders should ensure that their documentation meets the text within the modal specific requirements as defined by the relevant UK law (References 1 to 4).
9. Applicants should recognise that the timescales involved in updating the IAEA regulations and associated modal requirements, as well as variations in implementation periods for modal requirements, mean that applications may occur in periods where multiple issues of the referenced documents are available. To ensure that the application meets the UK regulatory requirements, at the time of presentation, the application should specifically identify the issue of the modal regulations under which the package is being applied for. Applicants should take care to ensure that any references to SSR-6 or SSG-26 are for the correct version as applicable to the modal requirements.
10. ONR’s regulatory responsibility with regards to transport of radioactive material is restricted to civil purposes. The Competent Authority for transport of dangerous goods for defence purposes is the Secretary of State for Defence. ONR and the Ministry of Defence (MOD) endeavour to work consistently and where relevant collaboratively with respect to transport of Class 7 goods for defence purposes. This is set out in the general agreement between ONR and the MOD [9] and a Letter of Understanding [10] which set out Competent Authority responsibilities and ways of working. This ensures consistency of standards and approach for the regulation of radioactive materials transport and approval of ‘dual-use’ (civil and defence) packages. If an Applicant is unclear regarding whether an application should be made to DNSR or to ONR they should consult either regulator, copying the correspondence to the other regulator.

# Applications for Competent Authority Approval

1. ONR considers it desirable for the applicant to engage with ONR before it makes a submission. This is particularly important if the safety case is novel or complex. This approach gives ONR the opportunity to:

* provide early advice
* clarify any general expectations
* witness tests
* inspect manufacturing e.g. prototypes
* assess any key technical supporting documents that may be available
* gain familiarity with the essential elements of the developing safety case.

1. However, ONR must remain independent of the process of developing the safety case and therefore any advice given by ONR will be in general terms (e.g. to clarify a design safety principle). Following ONR advice does not guarantee to make the case acceptable when ONR formally assesses the application.
2. This guidance uses the term ‘safety case’ 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 (apart from 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).
3. Applications for CA approval should be sent by the applicant to the ONR Transport Competent Authority (TCA) at our Cheltenham offices (St James House, St James Square, Cheltenham, Gloucestershire, GL50 3PR) or by email to [class7@onr.gov.uk](mailto:class7@onr.gov.uk).
4. The applicant should submit the application using the International System of units; and the application should be in English to avoid delays and additional charges. The applicant should assist ONR by using informative file and folder names (or at least provide an index to these). Applications should be prepared using a process that consistently produces safety cases that are of a good quality, fit for purpose and useable. Section 3.5 of this guidance provides guidance on the qualities of safety cases.
5. All those involved in the various aspects of the preparation of safety cases should be suitably competent, including any contractors involved in the work. The applicant should conduct checking and verification of the detailed information in these documents; there then should be an independent review of the complete safety case by someone not involved in its preparation; and finally, approval of the safety case should be by a person in a position of appropriate responsibility in the applicant’s or design authority’s organisation.

## Contents of Applications

1. 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. The applicant should identify the specific modal requirements within the documentation; if an application requires multiple modes of transport, then reference to the SSR-6 paragraph numbers may be appropriate if supported with a suitable cross reference to the modal requirements. The applicant should present this in a format that demonstrates the application has met all modal regulatory requirements.
2. Applicants should be aware that although the regulations contain sections or chapters setting out Class 7 specific design requirements, there are other sections on general provisions and requirements that also apply, e.g. management systems, which are applicable. Applicants may find SSG-33 [11], which contains schedules of regulatory provisions, useful in this respect. The regulations require Certificates of Approval (CoA) to include certain information relating to the safety case. If this information is clearly presented in the submission, with evidence of its adequacy, this may expedite the processing of the application.
3. 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.
4. For renewals of existing approvals, ONR recommends that applicants include a design review in their application (Section 5.1 provides further details). This should address all changes to the safety case since the previous approval; providing this information may shorten the length of time taken to assess the application.
5. The fundamental requirement that a submission must address is whether a design / consignment is safe, i.e. compliant with the regulations. The submission therefore should describe the aspects of the design and operations that ensure safety, i.e. 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, succinctly and supports all claims by adequate arguments and evidence.

## Structure of Applications

1. ONR considers the IAEA specific safety guide SSG-66 [12] to be relevant good practice and recommends that applications should have the two-part structure and content detailed in that guidance:

* Part 1: Information supporting the demonstration of compliance with the Transport Regulations
* Part 2: Technical analyses

1. SSG-66 is based on European Technical Guide on Package Design Safety Reports for the Transport of Radioactive Material [13], consequently applications based on this guide are also acceptable.
2. Applicants may submit applications with structures and content that differ from those recommended, however this will likely result in increased effort in assessing and approving the applications.

## Application Part 1

1. Part 1 should:
2. contain general and administrative information, including as appropriate:
   1. name of design of package / material
   2. contact details of applicant, design authority etc.
   3. CA identification mark
   4. type of approval requested, and the modal specific regulations under which the application is being made (this should be specific, especially in the case where the application is submitted during a transition period for implementing new modal requirements)
   5. modes of transport and any restrictions on the types of vehicles or freight containers
   6. whether the CA of another country has approved the design
   7. details of manufacturers, should the CA wish to inspect
   8. information relating to packaging serial numbers in accordance with SSR-6 paragraph 824, which should include the user of the packaging (where known)
   9. the requested date for the Approval (state any strategic or timing factors that may be useful to ONR in prioritising the approval work);
3. for shipment approvals (including special arrangements) provide details as appropriate of:
   1. the consignor, originator of shipment, consignee, conveyance, packages per load, loads per conveyance
   2. the probable or proposed route
   3. the place, nature, duration of any transit storage, and person responsible for custody
   4. intended dates of shipments or requested duration of approval;
4. provide a full engineering description and specification of the design of the package / material;
5. specify the contents including any restrictions on the radioactive and fissile material contents;
6. describe the intended use, and any operational and maintenance requirements, demonstrating their adequacy for the intended use;
7. provide details of contingency and emergency arrangements, demonstrating their adequacy;
8. 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;
9. for design approvals, provide an overview of the safety case, which should include, but not be restricted to:
   1. the main design principles and safety performance characteristics, summarising and making reference to the detailed evidence (Part 2) that substantiates these claims
   2. the human-based safety claims supporting safety, summarising and making reference to the detailed evidence (Part 2) that substantiates these claims;
10. include a ‘route map’ showing where in the submission compliance with the requirements of the regulations has been demonstrated; and
11. for all renewal applications, provide a design review (see paragraph 69).
12. 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, for certain shipment approvals, in other documents, e.g. relating to the package design approval).
13. The description and substantiation of the design should clearly set out, in sufficient detail, the design features and components that influence:

* the containment of radioactive materials (e.g. seals, flask lid / body assembly);
* the control of external radiation levels (e.g. shielding and associated support structures);
* thermal performance (e.g. internal heat generation and heat removal);
* preventing criticality (e.g. neutron absorbers and associated support structures); and
* the impact and structural performance (e.g. shock absorbers, lifting / securing features).

1. Where appropriate, the operational limits of these safety-significant design features and components may be specified. This enables these limits to be compared (in Part 2) with claimed performance and allows the margins to loss of safe performance to be established for each design feature or component.
2. 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, e.g. for operation, handling and maintenance;
* Supervision of operations, qualification and training of staff, and other safety management requirements; and
* Inputs to radiation protection programmes and emergency planning.

## Application Part 2

1. Part 2 of the application should contain the technical analyses and the detailed evidence to support the demonstration that:

* The design is compliant with the requirements and performance standards of the regulations;
* The human-based safety claims can be achieved and implemented reliably to ensure the package meets its design requriements; 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.

1. In other words, Part 2 should answer the question ‘why 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 (i.e. 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. 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.
3. Each analysis section, or report, should explicitly state its purpose and conclusion, 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 14 about informative file / folder names for electronic submissions.)
4. The regulations allow for the substantiation of the design (i.e. the demonstration that it meets the performance standards in the regulations) by physical testing, calculation or reasoned argument. Applications often use a combination of all three, interpreting the results of physical testing by calculation and reasoned argument. This is especially so for mechanical performance testing. Adequacy of shielding often uses calculation but may also involve or be based on physical measurements. Criticality safety justifications are more likely to be entirely by calculation. Calculational 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 SSG-26guidance on Section VII of SSR 6.

### Physical Testing

1. Physical testing may be on prototypes or scale models (with the test parameters suitably adjusted). The items being tested should be representative of, and simulate as closely as practicable, the materials and packagings for which the applicant is seeking design approval. It may be permissible to use the results from previous tests or from tests on similar designs if the application provides sufficient justification for their use (i.e. shown to be valid for the design in question). The applications should explain and justify any differences between the items tested and those described and specified. Mathematical models substantiating the design may also require validation and verification using tests and experiments.
2. The applicant should notify ONR prior to physical manufacture and/or testing of mature models or prototypes to enable ONR to arrange to witness the manufacture and/or test(s), at its discretion. The notification should include 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. Applicants should also submit a test Quality Plan, identifying responsible persons / organisations for each element of the proposed test. The applicant should raise these matters with ONR during early engagement (see paragraph 11).

### Mathematical Modelling

1. Applicants must ensure that mathematical modelling is undertaken by analysts that are competent with the chosen modelling software. The mathematical modelling section of the analysis report serves, in part, as the confidence test of the competence of the analysts.
2. ONR expects applicants to demonstrate that mathematical models and computer codes are tested and evaluated to ensure fitness for purpose, and that the code suitably represents the physical model. Analysis reports should demonstrate validation and verification of all mathematical models used.
3. The definitions of validation and verification used by ONR are as follows:

* Validation: is the process of testing and evaluation of the whole computer code or calculation method after the completion of its development and prior to its application to ensure compliance with the requirements of the intended application. Validation provides the evidence that the computer code or calculation method is fit for purpose by comparison of their results with data from experiments or other trusted sources.
* Verification: is the process of ensuring that the model specification has been complied with and that controlling physical equations have been correctly translated into the computer code or, in the case of hand calculations, correctly incorporated into the calculation procedures.

1. Validation means explaining why the model used in the analysis is an adequate simulation of the ‘real world’ problem, i.e. it should answer the question: ‘why is this model the right one for solving this problem?’ Consequently, 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.

1. ONR may consider a simple, bounding model based on pessimistic assumptions an acceptable simulation, provided the assumptions do not make the implementation of the design impracticable.
2. Model verification should answer the question ‘is the model error-free?’ This part of the analysis report should:

* 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.
* Confirm that the analysts are competent and have used the model correctly, this is particulary important for complex codes.

1. This part of the analysis report should also demonstrate the use of accurate and appropriate physical and material property data, especially for novel designs and materials. The point of validation is that the package design that is presented to ONR for approval bears a close corelation to the design that is eventually manufactured and used in the public domain. This means that the design data used in the validation model must be for a package design that is in the mature or late part of the design evolution.

### Test Cases and Results

1. The application should present sufficient tests and calculational cases to provide answers to the question ‘is it safe?’ and where appropriate ‘how safe is it?’ 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, e.g. a 9 m drop followed by a 30 minute 800 °C fire. In the latter case, tests and calculations should address the potential for a challenge making the package more vulnerable to a following challenge. For example paragraph 727 of SSR-6 specifies that mechanical drop test “shall be such that, on completion of the mechanical test, the specimen shall have suffered such damage as will lead to maximum damage in the thermal test that follows
2. The application should establish the validity of presented calculational results by:

* Demonstrating that the initial results confirm modelling assumptions (e.g. for elastic behaviour, temperature range for material data, meshing refinement etc.);
* Performing enough sensitivity cases to cover uncertainties (e.g. 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.

### Human Factors

1. Human factors analysis seeks to ensure that the human contribution to risk is minimised by accounting for human physiological and psychological capabilities.
2. To understand and reduce the potential for human error, the application should include analysis of transport activities relying on human-based safety claims, i.e. human action and managerial measures. This section should seek to answer, “has the human contribution to risk been reduced to as low as reasonably practicable (ALARP)?”. Therefore, this part of the submission should:

* Identify all important human actions and managerial controls supporting operations and maintenance;
* Analyse those human actions and managerial controls to understand the potential for human error and its contribution; and
* Implement appropriate engineered or managerial measures to reduce the potential for human error.

### Managing Analysis by Third-party Contractors

1. When a third-party contractor undertakes analysis in a submission, the regulator may have to interact with this contractor as well as the applicant. The GB CA has historically interacted with a range of applicants’ third-party contractors, including manufacturers, suppliers, material test laboratories, design authorities and analysis specialists. ONR adopts the same principles of interaction with third party contractors as it does with applicants, 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

1. Submissions should:

* Describe the safety-significant design features, components of the design / consignment (i.e. those which have an effect on safety), human-based safety claims, 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 (e.g. Part 1) and the supporting documentation / evidence.

1. 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).

1. The following sub-sections provide details of the desirable qualities of safety cases.

### Intelligible

1. 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

1. 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

1. 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, i.e. they will continue to meet all the applicable regulations (explaining why any regulations are 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

1. The safety case should be evidential. The safety case should include verifiable and relevant evidence supporting the arguments developed (i.e. 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

1. 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

1. 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

1. The safety case should present a balanced account, taking into consideration the level of knowledge and understanding. It should identify areas of relative uncertainty, not just strengths and claimed conservatisms. It should clearly and openly explain the limitations or potential areas for improvement in the design or operation (e.g. in the summary or main conclusions of the safety case).

### Forward looking

1. The safety case should be forward looking and demonstrate that the proposed design will remain safe throughout a defined lifetime, taking account of the effects of ageing and degradation. It should identify the important aspects of operation and management that 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 is also desirable to consider the impact of known, future changes to the regulations.

# Validations

1. Certain designs and shipments require multilateral approval. 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. These subsequent countries may grant multilateral approvals either by a new CoA or, if the relevant CA does not apply any additional controls or restrictions, by the validation of the original CoA.
2. 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 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. For validations of CoAs, ONR uses a format like a CoA, 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.
4. For the situation where a ship transporting a CA approved package containing fissile material 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.
5. Designs requiring only unilateral approval but originating outside the contracting parties to ADR and RID require further endorsement or approval by a contracting party. ONR may validate these by countersigning the original certificate, following a proportionate degree of assessment.
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. For a renewal of a validation previously issued in the UK the applicant should provide a design review in accordance with section 5 below. The applicant must provide a copy of the overseas Approval Certificate. It is particularly useful to provide a route map (paragraph 18) cross-referencing the submission to the regulations if the format of the overseas safety case is different to that specified in SSG-66. Where appropriate the applicant should also provide the design substantiation (as described under Application Part 2), especially if this is available in electronic form.

# Renewals and Extensions

## Renewals

1. ONR grants, at its discretion, CoAs for a period of up to five years. If the applicant intends to use the design, or make shipments, after the certificate expiry date, it must make an application for renewal.
2. Applications for renewal should include the documentation to justify safety (i.e. the safety case) over the renewal period, and a periodic design review report (paragraph 69). Where there have been 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 mostly administrative, and the periodic design review report will present the justification of any changes.
3. A new revision of the safety case may be appropriate where significant changes to the safety case are necessary, or to consolidate the accumulated effects of changes over several renewals. A separate periodic design review report should explain the changes that have been made.
4. All modifications that have been appended to the previous certificate of approval must be consolidated within the renewal safety case. This includes any modifications that did not originally require competent authority approval.
5. The periodic design review report will be an important focus of the ONR assessment. It can lead to an earlier response and lower charges, if applicable. Renewal applications should also include a route map (paragraph 18). The periodic design review should be systematic and comprehensive, proportionate in depth taking account of the potential hazards, conducted by a competent person(s) and subjected to an independent peer review.
6. The periodic design review should consider 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 (e.g. research findings, inspection techniques, etc.) or in knowledge (e.g. operational experience, physical property data, etc.);
* 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 e.g. 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).

1. The periodic design review should be forward looking, considering life-limiting aspects of the design, and 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 consider known, future changes to the regulations.
2. The applicant should supply the serial numbers of packaging, manufactured against the CoA and meeting the criteria specified in SSR-6 paragraph 824. This should include any new packages manufactured since the last approval was issued. The applicant should also supply details of the user(s) of the packaging (where known).

## Extensions

1. ONR may grant an extension to an existing approval as an interim measure to enable continued use of a transport package / material design for strategic safety and security reasons. This is based on ONR being satisfied with the package’s continuing safety. ONR will not grant an extension for situations where the applicant has applied for a renewal with insufficient time before the certificate expiry date. The granting of an extension by ONR is justifiable on the basis that the normal five-year life of an Approval is not a statutory requirement but is at the discretion of the CA.
2. In certain circumstances, ONR may consider granting an extension without receiving an application for a full renewal, although there must still be a valid PDSR. An example might be when an applicant needs to use a package / material design beyond the current expiry date of the approval, to ensure strategic safety / security benefits, before permanently removing the package from service.
3. 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.

# Modifications

1. Any proposed changes (e.g. modification, etc.) 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; needs 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

1. Proposed modifications should be categorised by the impact on safety provisions and how significant the impact would be if the modification is inadequately conceived or executed.
2. A proposed modification impacts 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 (e.g. relating to structural integrity, containment, external contamination, shielding, heat transfer, criticality etc.). An applicant may amend management systems previously assessed as adequate by ONR in relation to the design without further ONR approval provided the alteration falls within the change control procedures set out in the applicant’s management system.
3. The modification is significant if, should it be inadequately conceived or executed, it could lead to the design or operation etc. becoming non-compliant with the regulations.
4. Modifications should be categorised A, B or C according to the above and as shown in the following table.

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

1. 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 applicant can put the modification 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.
2. ONR approves Category A and Category B modifications either by the issuing of a revised CoA, (particularly if a change in information on the CoA is necessary) or by endorsement of the Modification Sheet (see paragraph 92). Where ONR endorses the Modification Sheet, the applicant should attach it to the existing CoA. Following ONR approval of the modification the applicant should consolidate it within the safety documentation prior to the next renewal of the CoA or as specified by ONR.
3. ONR expects the applicant to review the cumulative impact of all modifications (A to C) on the safety of a design and its operation at each renewal (i.e. considered in the periodic design review report) and reflected in the revised PDSR covering the renewal period.
4. 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. Although Category C modifications do not require prior approval by the CA, the design authority should supply copies of documents detailing the modification and its internal authorisation to ONR as soon as practicable following this authorisation, ideally within one month. Applicants may wish to discuss the Category C modifications with ONR if there is any uncertainty over a particular proposal, to reduce the risk of becoming non-compliant and attracting enforcement action.
6. On receipt of a Category C modification ONR may choose to review it against the process above. If ONR determines that a modification is incorrectly categorised as Category C, this may invalidate the extant CoA resulting in restrictions to transport activities until ONR has assessed the modification and granted approval.

## Amendments and Concessions

1. Previous versions of the Applicants Guide considered ‘amendments’ and ‘concessions’. These types of changes should be categorised according to the modification principles discussed above and managed in the same manner as other modifications.
2. 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.

1. A concession is the authorisation of the continued use of a package / material which has deviated from the design specification, and where there is no intention to introduce the change systematically. Applicants should treat concessions as modifications.
2. The requirement for concessions may arise during manufacture if components are out of tolerance. The design authority will need to decide whether to grant a concession to allow retention of the items for eventual use and for manufacturing to continue, at commercial risk and in accordance with the management system. The design authority will need to assess the cumulative effect of concessions against the modification categorisation scheme described above before using the manufactured package / material. Unless the design authority is satisfied that the cumulative effect could not impact on safety provisions or compliance with the regulations (i.e. 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

1. 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 and CoA affected, i.e. 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; and
* Demonstrate that the modified design / operation / management system will be compliant with the regulations, properly implemented, and remain safe.

1. Applications should include a Modification Sheet, which should summarise the information required in paragraph 92. For complex modifications, the Modification Sheet will need supporting by either a revised safety case or reports justifying amendments to the existing safety case.
2. 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; and
* signature of the applicant’s responsible officer(s) and date.

1. The Modification Sheet should include a section for ONR comments and endorsement.

# Special Arrangements

## Background

1. Requirements for transporting radioactive material are constantly evolving. There are:

* Decommissioning activities and uncertainty associated with the nature of some legacy radioactive materials;
* Strategic safety and security imperatives that require movement of radioactive materials; and
* Novel nuclear materials / components, which will need to be transported now or in the near future.

1. Given the uncertainties associated with these areas, circumstances may arise where it may be difficult to design (or modify) a package so that it meets all the standard package design features prescribed in the regulations with sufficient certainty. Therefore, to enable the use of such package designs for unique radioactive material shipments the regulations permit for shipments in these situations under a provision known as a Special Arrangement.
2. Paragraph 310 of SSR-6 describes the Special Arrangement approval.

*Consignments for which conformity with the other provisions of these Regulations is impracticable shall not be transported except under special arrangement. Provided the competent authority is satisfied that conformity with the other provisions of these Regulations is impracticable and that the requisite standards of safety established by these Regulations have been demonstrated through means alternative to the other provisions, the competent authority may approve special arrangement transport operations for single or a planned series of multiple consignments. The overall level of safety in transport shall be at least equivalent to that which would be provided if all the applicable requirements had been met. For consignments of this type, multilateral approval shall be required.*

1. Special Arrangements provide applicants with flexibility to propose alternative safety measures. These measures must still deliver an overall level of transport safety that is at least equivalent to those measures required by the regulations.
2. Regulation 12 of CDG - Authorisation offers an alternative flexible approach, for road and rail transport. This enables the CA to authorise the domestic transport of radioactive materials for unusual and exceptional situations, which are contrary to the provisions and requirements of the prescriptive international regulatory framework, provided safety is not compromised (i.e. it is demonstrated that risks are ALARP). For example, a Regulation 12 Authorisation might be used to permit the transport of very low levels of radioactive material if there are administrative compatibility issues between different regulations governing radiological risk.
3. The regulations also require, in certain circumstances, a Special Arrangement approval for sea transport and for air transport if the surface radiation levels of the package exceed 2 mSv/h (see SSR-6 paragraphs 575 and 579).

## Application Requirements

1. Special Arrangements are not a package design option for routine transport operations. ONR only considers and approves Special Arrangements in exceptional circumstances and therefore considers them on a case-by-case basis. Applicants must contact and engage with ONR at an early stage in their deliberations.
2. Primarily, ONR expects applicants to design and manufacture (or modify) a transport package to be fully compliant with Type A, B or C (or other relevant) requirements. ONR will only consider a Special Arrangement in circumstances where a package complies with the majority of the specific package design requirements, and the applicant can show that compliance with a certain provision or related set of provisions of the regulations is impracticable.
3. The regulations require that an application for approval of shipments under Special Arrangement shall include all the information necessary to satisfy the CA that the overall level of safety in transport is at least equivalent to that which would be provided if all the applicable requirements of the Regulations had been met. Moreover, the regulations ask for a statement of the respects in which, and reasons why, the shipment cannot be made in full accordance with the applicable requirements. They also ask for a statement of any special precautions or special administrative or operational controls (compensatory measures) that are to be employed during transport to compensate for the failure to meet the applicable requirements.
4. To satisfy paragraph 102 above, the applicant will need to develop and submit an adequate transport safety case to ONR. The safety case should clearly demonstrate which requirements of the regulations the package cannot meet and why it is impracticable to do so. It should provide a clearly substantiated demonstration and conclusion that the proposed compensatory measures will reduce the overall risk from the transport operation to ALARP and will ensure compliance with relevant provisions of the Ionising Radiations Regulations including prior risk assessment, restriction of exposure and dose limitation. Hence a safety outcome will be achieved at least equivalent to that if the package met all the applicable requirements of the regulations.
5. The Special Arrangement safety case should include as a minimum the following:
6. Demonstration that the design is compliant with the regulations apart from those provisions for which a Special Arrangement is requested.
7. Justification of the reason for the need for a Special Arrangement. This should demonstrate that a suitably robust optioneering process has been conducted in relation to achieving compliance of the package design with relevant Type-requirements. This should consider aspects such as a new design, use of alternative packages, modifications etc.
8. Justification, with suitable evidence, of why it is impracticable for the package design being proposed to be used for the shipment(s) to meet all the applicable requirements.
9. Description of the additional safety measures (compensatory measures): i.e. special precautions or special administrative / operational controls that are to be employed to provide at least an equivalent level of safety to that if all the applicable requirements had been met. This part of the safety case will need to contain much more than a statement of such controls. The applicant should present the safety case in a claims, arguments and evidence format for each of the compensatory measures to be employed, and clearly justify how and why, they will deliver at least an equivalent level of safety to that if all the applicable requirements had been met.
10. The safety case should include a suitably comprehensive and appropriate hazard identification study for all stages of the transport operation to determine the nature and magnitude of the hazards and associated risks that will need to be controlled by compensatory measures.
11. An analysis of the hazards and associated risks and of the suitability of the proposed compensatory measures against each of these, to deliver at least an equivalent level of safety / risk reduction, should be carried out and recorded. Depending on the circumstances and complexity, this part of the safety case (or supporting documentation) may also require formal fault analysis such as design basis / deterministic safety analysis and/or probabilistic safety analysis.
12. The safety case should include suitably robust engineering, management system and where appropriate human factors substantiation of the adequacy of the compensatory measures and feasibility of their implementation during all stages of transport.
13. ONR also acts on behalf of the UK CAs for sea and air transport with respect to the issuing of transport approvals. ONR may therefore consult these organisations before granting a Special Arrangement approval that covers these modes of transport. ONR is likely to carry out inspections during the assessment process and/or prior to commencement of shipments under a Special Arrangement, to confirm the feasibility and adequacy of implementation of the compensatory measures.

# Approval Process

## Management

1. On receipt of an application, ONR will conduct 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.
2. If the Q0 check reveals that the submitted application does not include the required information or is in a format that does not meet the expectations of this guidance ONR may reject the application and request that it is resubmitted when complete and in good order. ONR may recover the cost of this process.
3. 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).
4. ONR will require resolution of the Tier 1 questions by the applicant before granting an approval. Whilst being safety related, ONR does not consider Tier 2 questions essential to the safety case, and it would be disproportionate to withhold the permissioning on these alone. Therefore resolution of Tier 2 questions by the applicant can be on a longer timeframe, subject to the provision of an adequate improvement / implementation plan agreed with ONR.
5. ONR will routinely engage with the applicant during the assessment phase. 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. ONR will record any initial findings that it raises in this manner (other than those which turn out to be simple clarification), and details of their resolution, within the Q1 question set that it sends to the applicant at the end of the assessment phase, so that a complete record exists. Prior to making an application for new designs or novel, complex or potentially difficult applications, the applicant should engage with ONR to present and discuss the options it is considering and outline the safety case.
6. The expectation is that the applicant will respond to the Q1 questions within six weeks. If the applicant requires a longer period e.g. to address significant shortfalls in a submission, the applicant should advise ONR. Once the applicant has resolved all the Q1 questions, 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 complete the final stages of its approval process, update its records and issue the Approval to the applicant.
7. If there are substantial problems with a submission it may be more efficient for the applicant to withdraw its application and resubmit when it has resolved the problems. ONR may reject an application if it considers that the resolution of any remaining issues is unlikely within a reasonable timescale.
8. ONR strives to be efficient and effective and to provide greater clarity about the costs of our regulatory decisions. However, the time required to complete the ONR approval process can vary significantly even for similar package or approval ‘type’. These variations are determined by a variety of factors, including:

* whether the applicants submission contains suitable and sufficient evidence for ONR to make its judgment
* the type of approval request;
* the novelty or complexity of the design and/or its safety substantiation;
* whether the design has been previously assessed and approved by ONR or other CAs;
* ONR’s knowledge of the package and / or applicant;
* for renewals, whether a periodic design review report has been provided;
* for modifications, what safety functions are affected (e.g. criticality, dose, containment). Further assessment may or may not be required);
* the work scope and the depth of assessment required as warranted by its significance; and
* the time taken to resolve issues with the submission.

1. Without prior knowledge of individual applications, ONR cannot provide accurate approval timescales within this guidance document. ONR recommends that, in advance of any submission, applicants engage directly with ONR to identify a potential approval date. Applicants should seek to undertake such engagement as far in advance as possible so that ONR can schedule the application into its work programme. Some examples of typical approval timescales are provided below for guidance purposes only.:

* New package design 12 months
* Validation 4 - 6 months
* Renewal (no change including design review) 3 - 4 months
* Category A or B Modifications 3 - 4 months

1. The factors listed above sometimes result in variations even to those timescales discussed during early engagement.
2. ONR acts as an enabling regulator and therefore committed to prioritising demands based on its available resource and strategic factors. An applicant can request ONR to revise the prioritisation of its application. However, ONR will base approval of this request on the strategic factors identified and ONR regulatory effort already spent on initial assessment. ONR will provide regular updates on progress including the latest Q1 date.
3. 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 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 work programme. This would not prevent the applicant resubmitting the application later as a new application.
4. ONR sometimes uses Technical Support Contractors (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 conduct any additional assessment of the submission themselves to make a regulatory decision in their technical area.
5. ONR may feed the TSC’s assessment findings into the Q1 question set that it sends 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. ONR will obtain agreement from the applicant before passing any of their proprietary information to a TSC.
6. ONR publishes details of its Project Assessment Reports (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. ONR will request that the applicant provides any suggestions for further redactions to ONR within ten working days.

## Charging

1. In April 2014 ONR was required through legislation to introduce a policy of charging to cover the costs of its work necessary to grant CA approvals.
2. 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 and commission an independent review prior to submitting an application to the ONR. ONR is likely to grant the approval sooner and the fees charged should be lower. Regarding the ONR use of TSC resource, ONR will pass the associated costs on to the applicant.
3. 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. Further information on how ONR charges can be found here <https://www.onr.org.uk/corporate-publications.htm>.

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