

Transport Inspection			
Type A packaging – demonstration of compliance of package design			
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1. Introduction

1. The carriage of dangerous goods by road and rail in Great Britain (GB), including radioactive materials, is regulated by the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (Statutory Instrument 2009 No. 1348) (CDG 2009) (Ref. 1).
2. The enactment in Great Britain of the international requirements defined in both the Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) (Ref. 2) and Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) (Ref. 3) is via CDG 2009, Regulation 5. ADR and RID establish standards of safety which provide an acceptable level of control of the radiation, criticality and thermal hazards to persons, property and the environment that are associated with the carriage of radioactive material.
3. These standards are based on the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive material, 2018 Edition, IAEA Safety Standards Series No. SSR-6, IAEA, Vienna (2018) (Ref. 4). Explanatory material can be found in “Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2012 Edition) SSG-26” (Ref. 5)¹.
4. These publications are considered Relevant Good Practice (RGP) and ONR’s policy is to reflect these standards and to encourage duty holders to use them where appropriate.
5. ONR inspects compliance with CDG 2009 (Ref. 1) and the arrangements made under them, to judge the suitability of the arrangements made and the adequacy of their implementation. To support inspectors undertaking compliance inspections, ONR produces a suite of guides to assist inspectors to make regulatory judgements and decisions in relation to the adequacy of compliance, and the safety of duty holder activities. This inspection guide is part of that suite of documents and provides guidance for inspections against CDG 2009.

2. Purpose and Scope

6. This guide has been prepared as an aid to inspection activities carried out by ONR inspectors at duty holder premises, and other relevant places, in judging the duty holder’s compliance with the requirement to demonstrate that Type A package design meets all the applicable requirements.

¹ IAEA Safety Standards Series No. SSG-26, IAEA, Vienna (2012) (Ref. 4). SSG-26 2012 is due to be superseded in 2021/22 to reflect changes introduced into SSR-6 2018, but the final edition is not currently available.

7. This guide does not cover use or management of packages, but may refer to these aspects in identifying interfaces between dutyholders². Note that although the guidance is based around the requirements for Type A packages, the general principles and expectations are applicable to all packages where competent authority approval is not required (e.g. Industrial Package, excepted)
8. This guidance provides inspectors with relevant good practice to help them in making informed regulatory judgments that are consistent with compliance inspection of CDG 2009 (Ref. 1).
9. The guidance is for use by inspectors in ONR; but may provide useful to duty holders in determining legal requirements and the expectations of ONR. The guidance does not indicate when or to what extent inspections of the requirements of CDG 2009 should be carried out, as these matters are covered in individual inspector's inspection plans, which take account of priorities established by the relevant ONR Programme.
10. The regulatory structure for the transport of class7 dangerous goods is complex and varies by mode of transport. In this guide the road transport modal requirements (ADR) will be referenced as well as international requirements and guidance (SSR-6 and SSG-26). This guidance is also relevant to other modes of transport and may be used in these cases.
11. The remainder of the guide is set out in five sections, as below:
 - Section 3: Consignors duty
 - Section 4: Designers/Suppliers
 - Section 5: Guidance on compliance with specific requirements
 - Section 6: Certificates of Compliance
 - Section 7: Package Design Safety Reports
12. The following definitions are provided for clarity, where a formal definition exists in regulations/requirements these take priority:
 - Consignor shall mean any person/organization that prepares a consignment for transport.
 - Designer shall mean any person/organisation that defines the design of a package and produces the safety documentation to justify its compliance.

² The term dutyholder is used as a generic term for people/organisations that have duties under the regulations (see ADR chapter 1.4 for partial list of dutyholders) Where a specific dutyholder (Consignor, carrier, manufacturer etc.) needs to be identified for clarity the specific term will be used as appropriate.

- Supplier shall mean any person/organisation that acts on behalf of the designer to sell/supply a package to consignors.

3. Consignor's Duty

13. ADR/RID para 5.1.5.2.3 (Ref. 2 & 3) requires that:

“For package designs where it is not required that a competent authority issue a certificate of approval the consignor shall, on request, make available for inspection by the competent authority, documentary evidence of the compliance of the package design with all the applicable requirements.”

14. This requirement places the entire duty of demonstrating compliance onto the consignor. However, there is no definition of what “documentary evidence” consists of or the standard of information required to demonstrate compliance. The following section provides guidance on what inspectors should expect as documentary evidence.
15. All documents should be up to date and relevant to the packaging being used, the consignor is responsible for putting in place and following management arrangements to ensure this. The arrangements should include regular review with the designer/supplier to establish whether new documentation has been issued and to provide feedback to designer/supplier if appropriate.

3.1. Certificate of Compliance

16. ADR/RID para 5.1.5.2.3 (Ref. 2 & 3) is based on Para 801 of SSR-6 (Ref. 4), the corresponding guidance provided in SSG-26 for this paragraph identifies that package manufacturers should produce and issue to consignors a certificate of compliance that summarizes the regulatory compliance of the package. Therefore, the consignor can demonstrate compliance of the package design by providing a certificate of compliance from the designer/supplier which meets the criteria defined in SSG-26 (Ref. 5) Para 801.3 (see Section 6 for details). The certificate of compliance must be available in English (this may be a translation of the original language), legible and in date at the time of any package use.
17. The consignor will still need to provide evidence that they have selected the correct package for the material being transported and are using it in the correct way.

3.2. Other documentary evidence

18. If a certificate of compliance is not available, or does not meet the criteria defined in SSG-26 Para 801.3, then the consignor is required to provide alternative documentary evidence to demonstrate compliance. This evidence may be obtained from the designer/supplier or written by the consignor. This

can include any or all of the documents identified in Section 4 below. Where a certificate of compliance meets some, but not all, of the criteria defined in SSG-26 (Ref. 5) para 801.3 then the other documentary evidence required is limited to the aspects not contained in the certificate of compliance.

3.3. Supporting documents

19. Where a certificate of compliance or other documentary evidence references supporting documents the consignor should have access to these and be able to demonstrate compliance with any requirements. This includes:
- Operational manuals
 - Maintenance and inspection
 - Handling and stowage

3.4. Lack of documentary evidence

20. Consignors have a responsibility to provide ONR with the required documentary evidence of compliance. If a consignor is not able to demonstrate compliance of the package design then they should not use the package until such time as they are able to do so.

3.5. Design changes by the consignor

21. If a consignor wishes to use a Type A package for a purpose not specifically identified by the designer – for example for carrying a different radioisotope or by utilising a different inner containment – this is permissible so long as the consignor can provide suitable evidence that the package still meets the requirements.
22. In this case the consignor must recognise that they take on the role of package designer with regards the modified aspects of the package, as such would need to meet the expectations of section 4 below.

4. Designers/Suppliers

23. Although ADR/RID (Ref. 2 & 3) para 5.1.5.2.3 places the legal duty on the consignor, it is not always possible for a consignor to provide the required documentary evidence without the support of the package designer/supplier. In addition, ADR/RID para 1.7.3 requires that:

“The manufacturer....shall be prepared:

....

(b) To demonstrate compliance with ADR to the competent authority.”

24. In the case of Type A package design ONR considers that the manufacturer duties apply equally to the designer or supplier of any packaging.

4.1. Design compliance evidence

25. ONR expects (following the guidance in SSG-26 (Ref. 5) para 801.1, that designers of packages compile a set of documentation that demonstrates compliance of the package to the regulations. Where the package compliance is reliant on additional components that are not supplied with the packaging (e.g. glass vials, tape, etc.) then the specification of those components must be provided in a way that enables the consignor to demonstrate that they are to an appropriate standard.
26. Documentation should be presented in a systematic manner providing clear statements with suitable evidence to demonstrate compliance against all relevant requirements of ADR/RID (Ref. 2 & 3). ONR recommends that the documentation is presented in a format that follows the general expectations of a package design safety report (see Section 7).
27. ONR recognises that the documentation required may include specific information that the designer does not wish to be made public. In these cases the documentation may be redacted in public facing documents or a reference to private records may be made. This information must however be provided to ONR, as the competent authority, on request.

4.2. Certificate of Compliance

28. The designer of a package should (following the guidance in SSG-26 (Ref. 5) para 801.3) produce a certificate summarising the compliance of the package (see Section 6). This 'certificate of compliance' should be provided with every package /or made available on request by any dutyholders (not limited to consignors)
29. The provision of certificates of compliance online is recommended, as this allows consignors to access the most up to date version in a timely manner.
30. Certificates of compliance not meeting the criteria defined in SSG-26 para 801.1 should be supplemented by additional documentary information provided to the consignor on request.

4.3. Supporting documents

31. The designer/supplier should provide with all packages, either physically or available electronically, any relevant documentation, in addition to that above, that the consignor requires to ensure that the package is used in accordance with the design.
32. Supporting documentation should be clear and simple to understand by the consignor, including being in an appropriate language. Up to date versions of

all documentation should be available on request by any dutyholder or competent authority.

5. Guidance on compliance with specific requirements

33. The following section will address clarifications of aspects of the SSR-6 (Ref. 4) requirements, it may be expanded over time and so the most recent issue of this TIG should be referenced.

- SSR-6 Para 616 and 639
 - The package must meet the requirements for the extreme temperature/pressure requirements.
 - Type A packages cannot be designed to less stringent conditions purely based on the intended geographic use of the package.
- SSR-6 Para 648 (a)
 - The requirement to prevent “loss or dispersal” of the radioactive contents is considered to include where a package contains multiple “containment systems” those containment systems should be retained within the body of the main package.
 - Therefore, damage to the outer body of a package during testing, where it could be considered that a “containment system” could be lost or dispersed from the package would not be considered to have met the requirement.
 - An example of this is where a package may contain multiple doses of radiopharmaceuticals in separate vials/shielded pots. The loss of one of more shielded pots from the main package would be considered a failure to meet this requirement.
 - It should be noted that loss of individual containment systems from within an outer package would likely breach the requirement of Para 648 (b), due to distance changes between the source and surface.

6. Certificates of Compliance

34. SSG-26 (Ref. 5) para 801.3 gives guidance on the contents of the certificate of compliance for packages that do not require competent authority approval. ONR considers this to be the minimum acceptable level of information that should be provided to a consignor by the designer/supplier of packaging.

The format of a certificate of compliance is not fixed, but the information provided should be clear and easy to read.

35. The following section gives supplementary guidance on ONR's expectations with regards to the contents of the certificate of compliance, which should be considered in conjunction with SSG-26 (Ref. 5) para 801.3.

SSG-26 para 801.3

- (a) Type of Package – this should be in accordance with SSR-6 (Ref. 4) para 231.
- (b) Identification of the packaging – this should include a designer name/number to uniquely identify the packaging.
- (c) The issue date and an expiry date – there is no fixed period for the expiry date, the date chosen should be based on factors such as design life, changes to regulations, design review period. ONR recommends a maximum of five years as a suitable period for most packages.
- (d) Any restrictions on the mode of transport, if appropriate – if no restrictions are identified then documentary evidence of compliance against all modes of transport (road, rail, sea and air) will be required. Restrictions could be either in the form of positive (Road and Rail only) or negative (Not for Air transport) statements.
- (e) List of applicable national and international regulations. – for non-UK supplied packages where SSR-6 is referenced no further reference to national regulations is required. For UK supplied packages or if SSR-6 is not referenced then the applicable modal regulations should be included. For packages originating in the USA, compliance with DOT 7A (49 CFR) is acceptable for road/rail transport in the UK.
- (f) The following statement – An exact copy of the statement in SSG-26 801.3(f) should be on the certificate in a prominent position, separate from other text.
- (g) Description of packaging and illustration. – The illustration should be clear and suitable to allow dutyholders and relevant authorities to correctly identify all parts of the packaging and their correct location within the package.
- (h) Specification of the design by reference to the drawings – The drawings referenced should provide a suitable level of detail relating to the shape/size, materials used and any specific design features of the packaging.
- (i) Specification of the allowed radioactive contents – the details should enable a consignor to correctly identify the amount, physical/chemical form, activity of material that is allowed to be transported in the package. If

multiple combinations of material are possible all permutations must be identified. High level statements such as “up to A2 quantities” or “liquid or solid” are acceptable so long as the documentary evidence can demonstrate compliance for all possible contents covered.

- (j) Reference to handling, packing and maintenance instructions – should include specific document reference/revision numbers and provide suitable information on how to obtain up to date versions of the documents identified.
- (k) Applicable management system – this should be the management system under which the package has been designed, manufactured and supplied. Reference to the relevant documents within the designer/manufacture organisation is required – not just noting that they meet an accredited standard such as ISO9001.
- (l) Emergency arrangements – The designer should provide any additional information which could be of benefit to the consignor in determining the response to an incident/radiation emergency involving the package.
- (m) Signature and identification of the person responsible for certifying the compliance – the individual within the designer organisation who is responsible for the design compliance of the package should be identified by name and position within the organisation alongside the signature on the certificate.

7. Package Design Safety report

- 36. The documentary evidence provided to demonstrate compliance of a package with the regulations is normally considered to consist of a primary document summarising the requirements and general details relating to compliance demonstration with relevant references to evidence and supporting documents where required. This primary document is referred to as the Package Design Safety Report (PDSR) and if produced according to guidance will provide the basis of a “safety dossier” as identified in SSG-26 (Ref. 5) para 801.1
- 37. ONR has produced guidance for applicants (TRA-PER-GD-014 - <https://www.onr.org.uk/transport/tra-per-gd-014.pdf>) relating to packages requiring competent authority approval. Although not written to support Type A package documentation specifically the guidance given in Section 2 of TRA-PER-GD-014 provides a useful baseline for the expectations for documentary evidence for Type A packages.

38. The European Association of Competent Authorities (EACA) has produced guidance³ on the production of a PDSR which includes specific expectations for Type A packages.
39. It is recommended that documentary evidence follows the PDSR structure and associate guidance.

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https://euraca.eu/doc_documents/PDSRGuide_Package%20Design%20Safety%20Reports%20for%20the%20Transport%20of%20Radioactive%20Material_Issue3_December2014.pdf

References

1. Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (Statutory Instrument 2009 No. 1348)
2. ADR applicable as from 1 Jan 2021, Agreement Concerning the International Carriage of Dangerous Goods by Road, ECE/TRANS/300.
3. Convention concerning International Carriage by Rail (COTIF) Appendix C – Regulations concerning the International Carriage of Dangerous Goods by Rail (RID), With effect from 1 January 2021
4. Regulations for the Safe Transport of Radioactive Material 2018 Edition, Specific Safety requirements No. SSR-6 (Rev. 1), IAEA.
5. Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2012 Edition), Specific Safety Guide No. SSG-26, IAEA

Glossary and Abbreviations

ADR	Agreement Concerning the International Carriage of Dangerous Goods by Road
CDG 2009	Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009
GB	Great Britain
IAEA	International Atomic Energy Agency
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SSG	Specific Safety Guide
SSR	Specific Safety Requirements
TAG	Technical Assessment Guide(s)