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| ONR Project Assessment Report  **PR-01206 – GB Competent Authority ADR and RID Validation of USA/9187/B(U)-96 Revision 14** |



ONR Project Assessment Report

**Project Name**: Validation of Type B(U) Package Design

**Report Title**: PR-01206 – GB Competent Authority ADR and RID Validation of USA/9187/B(U)-96 Revision 14

**Dutyholder/ Applicant**: QSA Global Incorporated

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# Executive Summary

This report presents the basis of a regulatory decision by the Office for Nuclear Regulation (ONR) as Great Britain (GB) Competent Authority (CA) for the 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 2009’, which invokes the following modal regulations into United Kingdom law:

* ‘Agreement concerning the International Carriage of Dangerous Goods by Road’ (ADR) 2023 Edition; and
* ‘Regulations concerning the International Carriage of Dangerous Goods by Rail’ (RID) 2023 Edition.

ADR and RID require that package designs granted unilateral approval by countries outside the ADR and RID agreements also need approval by the CA of a country that is a ‘Contracting Party’ to the agreements if packages are being transported in a country that is a ‘Contracting Party’. ADR and RID are based on the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material SSR-6 (2018 Edition).

QSA Global Incorporated have applied to ONR, requesting ADR and RID validation of QSA Global Incorporated Type B(U) package design Model No. 865, which has been approved by the United States of America (USA) CA in certificate USA/9187/B(U)-96 Revision 14.

The Model No. 865 package design is used as an industrial radiography device and transport package for Type B quantities of Iridium-192 special form radioactive material.

An ONR assessment of the package design safety report and its supporting documents has been undertaken in accordance with ONR guidance.

Based on my assessment:

* I find that the package design is compliant with ADR, RID and SSR-6 (2018 Edition).
* I will advise the QSA Global Incorporated that use of the package after 31 December 2025 in countries contracting to ADR and RID (other than the UK) may be noncompliant with 1.6.6.2.1 (b) (i) of ADR and RID.

I recommend that ONR as GB CA should issue a countersigned validation of United States Department of Transportation certificate USA/9187/B(U)-96 Revision 14, with an expiration date of 31 March 2029.

# List of Abbreviations

# ADR Agreement concerning the International Carriage of Dangerous Goods by Road

# CA Competent Authority

# GB Great Britain

# IAEA The International Atomic Energy Agency

# ONR Office for Nuclear Regulation

# PDSR Package Design Safety Report

# RID Regulations concerning the International Carriage of Dangerous Goods by Rail

# SSR (IAEA) Specific Safety Requirements

# UK United Kingdom

# USA United States of America

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# Permission Requested

1. This report presents the basis of a regulatory decision by the Office for Nuclear Regulation (ONR) as Great Britain (GB) Competent Authority (CA) for the 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 2009’ [1], which invokes the following modal regulations into United Kingdom (UK) law:

* Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2023 Edition [2]; and
* Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2023 Edition [3].

1. ADR [2] and RID [3] require that package designs granted unilateral approval by countries outside the ADR [2] and RID [3] agreements, also need approval by the CA of a country that is a ‘Contracting Party’ to the Agreements, if packages are being transported in a country that is a ‘Contracting Party’. ADR [2] and RID [3] are based on the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material SSR-6 (2018 Edition) [4].
2. QSA Global Incorporated have applied to ONR, requesting ADR [2] and RID [3] validation of QSA Global Incorporated Type B(U) package design Model No. 865, which has been approved by the United States of America (USA) CA in certificate USA/9187/B(U)-96 Revision 14 [5].

# Background

## Package Design

1. The QSA Global Incorporated Model No. 865 is designed as an industrial radiography device and transport package for Type B quantities of Iridium-192 special form radioactive material.
2. Model No. 865 is 311mm long, 194mm tall and 133mm (outer diameter). The device is provided with a handle and two triangular shaped legs. Primary components consist of an outer steel shell, internal bracing, depleted uranium shield, and a source tube. The contents are securely positioned in the source tube by a source holder assembly and actuator and locking assembly. Tamper-indicating seals are provided on the packaging and a 3mm thick steel outer cover is bolted over the source actuator and locking assembly for additional protection during transport. The maximum total weight of the package is approximately 27.2kg. Schematic diagrams of the Model No. 865 are shown in the Appendix.

## Validation History

1. The last GB CA ADR and RID validation of this package was in 2018, see validated USA/9187/B(U)-96 Rev 13 certificate [6]; High Technology Sources Ltd applied for this validation on behalf of QSA Global Incorporated. For this application QSA Global Incorporated have applied directly to ONR.
2. Certificate USA/9187/B(U)-96 Revision 14 [5] has been issued in compliance with SSR-6 (2012 Edition) [7].

# Assessment and Inspection Work Carried out by ONR

## Assessment and Inspection Strategy & Scope

1. An ONR assessment of the Package Design Safety Report (PDSR) and its supporting documents, in [8], has been undertaken in accordance with guidance in ‘Validation of Type B(U) Package Designs’ [9] and with reference to ONR expectations in ‘Guidance for Applications for UK Competent Authority Approval’ [10]. The approved assessment strategy and scope is in WIReD record PR-01206. A summary of the assesment and inspection activies undertaken is listed below:

* **Package Design Effects of Ageing and Degradation Assessment**: The UK CA guidance to applicants, paragraph 2.44 [10] expects package design applications to be forward-looking including consideration of the impact of known, future changes to regulations. Of relevance to this UK CA expectation, is that SSR-6 (2018 Edition) [4] is applicable in the UK. The 2018 Edition introduced paragraph 613A, which is translated into paragraph 6.4.2.8 in ADR [2] and RID [3] and requires that ‘The design of the package shall take into account ageing mechanisms’.

The route-map in ‘Transposition Note for USA/9187/B(U)-96 (QSA Global Model 865) issue 5’, in [8], cross-references the contents of the PDSR to the requirements of ADR [2] and RID [3]. However because the USA CA has assessed the package and issued a certificate in compliance with SSR-6 (2012 Edition) [7] I have assessed the PDSR and its supporting documents, in [8], to ensure it meets the requirements of 6.4.2.8 in ADR [2] and RID [3].

* **Package Design ADR and RID Compliance Assessment**: The route-map in ‘Transposition Note for USA/9187/B(U)-96 (QSA Global Model 865) issue 5’, in [8], cross-references the contents of the PDSR to the requirements of ADR [2] and RID [3]. However because the USA CA has assessed the package and issued a certificate in compliance with SSR-6 (2012 Edition) [7] an Enhanced Q0 assessment on the PDSR and its supporting documents, in [8], was undertaken to confirm its scope is consistent with ADR [2] and RID [3].
* **Package Inspection**: Following guidance in ‘Validation of Type B(U) Package Designs’ [9], no inspection work is required for the validation of USA CA approved packages and none was carried out.

## Assessment

### Package Design Effects of Ageing and Degradation Assessment

1. The ‘Transposition Note for USA/9187/B(U)-96 (QSA Global Model 865) issue 5’, in [8], contains an Appendix titled ‘Ageing Assessment’, that discusses ageing mechanisms that could lead to package degradation and non-compliance, and measures for their mitigation.
2. QSA Global Incorporated ‘Quality System Manual’, see ‘A08-QSA Global Quality System Manual, QSM-1, Rev 15.pdf’, in [8], describes procedures that mitigate against the effects of package ageing and degradation.
3. In addition, supporting information provided by QSA Global Incorporated, for validation of a similar package, see ‘Model 650L Supplement Oct 27, 2022’, in [11], demonstrates how they proactively and adequately addressed a material degradation issue concerning package lids with the USA CA.
4. Based on my review of the information above I am satisfied that the PDSR and its supporting documents, in [8], have adequately taken into account ageing and degradation of the package design and it is therefore compliant with SSR-6 (2018 Edition) [4].

### Package Design ADR and RID Compliance Assessment

1. I confirmed that the PDSR and supporting documents, in [8], submitted to ONR for GB validation was the same as that submitted to the USA CA for approval of the package design, resulting in the issue of certificate USA/9187/B(U)-96 Revision 14 [5]. This is to ensure that the USA certificate and ONR validation of that certificate are based on the same PDSR.
2. ADR [2] and RID [3] state that packaging’s manufactured to a package design approved by a CA under the provisions of the SSR-6 (2012 Edition) [7] may continue to be used provided that transitional conditions in 1.6.6.2.1 (b) are met. I assessed the PDSR and its supporting documents, in [8], against the requirements of 1.6.6.2.1 (b) and confirmed the following.

1.6.6.2.1 (b) (i)

1.6.6.2.1 (b) (i) in ADR [2] and RID [3] states: ‘The package design is subject to

multilateral approval after 31 December 2025’.

The expiration date on certificate USA/9187/B(U)-96 Revision 14 [5] is 31 March 2029. This extends beyond the date of 31 December 2025 following which multi-lateral approval is required; however based on the findings of my assessment in section 3.2.1 above, I consider that the package design is compliant with SSR-6 (2018 Edition) [4]. Section 4 of this report provides further detail on this matter.

1.6.6.2.1 (b) (ii)

1.6.6.2.1 (b) (ii) in ADR [2] and RID [3] requires that the applicants management system must meet the requirements of 1.7.3 in ADR [2] and RID [3].

The management systems of QSA Global Incorporated are accredited to ISO 9001:2015, see in [8]; QSA Global Incorporated quality assurance program is approved by the US Nuclear Regulatory Commission, see in [8].

QSA Global Incorporated have confirmed that they can provide facilities for inspection of package use and demonstration of compliance with ADR [2] and RID [3]; and that they can facilitate access for inspection of package use in the UK once the packaging is used by a UK dutyholder, see [12].

QSA Global Incorporated currently have no plans to manufacture anymore packaging’s using the ‘Model No. 865 package design, see [12].

Based on the information above I consider the applicable requirements of 1.7.3 in ADR [2] and RID [3] have been met.

1.6.6.2.1 (b) (iii)

1.6.6.2.1 (b) (iii) in ADR [2] and RID [3] requires that activity limits in 2.2.7 of ADR [2] and RID [3] are applied.

I confirmed that the maximum activity of the special form sources to be transported is within the limits and material restrictions of 2.2.7 in ADR [2] and RID [3].

1.6.6.2.1 (b) (iv)

1.6.6.2.1 (b) (iv) in ADR [2] and RID [3] requires that controls for carriage in Parts 1, 3, 4, 5 and 7 of ADR [2] and RID [3] are applied.

I confirmed that the PDSR and its supporting documents, in [8], meet the requirements and controls for carriage as specified in Parts 1, 3, 4, 5 and 7 of ADR [2] and RID [3].

1. Based on the findings of my assessment I confirm that the PDSR and its supporting documents, in [8], meet the requirements 1.6.6.2.1 (b) in ADR [2] and RID [3].

# Matters Arising from ONRs Work

1. Based on my assessment I find that package design is compliant with ADR [2], RID [3] and SSR-6 (2018 Edition) [4] and recommend ONR as GB CA should validate the certificate USA/9187/B(U)-96 Revision 14 [5], to the same expiration date as that applied by the USA CA. However, I recommend that the QSA Global Incorporated are advised that use of the package after 31 December 2025 in countries contracting to ADR [2] and RID [3] (other than the UK) may be noncompliant with 1.6.6.2.1 (b) (i). The basis of this recommendation is that ONR has performed additional regulatory assessment work to ensure that the package design meets UK law i.e. that the package design complies with SSR-6 (2018 Edition) [4].

# Conclusions

1. Based on the findings of my assessment, I am satisfied that the package design meets the relevant requirements of ADR [2], RID [3] and SSR-6 (2018 Edition) [4].

# Recommendations

1. I recommend that ONR as GB CA should issue a countersigned validation of United States Department of Transportation certificate USA/9187/B(U)-96 Revision 14, with an expiration date of 31 March 2029.

# References

[1] The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (CDG) 2009, (SI 2009 No. 1348).

[2] United Nations Economic Commission for Europe (UNECE), Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2023 Edition. www.unece.org.

[3] Intergovernmental Organisation for International Carriage by Rail (OTIF), Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2021 Edition. [www.otif.org](http://www.otif.org).

[4] IAEA Safety Standards: SSR-6, ‘Regulations for the Safe Transport of Radioactive Material (2018 Edition)’, IAEA, Vienna, 2018. [www.iaea.org](http://www.iaea.org).

[5] A01-USA-9187-B(U)-96 Rev 14.pdf, ONRW-2019369590-4374.

[6] CM9: 2018/370322 USA/9187 (SVC4385943) - Certificate for USA/9187/B(U)-96 Rev 13 - 14 November 2018.

[7] IAEA Safety Standards: SSR-6, ‘Regulations for the Safe Transport of Radioactive Material (2012 Edition)’, IAEA, Vienna, 2012. [www.iaea.org](http://www.iaea.org).

[8] WIReD PR-01206, Documents.

[9] CM9: 2021/41528, TRA-PER-GD-006, Validation of Type B(U) Package Designs - Issue 3.

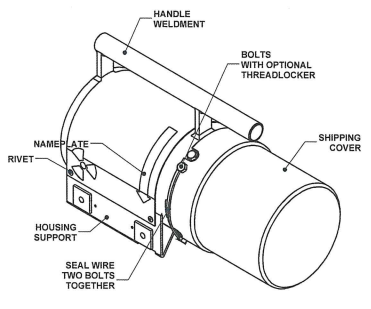
[10] CM9: 2019/335838, TRA-PER-GD-014, Revision 3 - Guidance for Application for UK Competent Authority Approval.

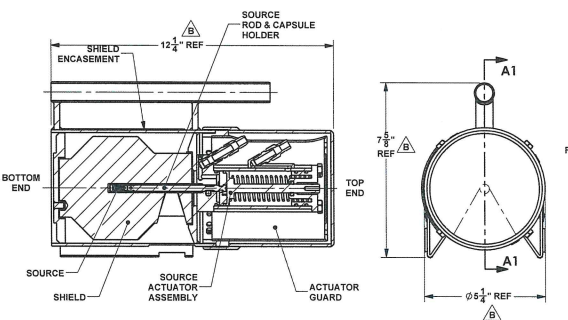
[11] usa-6269-rev-13.zip, ONRW-2019369590-2288.

[12] RE\_ Re USA\_9187\_B(U)-96 Questions - QSA Global Inc Model No\_ 865 .msg. - ONRW-2019369590-5684.

# Appendix

Schematic diagrams of the QSA Global Incorporated Model No. 865 radiography device and transport package.





The maximum total weight of the QSA Global Incorporated Model No. 865 package is approximately 27.2kg.