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| ONR Project Assessment Report  **PR-01295 – GB Competent Authority ADR and RID Validation of USA/9371/B(U) Revision 4** |



ONR Project Assessment Report

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

**Report Title**: PR-01295 – GB Competent Authority ADR and RID Validation of USA/9371/B(U) Revision 4

**Dutyholder/ Applicant**: Gilligan Engineering Services Ltd

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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).

Gilligan Engineering Services Ltd have applied to ONR, on behalf of QSA Global Incorporated, requesting ADR and RID validation of QSA Global Incorporated Type B(U) package design ‘Model No. 360 Series’, which has been approved by the United States of America (USA) CA in certificate USA/9371/B(U)-96 Revision 4.

The ‘Model No. 360 Series’ package design is used as an industrial radiography source changer and transport package for either Iridium-192, Ytterbium-169 or Selenium-75 special form radioactive material.

An ONR assessment of the Package Design Safety Report (PDSR) 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) and recommend that ONR as GB CA should validate the certificate USA/9371/B(U)-96 Revision 4 with the same expiration date as that applied by the USA CA i.e. 31 August 2028.
* I will advise the applicant and package design authority 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 raised Regulatory Issue (RI-11592) to advise the Applicant to update the route-map in ‘Transposition Note for USA/9371/B(U)-96 (QSA Global Model 360) issue 6’, to cross-reference the PDSR contents to the requirements of ADR and RID before the next GB validation application. Otherwise more work may be necessary to process the validation application, with higher associated charges. I have requested that the Applicant respond to me within three months informing me of how they intend to address the regulatory issue.

I recommend that ONR as GB CA should issue a countersigned validation of United States Department of Transportation certificate USA/9371/B(U)-96 Revision 4, with an expiration date of 31 August 2028.

# List of Abbreviations

# ADR European 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

Table of Contents

[Executive Summary 4](#_Toc143507562)

[List of Abbreviations 6](#_Toc143507563)

[1. Permission Requested 8](#_Toc143507574)

[2. Background 9](#_Toc143507575)

[2.1. Package Design 9](#_Toc143507576)

[2.2. Validation History 9](#_Toc143507577)

[3. Assessment and Inspection Work Carried out by ONR in Consideration of this Request 10](#_Toc143507578)

[3.1. Assessment Strategy & Scope 10](#_Toc143507579)

[3.2. Assessment 10](#_Toc143507580)

[3.2.1. Package Design Effects of Ageing and Degradation Assessment 10](#_Toc143507581)

[3.2.2. Package Design ADR and RID Compliance Assessment 11](#_Toc143507582)

[4. Matters Arising from ONRs Work 12](#_Toc143507583)

[5. Conclusions 12](#_Toc143507584)

[6. Recommendations 12](#_Toc143507585)

[References 13](#_Toc143507586)

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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 and RID are based on the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material SSR-6 (2018 Edition) [4].
2. Gilligan Engineering Services Ltd have applied to ONR, on behalf of QSA Global Incorporated, requesting ADR [2] and RID [3] validation of QSA Global Incorporated Type B(U) package design ‘Model No. 360 Series’, which has been approved by the United States of America (USA) CA in certificate USA/9371/B(U)-96 Revision 4 [5].

# Background

## Package Design

1. The QSA Global Incorporated ‘Model No. 360 Series’ package design consists of a family of five package configurations used as an industrial radiography source changer and transport package for either Iridium-192, Ytterbium-169 or Selenium-75 special form radioactive material. The five package configurations are the Model Nos. 360-2, 360-4, 360-4W, 360-10, and 360-10W. The external dimensions of all models are identical and are approximately: 38 cm long, 32 cm wide, and 40 cm tall.
2. The major components of the package include: (i) the container assembly, (ii) the shield assembly, (iii) the shield retainer, (iv) the source securing assembly, (v) the cover assembly, and (vi) the source assemblies. Shielding is provided by either all tungsten or a combination of tungsten and depleted uranium shields. Models with the “W” designation use all tungsten shielding. An optional adapter tungsten shield can also be added to the top side of the ‘Model No. 360 Series’ for additional shielding.
3. Depending on the source assembly to be transported, the source capsule will be attached to either a flexible steel wire or will be incorporated into a segment of a source chain. Each source securing mechanism incorporates a locking mechanism to secure the source inside the package and a source dust cap to further protect the end of the source assembly during transport. A lock assembly will secure the various lengths of the source assembles in the model numbers 360-2, 360-4, and 360-4W; which have the option of three loading positions: bottom, middle, or top. For the model numbers 360-10 and 360-10W, chain assemblies, which are shorter in length, will be secured to the locking assembly via stainless steel jumper extensions.

## Validation History

1. The packaging for the QSA Global Incorporated Type B(U) package design ‘Model No. 360 Series’, was first manufactured in 2014. ONR has previously validated the USA CA approval of the package design against the requirements of ADR [2] and RID [3] on 13 August 2015 [6], 24 May 2016 [7] and 01 November 2018 [8].
2. Certificate USA/9371/B(U)-96 Revision 4 [5] has been issued in compliance with SSR-6 (2012 Edition) [9].

# Assessment and Inspection Work Carried out by ONR in Consideration of this Request

## Assessment Strategy & Scope

1. An ONR assessment of the Package Design Safety Report (PDSR) and its supporting documents [10] has been undertaken in accordance with guidance in ‘Validation of Type B(U) Package Designs’ [11] and with reference to ONR expectations in ‘Guidance for Applications for UK Competent Authority Approval’ [12]. The approved assessment strategy and scope is in WIReD record PR-01295. A summary of the assesment activies undertaken is listed below:

* **Package Design Effects of Ageing and Degradation Assessment**: Certificate USA/9371/B(U)-96 Revision 4 [5], has been issued in compliance with SSR-6 (2012 Edition) [9]. The UK CA guidance to applicants, paragraph 2.44 [12] 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 ‘The design of package shall take into account ageing mechanisms’.
* **Package Design ADR and RID Compliance Assessment**: Because the route-map in ‘Transposition Note for USA/9371/B(U)-96 (QSA Global Model 360) issue 6’, in [10], does not cross-reference the contents of the PDSR to the requirements of ADR [2] and RID [3], an Enhanced Q0 assessment on the PDSR and its supporting documents, in [10], was undertaken.

## Assessment

### Package Design Effects of Ageing and Degradation Assessment

1. Appendix B of ‘Transposition Note for USA/9371/B(U)-96 (QSA Global Model 360) issue 6’, in [10], has a section titled ‘Ageing Assessment’, that discusses ageing mechanisms that could lead to package degradation and non-compliance, and measures for their mitigation.
2. The Applicants ‘Quality System Manual’, see [13] and [14] describe procedures that mitigate against the effects of package aging and degradation.
3. In addition, supporting information provided by the Applicant, for a similar package, see ‘Model 650L Supplement Oct 27, 2022’, see [15], demonstrates how the Applicant proactively and adequately addressed a material degradation issue concerning the 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 [10], 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 obtained evidence from the Applicant confirming that the PDSR submitted to ONR for GB validation was the same as that submitted to the USA CA for approval of the package design, resulting in certificate USA/9371/B(U)-96 Revision 4; see [16].
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) [9] may continue to be used provided that conditions in 1.6.6.2.1 (b) are met. I assessed the PDSR and its supporting documents, in [10], against the requirements of 1.6.6.2.1 (b) and confirmed the following:

1.6.6.2.1 (b) (i)

The expiration date on certificate USA/9371/B(U)-96 Revision 4 [5] is 31 August 2028. 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)

The management systems of QSA Global Incorporated and Gilligan Engineering Services Ltd are accredited to ISO 9001:2015, see in [10]; QSA Global Incorporated quality assurance program is approved by the US Nuclear Regulatory Commission, see in [10]. I confirmed that QSA Global Incorporated can provide facilities for inspection of package use and demonstration of compliance with ADR [2] and RID [3]; and that Gilligan Engineering Services can provide facilities for inspection of package use, see [17]. I confirmed that QSA Global Incorporated are currently in the process of manufacturing more packaging’s using the ‘Model No. 360 Series’ package design, see [18] and they intend to have the package design approved by the USA CA to comply with SSR-6 (2018 Edition) [4]. Based on this information 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)

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 (c) (iv)

The PDSR and its supporting documents, in [10], 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 [10], 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/9371/B(U)-96 Revision 4 [5] to the same expiration date as that applied by the USA CA; but that the applicant and design authority 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].
2. I raised Regulatory Issue (RI-11592) to advise the Applicant to update the route-map in ‘Transposition Note for USA/9371/B(U)-96 (QSA Global Model 360) issue 6’, to cross-reference the PDSR contents to the requirements of ADR [2] and RID [3] before the next GB validation application. Otherwise more work may be necessary to process the validation application, with higher associated charges. I have requested the Applicant respond to me within three months informing me of how they intend to address the regulatory issue.

# 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/9371/B(U)-96 Revision 4, with an expiration date of 31 August 2028.

# 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] DOT CoA USA-9371 Rev 4.pdf, ONRW-2019369590-3518.

[6] CM9: 2015/300754 USA/9371 (SVC4299194) - ONR Certificate - High Technology Sources Ltd - 13 August 2015.

[7] CM9: 2016/202928 USA/9371 (SVC4324414) - Validated DoT Certificate for USA-9371-BU-96 Rev 2 - High Technology Sources Ltd - 25 May 2016.

[8] CM9: 2018/350756 USA/9371 (SVC4383361) - ONR Certificate (Annotated DoT Certificate USA-9371-BU-96 Rev 3) - 1 November 2018.

[9] 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).

[10] WIReD PR-01295, Documents.

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

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

[13] QSA Global Incorporated QSM.msg, ONRW-2019369590-3791.

[14] QSA Global Incorporated QSM - Aging Issues.msg, ONRW-2019369590-3790.

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

[16] ADR & RID Validation of USA-9371 - Confirmation SAR Rev approved by USA CA.msg, ONRW-2019369590-3786.

[17] RE\_ USA\_9269 and 1\_7\_3 of ADR\_RID.msg, ONRW-2019369590-3304.

[18] Re\_ QSA Global Incorporated future plans to Manufacture ‘Model No\_ 360 Series’ packaging's\_.msg, ONRW-2019369590-3797.

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