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| ONR Project Assessment Report  PR-01205 – GB Competent Authority ADR Validation of USA/9314/B(U)-96 Revision 9 |



ONR Project Assessment Report

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

**Report Title**: GB Competent Authority ADR Validation of USA/9314/B(U)-96 Revision 9

**Dutyholder/ Applicant**: QSA Global Incorporated

**Authored by**:

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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.

ADR requires that package designs granted unilateral approval by countries outside the ADR agreement also need approval by the CA of a country that is a ‘Contracting Party’ to the agreement if packages are being transported in a country that is a ‘Contracting Party’. ADR is 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 validation of QSA Global Incorporated Type B(U) package design Model No. 976, which has been approved by the United States of America (USA) CA in certificate USA/9314/B(U)-96 Revision 9.

The Model No. 976 package design series (including A, C and F variants) are transport packages and storage containers for Type B quantities of special form radioactive material including Iridium-192, Selenium-75 and Ytterbium-169 sources.

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 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 (other than the UK) may be noncompliant with 1.6.6.2.1 (b) (i) of ADR.

I recommend that ONR as GB CA should issue a countersigned validation of United States Department of Transportation certificate USA/9314/B(U)-96 Revision 9, with an expiration date of 31 July 2029.

Table 2: List of abbreviations

|  |  |
| --- | --- |
| Term/Acronym | Description |
| ADR | Agreement concerning the International Carriage of Dangerous Goods by Road |
| CA | Competent Authority |
| DR | Decision Record |
| DoT | Department of Transportation |
| DU | Depleted uranium |
| GB | Great Britain |
| IAEA | International Atomic Energy Agency |
| NRC | Nuclear Regulatory Commission |
| ONR | Office for Nuclear Regulation |
| PDSR | Package Design Safety Report |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| SAR | Safety Analysis Report |
| 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].

1. ADR requires that package designs granted unilateral approval by countries outside the ADR agreement, also need approval by the CA of a country that is a ‘Contracting Party’ to the Agreement, if packages are being transported in a country that is a ‘Contracting Party’. ADR is based on the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material SSR-6 (2018 Edition) [3].
2. QSA Global Incorporated have applied to ONR [4], requesting ADR [5] validation of QSA Global Incorporated Type B(U) package design Model No. 976, which has been approved by the United States of America (USA) CA in certificate USA/9314/B(U)-96 Revision 9 [6].

# Background

## Package Design

1. The QSA Global Incorporated Model No. 976 package design series (including A, C and F variants) are transport packages and storage containers for Type B quantities of special form radioactive material including Iridium-192, Selenium-75 and Ytterbium-169 sources.
2. Model No. 976 (as described [7]) is a steel jacketed lead and/or depleted uranium (DU) shield container housed within a cork lined, stainless steel drum. The external dimensions of the drum are 502 mm diameter and 540 mm height. The maximum gross package weights vary from approximately 86 kg (C variant) up to 136 kg (A variant), with maximum nett weights from 176 g (A variant) up to 220 g (both C and F variants). The different variants allow for a greater mass and/or number of sources, with an associated greater degree of shielding.
3. The sources for these packages are all special form, welded capsules which may or may not be attached to flexible handling wires. Sources attached to flexible wires are held in place either by lock mechanism or source tube caps installed after the source wires are inserted into shielded J-tubes. Sources inserted into a cavity style shield container are held in place within the shield by means of a shield plug assembly and/or cover secured to the shield base. All shield containers are installed within cork liners in the 976 drum assembly and the drum lid is secured to the container by means of a bolted, seal wired lid closure band and four lid drum bolts.

## Validation History

1. The last GB ADR validation of this package was given in 2019 [8]. Gilligan Engineering Services Limited applied for this validation, on behalf of QSA Global Incorporated. The Decision Record (DR) for this validation can be found in CM9 [9].

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

1. In accordance with the regulatory permissioning strategy ONR has carried out an assessment of QSA Global Incorporated application for ADR validation of it’s transport package Model No. 976, certificate USA/9314/B(U)-96 Revision 9 [6]. This has been undertaken in accordance with ‘Validation of Type B(U) Package Designs’ guidance [10] (in particular the guidance for validation of USA certificates) against which the following permissioing plan (PR-01205) was agreed:

* Confirmation that the Package Design Safety Report (PDSR) submitted to ONR is the same as the PDSR submitted to the USA DoT for it to issue USA/9187/B(U)-96, Revision 14.
* Q0 completeness check on the Transposition Note, to confirm the USA Safety Analysis Report (SAR) paragraphs listed therein correspond to the required ADR paragraphs.
* Confirm the correct edition of ADR is being used for validation and any transitional arrangements are appropriately applied.

1. It was agreed in the plan that no inspection work is required.

**Confirmation that the PDSR submitted to ONR is the same as the PDSR submitted to the USA DoT for it to issue USA/9187/B(U)-96, Revision 14**

1. The PDSR is termed a SAR in the application. The Department of Transportation (DoT) certificate [6] references the Nuclear Regulatory Commission (NRC) certificate [11] with regards the package description. This NRC certificate [11] refers to the QSA Global Incorporated application [12] for renewal of the package certificate, attached to which was the SAR [7] also included in the application for this ADR validation. NRC carried out a review of changes [13] to this SAR from its previous issue, concluding that the “…*package design has been adequately described and evaluated*…”.
2. The SAR that NRC, and hence DoT, assessed is the same version as that submitted with this ADR validation application, hence I consider this point is satisfied.

**Q0 completeness check on the Transposition Note, to confirm the USA SAR paragraphs listed therein correspond to the required ADR paragraphs**

1. The Transposition Note [14] provides a ‘route-map’ which cross-references the submission to the applicable ADR regulations. Adhering to the guidance given [10] for assessing USA applications that include route-maps, these cross-references have been checked to confirm they exist in the SAR as submitted with the application.
2. A number of these cross-references for ADR requirements were sampled in slightly more detail, which confirmed the technical points described in the SAR satisfy the ADR requirements, and also a number of the ‘N/A’ entries were sampled to confirm they are indeed not applicable to the transport package.
3. Hence overall I consider this point to be satisfied.

**Confirm the correct edition of ADR is being used for validation and any transitional arrangements are appropriately applied**

1. The version of ADR referenced in the Transposition Note [14] is the version applicable from 1 January 2023, which is the current correct version.
2. The DoT certificate [6] states that the 2012 edition of the ‘IAEA Regulations for the Safe Transport of Radioactive Material (SSR-6)’ was used by the CA to assess whether the regulatory requirements for the transport package had been met. ADR [2] details transitional conditions (paragraph 1.6.6.2.1 b)) that, if met, allow the 2012 edition to be used for ADR validation.
3. There are four parts to paragraph 1.6.6.2.1 b), each to be considered in turn:
   * 1. The package design is subject to multilateral approval after 31 December 2025.
     2. The applicable requirements of 1.7.3 are applied.
     3. The activity limits and material restrictions of 2.2.7 are applied.
     4. The requirements and controls for carriage in Parts 1, 3, 4, 5 and 7 are applied.
4. **i)** The expiration date on certificate USA/9314/B(U)-96 is 31 July 2029, hence the package will require multilateral approval when its certificate is next renewed.
5. **i)** The package design will be subject to multilateral approval after 31 December 2025 for use in countries contracting to ADR, unless the USA CA approves the package design against IAEA SSR-6 2018 edition.
6. **ii)** Paragraph 1.7.3 in the ADR [2] states a management system, acceptable to the CA, should be established and implemented to ensure compliance with the ADR. The management systems of QSA Global Incorporated are accredited to ISO 9001:2015 [15], and NRC have approved QSA Global Incorporated’s ‘Quality Assurance Program’ [16].
7. Paragraph 1.7.3 a) requires the manufacturer, consignor or user to be prepared to provide facilities for inspection during manufacture and use of the package. These requirements are detailed within QSA Global Incorporated’s ‘Quality System Manual’ [17], and QSA Global Incorporate have confirmed that inspection of the packages would be possible at one of the package user sites.
8. Paragraph 1.7.3 b) requires compliance with ADR to be demonstrated to the CA, which has been met via the Transposition Note (see paragraph ‎12).
9. **iii)** Paragraph 2.2.7.2.4.6.2 of ADR [2] states that the activity limits for a Type B(U) package are those specified in the certificate of approval, hence this point is satisfied.
10. **iv)** There are numerous requirements and controls for carriage detailed within Parts 1, 3, 4, 5 and 7 of the ADR [2], and there are numerous potential carriers/users of the package. These requirements are required to be met by those carriers/users, hence this part iv) would be considered under ONR inspection duties, rather than assessment.
11. Paragraph 613A of IAEA 2018 [3] is also a new addition to the 2012 edition, which is translated to paragraph 6.4.2.8 in ADR [2], stating that the design of the package should take into account ageing mechanisms. These have been considered by QSA Global Incorporated and included with the Transposition Note [14], hence I conclude this additional requirement has been met.

# Matters Arising from ONRs Work

1. I recommend to QSA Global Incorporated that the package will require multilateral approval after 31 December 2025 (in compliance with 1.6.6.2.1 b) i)) for its use in countries contracting to ADR [2].

# Conclusions

1. Based on the work carried out by ONR, I am satisfied that the package design meets the relevant regulatory requirements of ADR [2] and IAEA SSR-6 [3].

# Recommendations

1. I recommend that ONR should issue a countersigned validation of US DoT certificate USA/9314/B(U)-96 Revision 9 [6], with an expiration date of 31 July 2029.

# References

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| [4] | ONRW-2019369590-9467, FW Validation of USA 9314 Rev 9, 19 February 2024. |
| [5] | ONRW-2019369590-9628, QSA Model 976 - Only ADR validation, 17 May 2024. |
| [6] | ONRW-2019369590-8198, A01 DoT Certificate USA-9314-B(U)-96 Rev 9, 1 February 2024. |
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| [8] | ONRW-157424439-98, USA-9314-B(U)-96 - UK Validation Certificate, Revision 8, 24 June 2019. |
| [9] | 2019/176608, ADR Validation of USA/9314/B(U)-96, Revision 0, 24 June 2019. |
| [10] | 2021/41528, TRA-PER-GD-006, Validation of Type B(U) Package Designs, Issue 3, August 2021. |
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| [12] | ONRW-2019369590-8202, Renewal Request for CoC number USA/9314/B(U)-96 Revision 10 (Model 976 Series), 11 July 2023. |
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| [14] | ONRW-2019369590-8197, A00-Model 976 Transposition Note for USA 9314, Issue 6. |
| [15] | ONRW-2019369590-8206, A09 QSA Global ISO 9001-2015, NQA 17590, 17 October 2022. |
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| [17] | ONRW-2019369590-8204, A07 QSA Global Quality System Manual, QSM-1, Rev 15, 7 December 2022. |