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| ONR Project Assessment Report  Validation of Type B(U) Package Design – GB Competent Authority Validation of USA/6613/B(U)-96 Revision 23 |



ONR Project Assessment Report

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

Report Title: GB Competent Authority Validation of USA/6613/B(U)-96 Revision 23

Dutyholder/Applicant: Gilligan Engineering Services Ltd

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# Executive Summary

Gilligan Engineering Services Ltd has applied to the Office for Nuclear Regulation (ONR) for validation of QSA Global Inc. Type B(U) Package Design Model 702 approved in Certificate USA/6613/B(U)-96 Revision 23.

The European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) and the European Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) require that package designs granted unilateral approval by countries outside the ADR and RID agreements also need approval by the Competent Authority (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’.

The Model 702 is designed as a transport package and storage container for Type B quantities of special form 192Ir, 75Se, 169Yb and 137Cs radioactive material. It conforms to the Type B(U)-96 criteria for packaging in accordance USA Codes for Federal Regulations 10 CFR 71 and 49 CFR 173, IAEA Regulations for the Safe Transport of Radioactive Material No. TS-R-1 (2009 Edition) and Canadian Nuclear Safety Commission (CNSC) PTNS Regulations SOR/2015-145.

The ONR assessment of this application has confirmed that:

* The application includes a summary of revisions to the Package Design Safety Report (PDSR) from Revision 15 to Revision 16 which indicates that there are no changes that impact on the packaging design, structural integrity, or safety functions.
* US Nuclear Regulatory Commission (NRC) safety evaluation report concludes that the Model No. 702 package design has been adequately described and evaluated, and that the changes do not affect the ability of the package to meet the requirements of 10 CFR Part 71.
* The US Department of Transportation (DoT) certification of the package design and US NRC certficate of compliance meet the relevant regulatory requirements of ADR/RID
* The PDSR is consistent with the relevant regulatory requirements of ADR/RID based on examination of the PDSR against the requirements of SSG-33 Schedule for a Type B(U) Package, non-fissile or fissile-excepted (UN2916).

Based on the work carried out by ONR, and the conclusions of the USA CA, I judge that the package design satisfies the technical requirements of ADR and RID.

I recommend that ONR should issue a countersigned validation of US DoT certificate USA/6613/B(U)-96, Revision 23.

# List of Abbreviations

CA Competent Authority

CFR Code of Federal Regulations

CNSC Canadian Nuclear Safety Commission

DoT Department of Transportation

GB Great Britain

IAEA International Atomic Energy Agency

NRC Nuclear Regulatory Commission

ONR Office for Nuclear Regulation

PDSR Package Design Safety Report

US United States

USA United States of America

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# Permission Requested

1. Gilligan Engineering Services Ltd has applied to the Office for Nuclear Regulation (ONR) for validation of QSA Global Inc. Type B(U) Package Design Model 702 approved in Certificate USA/6613/B(U)U-96 Revision 23 [1].

# Background

1. This Report presents the basis of the regulatory decision by the ONR as Great Britain (GB) Competent Authority (CA) for the transport of Class 7 (radioactive material) dangerous goods, to grant a validation of United States of America (USA) CA design approval for the QSA Global Inc. Type B(U) Package Design Model 702.
2. This statutory duty is given to ONR through The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (CDG) [2]. In accordance with Agency Agreements [3] (legal documents used to transfer statutory responsibilities between bodies) ONR also acts on behalf of:

* The Competent Authority of the United Kingdom of Great Britain and Northern Ireland in respect of sea transport, being the Secretary of State for Transport including the Maritime and Coastguard Agency [4].
* The Competent Authority of the United Kingdom of Great Britain and Northern Ireland in respect of air transport, being the Civil Aviation Authority [5].
* The Competent Authority of Northern Ireland in respect of road transport, being the Department of Agriculture, Environment and Rural Affairs - Northern Ireland [6].

where Competent Authority (CA) approval of a package design is required by sea, air and road in Northern Ireland respectively.

1. The following modal regulations apply to allow transport by road, rail, sea and air:

* European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) 2021 Edition [7];
* European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) 2021 Edition [8];
* Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2021 Edition [9].
* International Maritime Dangerous Goods Code (IMDG) Code 2020 Edition [10].
* Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO) 2021-2022 Edition [11].

1. The above modal regulations are based on the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material (2018 Edition), SSR-6 [12] supported by advisory material in SSG-26 [13].
2. ADR and RID require that package designs granted unilateral approval by countries outside the ADR and RID agreements also need approval by the Competent Authority (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’.
3. ADR 6.4.22.8 states:

“Any design that requires unilateral approval originating in a country Contracting Party to ADR shall be approved by the competent authority of this country; if the country where the package has been designed is not a Contracting Party to ADR, carriage is possible on condition that:

* + - * 1. A certificate has been supplied by this country, proving that the package design satisfies the technical requirements of ADR, and that this certificate is countersigned by the competent authority of the first country Contracting Party to ADR reached by the consignment;
        2. If no certificate and no existing package design approval by a country Contracting Party to ADR has been supplied, the package design is approved by the competent authority of an ADR Contracting Party.”

1. There is similar text in RID 2021 (paragraph 6.4.22.8).
2. The Model 702 is designed as a transport package and storage container for Type B quantities of special form 192Ir, 75Se, 169Yb and 137Cs radioactive material. It conforms to the Type B(U)-96 criteria for packaging in accordance 10 CFR 71 [14], 49 CFR 173 [15], IAEA Regulations for the Safe Transport of Radioactive Material No. TS-R-1 (2009 Edition) and Canadian Nuclear Safety Commission (CNSC) PTNS Regulations SOR/2015-145. tmper tantrum
3. ONR has validated this package design approval on a number of previous occasions. The most recent validation for five year renewal was approved in April 2018 [16] and has been followed by two further validations, in October 2018 [17] and July 2022 [18], resulting from package design modifications.

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

1. USA Type B(U) package designs approved by both the US Department of Transportation (DoT) and US Nuclear Regulatory Commission (NRC) have been considered against the criteria set out in iONR Guidance on Validation of Type B(U) Package Designs [19]. Based on previous evidence, ONR considers that these USA approvals are to a similar standard to that required by the ADR and RID Agreements. Therefore, ONR assessment is limited to confirming that the application to the GB CA is complete and as submitted to the USA CA.
2. ONR’s current Applicants Guide [20] reccomends that the application includes a a ‘route map’ showing where in the submission compliance with the requirements of the regulations has been demonstrated. In this instance such a “route map” has not been provided as the application has been submitted in compliance with superseded guidance. Consequently, an “enhanced Q0” assessment has been undertaken.

## Enhanced Q0 Assessment

1. A Q0 check confirms all relevant information has been provided in compliance with the Applicants Guide [20]. The enhanced assessment examines the application in greater detail to confirm that its scope of the Package Design Safety Report (PDSR) is consistent with the applicable regulatory requirements of ADR/RID and does not include any detailed technical assessment of the claimes, arguments and evidience within the PDSR.
2. The ONR assessment of this application has confirmed that:

* The application includes a summary of revisions to the PDSR from Revision 15 to Revision 16 which indicates that there are no changes that impact on the packaging design, structural integrity, or safety functions [21].
* US NRC safety evaluation report [22] concludes that the Model No. 702 package design has been adequately described and evaluated, and that the changes do not affect the ability of the package to meet the requirements of 10 CFR Part 71.
* The US DoT certification of the package design [1] and US NRC certficate of compliance [23] meet the relevant regulatory requirements of ADR/RID
* The PDSR is consistent with the relevant regulatory requirements of ADR/RID based on examination of the PDSR against the requirements of SSG-33 [24] Schedule for a Type B(U) Package, non-fissile or fissile-excepted (UN2916).

# Matters Arising from ONRs Work

1. The USA CA approval certificate has been issued in compliance with SSR-6 (2012 Edition) [25]. The UK guidance to applicants [20] expects submissions to be forward looking including consideration of the impact of known, future changes to the regulations. Of relevance to this UK expectation, the 2018 edition of SSR-6 is applicable in the UK. The 2018 Edition introduced Paragraph 613A, which is translated into ADR/RID (Paragraph 6.4.2.8) and requires “The design of the package shall take into account ageing mechanisms”.
2. In response to a request from the ONR, the applicant has provided additional arguments that demonstrate that the existing design has adequately considered ageing mechanisms [26]. These arguments have been presented aginst the supporting guidance for comlying with Para 613A detailed in SSG-26 [27].

# Conclusions

1. Based on the work carried out by ONR, and the conclusions of the USA CA, I judge that the package design satisfies the technical requirements of ADR and RID.

# Recommendations

1. I recommend that ONR should issue a countersigned validation of US DoT certificate USA/6613/B(U)-96, Revision 23.

# References

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| [1] | US Department of Transportation, Competent Authority Certification for a Type B(U) Radioactive Materials Package Design Certificate, USA/6613/B(U)-96, Revuion 23. |
| [2] | *The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (CDG) 2009, (SI 2009 No. 1348).* |
| [3] | Agency Agreements, Memoranda of Understanding (MoUs) and working arrangements protocol - http://www.onr.org.uk/agency-agreements-mou.htm. |
| [4] | Agreement with Secretary of State for Transport (including the MCA) - http://www.onr.org.uk/documents/2014/mca-aa.pdf. |
| [5] | Agreement with the Civil Aviation Authority - http://www.onr.org.uk/documents/2014/caa-aa.pdf. |
| [6] | Agreement with Department of Agriculture Environment & Rural Affairs (DAERA) (Northern Ireland) - http://www.onr.org.uk/documents/2014/transport-aa-northern-ireland.pdf. |
| [7] | United Nations Economic Commission for Europe (UNECE), European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2021 Edition. www.unece.org. |
| [8] | *United Nations Economic Commission for Europe (UNECE), European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) 2021 Edition.* |
| [9] | Intergovernmental Organisation for International Carriage by Rail (OTIF), Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2021 Edition. www.otif.org. |
| [10] | International Maritime Dangerous Goods Code (IMDG) 2020 Edition incorporating Amendment 40-20. |
| [11] | Technical Instructions for the Safe Transport of Dangerous Goods by Air 2021-2022 Edition. |
| [12] | IAEA Safety Standards: SSR 6, ‘Regulations for the Safe Transport of Radioactive Material (2018 Edition)’, IAEA, Vienna, 2018. www.iaea.org. |
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| [14] | NRC Regulations Title 10, Code of Federal Regulations, Part 71—Packaging and Transportation of Radioactive Material. |
| [15] | DoT Regulations Title 49, Code of Federal Regulations, Part 173—Shippers - General Requirements for Shipments and Packagings. |
| [16] | ONR Decision Record, ADR Validation of USA/6613/B(U)-96 Rev. 20, ONR-TRA-DR-18-002, April 2018, ONRW-2019369590-991. |
| [17] | ONR Decision Record, ADR Validation of USA/6613/B(U)-96 Rev. 21, ONR-TRA-DR-18-009, October 2018, ONRW-2019369590-990. |
| [18] | ONR Decision Record, ADR Validation of USA/6613/B(U)-96 Rev. 22, ONR-TRA-DR-22-007, July 2022, ONRW-2019369590-989. |
| [19] | ONR Guidance Document, Validation of Type B(U) Package Designs, TRA-PER-GD-006 Issue 3. |
| [20] | *TRA-PER-GD-014 Guidance for Applications for UK Competent Authority Approval, (HOW 2 or www.onr.org.uk).* |
| [21] | Summary of Revisions to the PDSR from Revision 15 to Revision 16, ONRW-2019369590-926. |
| [22] | US Nuclear Regulatory Commission, Safety Evaluation Report, Docket No. 71-6613, ONRW-2019369590-921. |
| [23] | US Nuclear Regulatory Commission, Certificate of Compliance for Radioactive Materials Packages, Certificat No. 6613, Revision 22. |
| [24] | Schedules of Provisions of the IAEA Regulations for the Safet Tansport of Radioactive Material (2018 Edition), Specific Safety Guide No. SSG-33 (Rev. 1). |
| [25] | IAEA Safety Standards: SSR 6, ‘Regulations for the Safe Transport of Radioactive Material (2018 Edition)’, IAEA, Vienna, 2012. |
| [26] | Response from Applicant to Query Regarding Ageing Mechanisms, ONRW-2019369590. |
| [27] | *SSG 26, ‘Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition)’, IAEA, Vienna, 2022.* |