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| ONR Project Assessment Report  Assessment of Application for Extension of GB Competent Authority Approval GB/3962A/B(U) |



ONR Project Assessment Report

Project Name: Extension of REVISS R7016 Package Design Approval

Report Title: Assessment of Application for Extension of GB Competent Authority Approval GB/3962A/B(U)

Dutyholder/Applicant: REVISS Services (UK) Ltd.

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# Executive Summary

REVISS Services (UK) Ltd. has applied to the Office for Nuclear Regulation (ONR) for an extension to the REVISS R7016 package design approval, which is effected by the extant GB/3962A/B(U) certificate. This extension request is for a specific programme of consignments in Argentina.

The extension is required because the existing certificate expires on 31 March 2023. The REVISS R7016 package is needed for the transport of Co-60 sources in Argentina from April to August 2023.

Extensions to existing approvals may be issued in exceptional circumstances to enable a transport package design to continue in use where this is justified by the strategic, safety and/or security reasons. In this case, the applicant has set out the intended near-term use of the package design outside of the United Kingdom (UK) for the transport of Co-60 sources and an extension will support the global supply of these materials for a range of uses, including sterilisation of foodstuffs, blood products and medical equipment. In parallel, the applicant intends to seek package design approval for the R7016 package by the Canadian competent authority, such that this will be the final issue of the GB/3962A/B(U) certificate by ONR.

ONR’s assessment of the extension request has been principally based on a general transport compliance inspection at the REVISS Services (UK) Ltd. premises at Milton Park, Abingdon. This has been supported by a review of the previous full renewal in 2018 to confirm that there are no outstanding issues relating to that approval, along with a review of operational experience and any relevant transport incidents.

The ONR assessment of this application has confirmed that:

* there are relevant strategic, safety and/or security circumstances that merit consideration of an extension to the GB/3962A/B(U) certificate of approval;
* the applicant complies with the requirements for the transport of Class 7 dangerous goods, as enacted in UK law;
* there are planned shipments using the R7016 package;
* there are no alternative approval routes for the package via overseas competent authorities that would meet the current planned shipment programme in Argentina;
* both the Canadian and Argentinean competent authorities have confirmed they support ONR approving the extension; and
* there are no outstanding issues from the previous renewal.

Based on the work carried out by ONR and the specific circumstances of this request, I judge that an extension of the package design approval GB/3962A/B(U) meets ONR’s requirements for granting an extension.

I recommend that ONR should grant an extension to certificate of approval GB/3962A/B(U) for a period of 6 months, with the use of the package being restricted to the planned shipments identified by the applicant in their request.

# List of Abbreviations

ADR Agreement Concerning the International Carriage of Dangerous Goods by Road

ARN Autoridad Regulatoria Nuclear (Argentina)

CA Competent Authority

CANDU Canada Deuterium Uranium

CDG The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009

CNSC Canadian Nuclear Safety Commission

GB Great Britain

IAEA International Atomic Energy Agency

ICAO International Civil Aviation Organization

IMDG International Maritime Dangerous Goods Code

IRR17 The Ionising Radiations Regulations 2017

ONR Office for Nuclear Regulation

PAR Project Assessment Report

PDSR Package Design Safety Report

PHWR Pressurised Heavy Water Reactor

RID Regulations Concerning the International Carriage of Dangerous Goods by Rail

SSG (IAEA) Specific Safety Guide

SSR (IAEA) Specific Safety Requirements

UK United Kingdom

WIReD (ONR) Well Informed Regulatory Decisions

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# Permission Requested

1. REVISS Services (UK) Ltd. has applied to the Office for Nuclear Regulation (ONR) as the Great Britain (GB) Competent Authority (CA) for an extension to the REVISS R7016 package design approval [1, 2], which is effected by the extant GB/3962A/B(U) certificate [3]. This extension request is for a specific programme of consignments in Argentina.

# Background

1. ONR is the GB CA for the civil inland surface transport of Class 7 dangerous goods. This statutory duty is given to ONR through The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG) [4]. CDG (as they apply to Class 7 dangerous goods) are both Relevant Statutory Provisions and Applicable Provisions of The Energy Act [5]. In accordance with Agency Agreements (legal documents used to transfer statutory responsibilities between bodies) [6, 7, 8, 9], ONR also acts on behalf of other civilian United Kingdom (UK) CAs in cases where CA approval of a package design is required, namely:

* 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;
* the Competent Authority of the United Kingdom of Great Britain and Northern Ireland in respect of air transport, being the Civil Aviation Authority; and
* the Competent Authority of Northern Ireland in respect of road transport, being the Department of Agriculture, Environment and Rural Affairs - Northern Ireland.

1. CDG [4] (and the Northern Ireland equivalent [10]) transpose into UK law the international standards ADR [11] and RID [12] for transport of dangerous goods by road and rail, respectively.
2. For transport of dangerous goods by sea, the international requirements are specified in the International Maritime Dangerous Goods (IMDG) Code [13] and are implemented in the UK by The Merchant Shipping Act 1995 [14] and The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 [15].
3. For transport of dangerous goods by air, the international requirements are specified in the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air [16] and are implemented in the UK by The Air Navigation Order 2016 [17] and The Air Navigation (Dangerous Goods) Regulations 2002 [18].
4. The above modal regulations (ADR, RID, IMDG Code and ICAO Technical Instructions)[[1]](#footnote-2), are based on the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material, currently SSR-6 (2018 Edition) [19] supported by the advisory material in SSG-26 [20].
5. The REVISS R7016 package design is intended for the shipment of high-activity encapsulated Co-60 sources. These are used in various applications, including the sterilisation of foodstuffs, blood products and medical equipment.
6. The REVISS Services business was acquired by Sotera Health in 2016. It is branded as Nordion (UK division) and registered as REVISS Services (UK) Ltd. Since the acquisition, there has been a strategy for the renewal of REVISS package design approvals by the Canadian Nuclear Safety Commission (CNSC), which is the Canadian Competent Authority for the transport of Class 7 dangerous goods. It was anticipated by ONR and CNSC that all of the REVISS package design approvals would follow this strategy in course as their extant certificates of approval approached expiry.
7. The REVISS R7016 package design approval under GB/3962A/B(U) is due to expire on 31 March 2023. The applicant expected that transfer of the design approval to Canada was progressing in line with the strategy. The applicant made contact with ONR in late 2022 when it was evident to them that the R7016 renewal was not being progressed. This early engagement led to an extension application [1] for the GB/3962A/B(U) certificate of approval.
8. At that stage, it was expected that a full renewal would be submitted to ONR in early 2023, i.e. the R7016 package design would be outwith the REVISS/Nordion approval strategy. It has subsequently been confirmed in [2] that the package design renewal will be progressed in Canada in 2023, in parallel with this extension request.
9. ONR has given package design approval for the REVISS R7016 package on a number of previous occasions, with the most recent full package design approval renewal completed in 2018 [21].

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

1. This permission relates to an application for an extension of approval for the REVISS R7016 package design. This has been assessed in accordance with ONR’s internal guidance for extensions to approvals in TRA-PER-GD-005 [22], as per the agreed permissioning strategy [23].
2. The guidance in [22] emphasises that extensions of no more than 12 months may be issued in exceptional circumstances, where the overall strategic, safety and/or security benefit is sufficient to justify an extension, e.g. project inspectors can exercise their professional judgement and discretion to ensure a proportionate regulatory decision in the interests of the safe transport of essential medical supplies.
3. This would normally be in cases where ONR had not been able to resource and process a renewal application in time, rather than the late submission of a renewal application. Extensions can be granted because the normal 5-year life of an approval is not a statutory requirement but is at the discretion of the CA.
4. It is further noted in [22] that extensions may also be considered without a full renewal application where a package design is required for a short period beyond the expiry date, prior to being taken out of service.
5. There have been no modifications to the REVISS R7016 package design or the Package Design Safety Report (PDSR) and supporting documentation since the 2018 renewal. ONR’s assessment of the extension request was therefore focused on:

* consideration of the exceptional circumstances;
* the transport compliance inspection of the applicant’s premises at Milton Park, Abingdon in March 2023;
* review of any outstanding issues from the 2018 renewal; and
* review of operational experience and relevant transport incidents since the 2018 renewal.

1. No specialist discipline input was necessary for this project due to the nature and circumstances of the extension request.

## Exceptional Circumstances

1. The applicant has explained the licensing situation with respect to the REVISS R7016 package design approval. The applicant fully accepts that this is an internal REVISS/Nordion licensing management and communication issue and is not due in any part to ONR as the GB CA.
2. Notwithstanding the above, ONR seeks to be an enabling regulator and has engaged with the applicant to explore the potential justification for an extension to the existing approval.
3. The applicant set out the circumstances behind their extension request in [1], as summarised below:

* there is a Nordion programme for Type B(U) package renewal applications to be submitted to the Canadian CA (CNSC) in sufficient time to ensure no gaps in licensing;
* there was no imminent use of the REVISS R7016 package envisaged and hence a renewal application was not submitted by Nordion to CNSC;
* it became apparent in November 2022 that the REVISS R7016 package was required to facilitate transport of Co-60 sources in Argentina after expiry of the extant GB/3962A/B(U) certificate on 31 March 2023;
* there was insuffiicent time for Nordion to prepare a renewal application and for CNSC to grant package design approval; and
* a full renewal application would be submitted for GB CA approval in Q1/Q2 of 2023 in sufficient time before expiry of any extension[[2]](#footnote-3).

1. The applicant also set out some of the strategic drivers behind their extension request in [1], as summarised below:

* the supply of Co-60 sources is essential to healthcare and food and agricultural product safety, for example the sterilisation of:
* about 30% of all single-use medical devices used globally;
* blood products, cosmetics and foodstuffs;
* there are only a small number of reactors producing Co-60 sources and these are stretched to capacity to meet global demand;
* the Co-60 sources need to be “harvested” without compromising reactor operations and further source production;
* Argentina is a major global supplier of Co-60 sources and there is an imminent requirement to transport harvested Co-60 from the Embalse CANDU Pressurised Heavy Water Reactor (PHWR) to the Dioxitek S.A. production facility at Ezeiza;
* these shipments are projected to commence in April 2023 and run to August 2023; and
* there are no suitable alternative transport packages available to meet this requirement.

1. I judge that the above discussion justifies ONR’s acceptance of the exceptional circumstances in the interests of the wider strategic, safety and/or security benefits achieved by extension of the package design approval.

## Transport Compliance Inspection

1. The transport compliance inspection was conducted at the REVISS Services (UK) Ltd. premises at Milton Park, Abingdon on 3 March 2023 [24].
2. The compliance inspection concluded that the applicant demonstrated compliance with the requirements for transport of Class 7 dangerous goods, as enacted in UK law. One regulatory issue was raised in respect of the scope of the radiation risk assessment. This requires a plan to be developed and implemented by the applicant for review/update of the radiation risk assessment to be suitable and sufficient in compliance with the requirements of The Ionising Radiations Regulations 2017 (IRR17), Regulation 8. The improvement required does not impact transport outside of the UK and hence resolution does not affect the decision to grant an extension for use of the REVISS R7016 package in Argentina.
3. I judge that there were no findings from the transport compliance inspection that prevent granting the extension request. Similarly, I judge that resolution of the regulatory issue is not required ahead of any extension being approved.

## Review of Previous Renewal

1. I have reviewed the Project Assessment Report (PAR) from the 2018 renewal [21] and there are no identified issues that remain outstanding. In addition, there have been no relevant changes in the requirements of IAEA SSR-6 (as reflected in the relevant modal regulations, as enacted in UK law) that require consideration.

## Review of Operational Experience & Relevant Transport Incidents

1. I have reviewed the operational experience and transport incidents summary provided by the applicant in support of the transport compliance inspection. There are no matters that impact on this extension request.
2. The applicant reported a transport incident to ONR in December 2022 that involved the consignment of a different package design from their site without the necessary tie-downs [25].The ONR lead inspector for this incident has confirmed that there are no issues relating to the circumstances and findings of that incident inquiry that impact on this extension request. This incident relates to a consignment in the UK and I judge that it is not relevant to the REVISS R7016 package design and its use in Argentina.

## Interaction with Overseas Competent Authorities

1. As described in paragraph 8, Nordion’s strategy is for all of the REVISS package designs to be relicensed by CNSC prior to expiry of their GB certificates of approval to ensure continuity of licensing.
2. I made contact with both CNSC and the Argentinian CA, Autoridad Regulatoria Nuclear (ARN), to ensure that they had full visibility of ONR’s permissioning strategy for the REVISS R7016 package design. They both confirmed that there were no credible alternatives and were in agreement with ONR’s approach [26].

# Matters Arising from ONRs Work

1. There are no matters arising from ONR’s assessment of this extension application.

# Conclusions

1. Based on the work carried out by ONR, I conclude that the REVISS R7016 package design continues to meet the requirements of the relevant modal regulations as enacted in UK law and the exceptional circumstances requirements defined in ONR’s guidance for the extension of approvals, as set out in TRA-PER-GD-005 [22].

# Recommendations

1. I recommend that:

* ONR grants an extension to the REVISS R7016 package design approval GB/3962A/B(U) for transport by road and sea.
* The extension should be limited to a period of 6 months to 30 September 2023, to facilitate the planned programme of shipments in Argentina and to provide sufficient time for Nordion to obtain a package design approval from the Canadian Competent Authority.
* Certificate of Approval GB/3962A/B(U) includes a restriction on contents to the transport of Co-60 sources between the Embalse CANDU PHWR and the Dioxitek S.A. production facility at Ezeiza, both of which are located in Argentina.

# References

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| [1] | "GB/3962A/B(U) Extension Request", December 2022. |
| [2] | "Amended GB/3962A/B(U) Extension Request", March 2023. |
| [3] | "Certificate of Approval of Package Design for the Carriage of Radioactive Material", GB/3962A/B(U)-96 (Rev 3), TRIM Ref: 2017/469860. |
| [4] | The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (CDG) 2009, (SI 2009 No. 1348). www.legislation.gov.uk. |
| [5] | The Energy Act 2013, Chapter 32. |
| [6] | Agency Agreements, Memoranda of Understanding (MoUs) and Working Arrangements Protocol - http://www.onr.org.uk/agency-agreements-mou.htm. |
| [7] | Agreement with Department of Agriculture Environment & Rural Affairs (DAERA) (Northern Ireland) - http://www.onr.org.uk/documents/2014/transport-aa-northern-ireland.pdf. |
| [8] | Agreement with Secretary of State for Transport (including the MCA) - http://www.onr.org.uk/documents/2014/mca-aa.pdf. |
| [9] | Agreement with the Civil Aviation Authority - http://www.onr.org.uk/documents/2014/caa-aa.pdf. |
| [10] | The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010, (SR 2010 No 160). www.legislation.gov.uk. |
| [11] | United Nations Economic Commission for Europe (UNECE), Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) 2021 Edition, www.unece.org. |
| [12] | Intergovernmental Organisation for International Carriage by Rail (OTIF), Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2021 Edition. www.otif.org. |
| [13] | International Maritime Dangerous Goods (IMDG) Code 2020 Edition incorporating Amendment 40-20. |
| [14] | The Merchant Shipping Act 1995 (1995 c. 21). www.legislation.gov.uk. |
| [15] | The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 (SI 1997 No. 2367). www.legislation.gov.uk. |
| [16] | International Civil Aviation Organisation’s Technical Instructions for the Safe Transport of Dangerous Goods by Air, ICAO TI, 2019-2020 Edition. |
| [17] | The Air Navigation Order 2016 (SI 2016 No. 765). www.legislation.gov.uk. |
| [18] | The Air Navigation (Dangerous Goods) Regulations 2002 (SI 2002 No.2786). www.legislation.gov.uk. |
| [19] | IAEA Safety Standards for Protecting People and the Environment, Specific Safety Requirements No. SSR-6, ‘Regulations for the Safe Transport of Radioactive Material’, 2018 Edition. www.iaea.org. |
| [20] | IAEA Safety Standards for Protecting People and the Environment, Specific Safety Guide No. SSG-26 (Rev. 1), "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2018 Edition)". |
| [21] | "Renewal of Certificate of Approval for Transport Package REVISS R7016", February 2018, TRIM Ref: 2018/18086. |
| [22] | "Extensions to Approvals", TRA-PER-GD-005 Revision 2, August 2021, CM9 Ref: 2021/63134. |
| [23] | WIReD Permissioning Record PR-01096. |
| [24] | WIReD Inspection Record IR-52369. |
| [25] | WIReD Incident Record INF-2609. |
| [26] | "GB/3962A Package Approval - Extension of Existing Certificate - Request for Discussions with Canadian and Argentinian Authorities", March 2023, WIReD Ref: ORNW-2019369590-2191. |

1. *Known as modal regulations as they apply to a specific mode of transport, e.g. road, rail, sea and air* [↑](#footnote-ref-2)
2. *This was subsequently changed to a Canadian CA package design approval by* [2]*, in line with the prior Nordion licensing strategy* [↑](#footnote-ref-3)