**Package Design Assessment to support Certificate of Approval GB/4122/B(U)**

**GB Competent Authority Approval of new package design GB/4122/B(U)**

Project Assessment Report ONR-TD-PAR-22-009

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**EXECUTIVE SUMMARY**

**Title**

GB Competent Authority Approval of new package design GB/4122/B(U)..

**Permission Requested**

In June 2018, Gesellschaft für Nuklear-Service mbH, the Applicant, applied to the Office for Nuclear Regulation (ONR) for approval of the package designs with manufacturer designation Transport and Storage flasks MOSAIK® II-15 EI (UK) and MOSAIK® II-15 U EI (UK) for road and rail transport.

**Background**

This package design has an approval from the German CA, Certificate D/2090/B(U)-96, however this approval does not include the required use in the UK which is to transport specific waste streams from Magnox Ltd sites. Therefore, the package for transporting UK-specific waste streams represents a new package design and has been given the package design number GB/4122.

The UK-specific waste streams are a subset of the original German sources but were not assessed as part of the German Competent Authority approval. These waste streams are as follows:

* Submersive caesium removal units containing IONSIV® material (glass fibre or stainless steel filtration material);
* Sludge (corrosion of spent Magnox fuel elements, graphite reactor components, leakage of ion exchange material from pond or effluent management systems);
* Miscellaneous activated components;
* Leaking fuel element bottle – emptied bottles previously used to store leaking fuel elements (so contain debris and corrosion product); and
* Fuel and fuel corrosion products (damaged/corroded fuel elements)

**Assessment and inspection work carried out by ONR in consideration of this request**

ONR carried out a programme of assessment of the transport safety case contained in the applicant’s Safety Analysis Report (SAR), its claims, arguments, supporting documentation and evidence.

ONR has considered the engineering, criticality, shielding and safety case requirements aspects of the safety submission in respect of compliance with the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material, currently SSR-6 (2018 edition), supported by advisory material in SSG-26 (2018 edition). The SCR assessment addresses the non-engineering means of achieving that compliance, such as in the use, operation, and maintenance of the approved package design. An SCR assessment also complements the engineering assessment of the package design by reviewing the manufacturing processes to ascertain that the manufactured package conforms to the design intent.

ONR assessments of all four aspects of the safety submission recommended approval of the package design.

**Matters arising from ONR's work**

During the assessment, a question was raised regarding a potential conventional (non-radiological) hazard associated with the package. The hazard relates to the potential for the large cylindrical package, weighing about 20000 kg when loaded, to become dislodged from its retention system during transport. On the one hand, such a conventional hazard could arise because the radioactive materials regulations require a "weak link" package retention system design that allows damage to the retention system so that there is no damage to the radioactive package. On the other hand, such a "weak link" design apparently represents a deliberate violation of other Great Britain law, for example, the Road Transport Act (1988).

In response to the question, additional documentation evidence was submitted to the Office for Nuclear Regulation by the Applicant and the Consignor (Magnox Ltd). There was a difference of opinion between ONR inspectors involved in the project regarding the adequacy of the responses. Consequently, an independent ONR review of the matter was undertaken to establish if adequate evidence had been submitted to address the question and based on the conclusion of this, determine if an approval should be issued.

The review established that the deliberately engineered feature (which ensured that the package retention system failed at a defined value in preference to damaging the package) was not a “weak link” as such. It was only a weak link relative to the forces required to damage the package itself; it was, arguably, a very strong link relative to the forces that will be experienced by a retention system that is compliant with the relevant GB law. The retention system therefore complies with both the transport regulations and the relevant Great Britain law.

Therefore, the independent review recommended approval of the package design.

**Conclusions**

The safety submission from the applicant, together with supporting documentation provided to ONR, is adequate to meet applicable regulatory requirements and the package design is judged to be safe.

**Recommendation**

Issue of Great Britain approval certificate GB/4122/B(U) (Rev.0), to be valid for a period of five years.

**LIST OF ABBREVIATIONS**

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

CA Competent Authority

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

DCI Deputy Chief Inspector

DMG Delivery Management Group

GB Great Britain

GNS Gesellschaft für Nuklear-Service mbH

HOW2 (Office for Nuclear Regulation) Business Management System IAEA International Atomic Energy Agency

IAEA The International Atomic Energy Agency IMDG International Maritime Dangerous Goods Code

ONR Office for Nuclear Regulation

PAR Project Assessment Report

PG Product Group

RID Regulations concerning the International Carriage of Dangerous Goods by Rail

SAR Safety Analysis Report

SCR Safety Case Requirements (Assessment)

SDFW Sellafield Decommissioning Fuel and Waste

SSG (IAEA) Specific Safety Guide

SSR (IAEA) Specific Safety Requirements

TAG Technical Assessment Guide (ONR)

UK United Kingdom

UNECE United Nations Economic Commission for Europe

**TABLE OF CONTENTS**

[1. PERMISSION REQUESTED 9](#_Toc383769010)

[2. BACKGROUND 9](#_Toc383769011)

[3. ASSESSMENT AND INSPECTION WORK CARRIED OUT BY ONR IN CONSIDERATION OF THIS REQUEST 10](#_Toc383769012)

[4. MATTERS ARISING FROM ONR’S WORK 10](#_Toc383769013)

[5. CONCLUSIONS 14](#_Toc383769014)

[6. RECOMMENDATIONS 14](#_Toc383769015)

[7. REFERENCES 15](#_Toc383769016)

1. PERMISSION REQUESTED
2. In June 2018, Gesellschaft für Nuklear-Service mbH (GNS), the Applicant, applied to the Office for Nuclear Regulation (ONR) for approval of the package designs with manufacturer designation Transport and Storage flasks MOSAIK® II-15 EI (UK) and MOSAIK® II-15 U EI (UK) for road and rail transport [1].
3. BACKGROUND
4. 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 an approval of the package designs with manufacturer designation Transport and Storage flasks MOSAIK® II-15 EI (UK) and MOSAIK® II-15 U EI (UK).
5. 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, currently SSR-6 [12] supported by advisory material in SSG-26 [13].
2. This package design has an approval from the German CA, Certificate D/2090/B(U)-96 [14], however this approval does not include the required use in the United Kingdom (UK) which is to transport specific waste streams from Magnox Ltd sites. Therefore, the package for transporting UK-specific waste streams represents a new package design and has been given the package design number GB/4122.
3. The packaging consists of a one-part, cylinder shaped cask body made of spherical graphite cast iron. The leak-proof enclosure is formed from the cask body, the lid with the fastener equipment for the lid penetrations and the screw connections, as well as the seals. The two designs differ in terms of their flask lids. For additional shielding it is possible to insert a lead lining of various wall thickness. Furthermore, it is possible to use additional internals. The shock absorber unit, consisting of a lid, central and floor shock absorber, forms part of the packaging.
4. The GB specific Product Groups (PG) waste streams are a subset of the original German sources but were not assessed as part of the German CA approval. These waste streams are as follows
* PG1.1: Submersive Caesium Removal Units containing IONSIV® material (glass fibre or stainless steel filtration material)
* PG2.1: Sludge (corrosion of spent MAGNOX fuel elements, graphite reactor components, leakage of ion exchange material from pond or effluent management systems)
* PG4.1: Miscellaneous activated components
* PG4.2: Leaking fuel element bottle – emptied bottles previously used to store leaking fuel elements (so contain debris and corrosion product)
* PG4.3: Fuel and fuel corrosion products (damaged/corroded fuel elements)
1. ASSESSMENT AND INSPECTION WORK CARRIED OUT BY ONR IN CONSIDERATION OF THIS REQUEST
2. ONR carried out a programme of assessment of the transport safety case contained in the applicant’s Safety Analysis Report (SAR), its claims, arguments, supporting documentation and evidence. The SAR is subdivided into three parts:
* Part 1 – Design [15]
* Part 2 – Construction [16]
* Part 3 – Operation/Maintenance [17]
1. The SAR is based on the safety case used for revision 8 of the German Package Design Approval D/2090/B(U)-96 which was issued on 21 July 2015 and is valid through 14 October 2019. Consequently, the ONR has undertaken a proportionate and targeted assessment focussing on the GB specific aspects of the package design and taking credit for work undertaken by the German Competent Authority in issuing a package design approval.
2. ONR has considered the engineering, criticality, shielding and safety case requirements (SCR) aspects of the safety submission in respect of compliance withSSR-6 [12] and SSG-26 [13]**.** The SCR assessment addresses the non-engineering means of achieving that compliance, such as in the use, operation, and maintenance of the approved package design. An SCR assessment also complements the engineering assessment of the package design by reviewing the manufacturing processes to ascertain that the manufactured package conforms to the design intent.
3. The key findings and conclusions for each assessment are summarised in sections 3.1 to 3.4 below. Further details that underpin the summaries are provided in the assessments that are referenced in the sections below.
	1. Engineering Assessment [18]
4. The engineering assessment considered the following aspects of the package design:
* Mechanical fastening
* Impact Loads
* Design and testing of the primary containment cask body
* Manufacturing aspects of the quality management system
1. Several technical questions were raised with the Applicant during the assessment and acceptable response provided.
2. The engineering assessment concluded that the applicant has provided suitable and sufficient evidence to demonstrate compliance with the transport regulations and the application meets the mechanical engineering requirements for a type B(U) package.
	1. Criticality Assessment [19]
3. The package limits and conditions ensure that the mass and/or concentration of fissile material in the package is sufficiently low that the package design does not need CA approval as a fissile package.
4. The criticality assessment has targeted the claims, arguments and evidence within the SAR that demonstrate contents remain compliant as non-fissile or fissile excepted. The assessment confirmed that the Applicant has correctly interpreted these requirements and produced adequate procedures for loading that ensure package content is limited to meet these requirements.
5. The criticality assessment concludes that there are no objections to issuing the package design approval as requested.
	1. Shielding Assessment [20]
6. A proportionate ONR shielding assessment has been undertaken. This targeted key documents contained in the PDSR in relation to radiation shielding, with a particular focus on the change in contents. Credit has been taken for the German Competent Authority approval of the packaging, although aspects of this have been sampled by the ONR shielding assessor.
7. Fifteen questions were raised with respect to dose rates under routine and accident conditions of transport. All responses from the Applicant were considered acceptable.
8. The ONR shielding assessment recommends approval of the package design with the Magnox Ltd content.
	1. SaFety Case Requirements Assessment [21]
9. The SCR assessment has targeted the aspects particular to the use of the package by Magnox Ltd. For requirements relating to the Applicant aspects of the package, reliance is placed on the German CA approval and regulatory processes.
10. The SCR assessment has confirmed that operating instructions, inspection, and maintenance arrangements have been documented. It also confirms that the Magnox Ltd management systems are adequate. Since this assessment was completed a further inspection of Magnox Ltd’s compliance with CDG has been undertaken and confirms that it remains compliant with relevant legislation [22].
11. The SCR assessment concludes that the package safety management arrangements are suitable and sufficient and recommends approval of the package design.
12. MATTERS ARISING FROM ONR’S WORK
	1. Safety Case Requirements assessment
13. During the SCR assessment a question was raised regarding a conventional (non-radiological) hazard associated with the package. The hazard relates to the potential for the large cylindrical package, weighing about 20000 kg when loaded, to become dislodged from its retention system during transport. On the one hand, such a conventional hazard could arise because the radioactive materials regulations require a "weak link" package retention system design that allows damage to the retention system so that there is no damage to the radioactive package. On the other hand, such a "weak link" design apparently represents a deliberate violation of other Great Britain law, including:
* Health and Safety at Work Act (HSWA) 1974 Part I, sections 2(10 and 3(1).
* The Management of Health and Safety at Work Regulations (MHSWR) 1999, Regulation 3, sections 3(1) and 3(3).
* Road Transport Act (1988)
1. In response to the question, additional documentation evidence was submitted to ONR by the applicant (GNS) and the consignor (Magnox Ltd), including:
* A risk assessment study undertaken by Magnox Ltd.
* A GNS report, based on the detailed analysis in, which considers the range of impact decelerations needed to release the package via failure of its retention system, and compares these with the range of decelerations needed to fail the package itself during impacts associated with accident conditions of transport.
* The minutes of a meeting of experts and members of the Transport Container Standardisation Committee (TCSC) that was specially convened at the request of Magnox Ltd, and a presentation by Magnox Ltd at that meeting.
1. There was a difference of opinion between ONR inspectors involved in the project regarding the adequacy of the responses. Consequently, an independent ONR review of the matter was undertaken to establish if adequate evidence had been submitted to address the question and based on the conclusion of this determine if an approval should be issued in response to the application [23].
2. The review established that the deliberately engineered feature (which ensured that the package retention system failed at a defined value in preference to damaging the package) was not a “weak link” as such. It was only a weak link relative to the forces required to damage the package itself; it was, arguably, a very strong link relative to the forces that will be experienced by a retention system that is compliant with the relevant GB law. The retention system therefore complies with both the transport regulations and the relevant Great Britain law.
3. Therefore, the independent review recommends that the package approval should be issued.
	1. Criticality Assessment
4. During the review of the draft GB Certificate of Approval it was identified that there was some discussion, regarding the number of packages being carried per conveyance, during the acceptance review of the ONR criticality assessment. Whilst it had been identified that due to the size of the package/transport container, only a single package will be transported per conveyance [24] it has been recommended that the GB Certificate of Approval should include a statement under the “Supplementary Operational Controls” section to ensure that only one package is transported per conveyance [25].
	1. competent authority identification mark
5. On receipt of the application, the ONR project inspector originally assigned an identification mark GB/5126 which various assessment reports have then added package type B(M) or B(U) in document titles. The 5000 series of design numbers is reserved for validations of B(M) packages, from non-GB applicants, that cannot be fully validated and have specific-GB restrictions. As this application is not a validation but a GB-specific design approval of a type B(U) package the preliminary identification mark assigned has been revised to GB/4122/B(U).
6. CONCLUSIONS
7. The safety submission from the applicant, together with supporting documentation provided to ONR, is adequate to meet applicable regulatory requirements and the package design is judged to be safe.
8. RECOMMENDATIONS
9. Issue of GB approval certificate GB/4122/B(U) (Rev.0), to be valid for a period of five years.
10. REFERENCES

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| [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.  |
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| [16]  | *Part II - Construction - Packages of type B of the MOSAIK® II-15 EI (UK) and MOSAIK® II-15 U EI (UK) series, GNS B 004/2018 Rev. 0, dated 29 May 2018. CM9 2020/267270..*  |
| [17]  | *Part III- Operation/Maintenance - Packages of type B of the MOSAIK® II-15 EI (UK) and MOSAIK® II-15 U EI (UK) series, GNS B 005/2018 Rev. 1, dated 5 September 2019. CM9 2020/259530..*  |
| [18]  | *Engineering Assessment for GB/5126 Package Design Approval , CM9: 2020/301352.*  |
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| [20]  | *Radiation Protection - Shielding/Dose Assessment, CM9: 2021/14217.*  |
| [21]  | *Safety Case Requirements Assessment for UK Approval for Package GB/5126, CM9: 2020/312488.*  |
| [22]  | *Class 7 Transport Compliance Inspection of Magnox Ltd, WIReD IR-52007.*  |
| [23]  | *Decision Record, Assessment of the conventional hazard associated with GB/5126 transport package, CM9 2022/20935.*  |
| [24]  | *Response to Queries regarding limits on number of packages transported per conveyance. CM9: 2019/307575..*  |
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