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| ONR Project Assessment Report  PR-01342: GB/4120/B(U) Modification – Assessment of Modification to DPR 200 Transport Package Design |



ONR Project Assessment Report

**Project Name**: PR-01342: GB/4120/B(U) Modification

**Report Title**: Assessment of Modification to DPR 200 Transport Package Design

**Dutyholder/ Applicant**: Synergy Health Sterilisation UK Ltd

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# Executive Summary

The applicant, Synergy Health Sterilisation UK Ltd, has applied to the Office for Nuclear Regulation (ONR) for the approval of a modification to transport package design DPR 200. This report presents the basis of the regulatory decision by ONR, as Great Britain competent authority (CA) for the transport of Class 7 (radioactive material) dangerous goods, to approve the modification.

The package is used to transport encapsulated high energy gamma sterilisation sources to and from irradiation plants and manufacturing sites. ONR completed the first regulatory approval of the DPR 200 package design in April 2022; certificate of approval (CoA) GB/4120/B(U) was issued. The approval was supported by a comprehensive ONR assessment undertaken in accordance with ONR guidance for new package designs that included a management system inspection and a compliance inspection of the applicant.

The modification consists of three minor design changes, the most significant of which is an alternative seal specification due to supply chain issues. ONR have undertaken a mechanical engineering assessment concluding that the applicant has supplied documentary evidence supporting the claim that the alternative seal can deliver the same function as the original, without undermining the safety claims, arguments and evidence in the package design safety report (PDSR). The ONR engineering assessor recommended that the design modification should be approved.

Based on the supporting mechanical engineering assessment and the recent regulatory intelligence of the applicant and package, ONR concludes that the modification to the package design meets the relevant statutory requirements and recommends that the CA approves the modification by endorsing the modification sheet supplied within the application.

Table 2: List of abbreviations

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| Term/Acronym | Description |
| CA  CDG | Competent Authority  The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 |
| CoA | Certificate of Approval |
| GB | Great Britain |
| ONR | Office for Nuclear Regulation |
| PDSR | Package Design Safety Report |
| SCR | Safety Case Requirements |

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# Permission Requested

1. Synergy Health Sterilisation UK Ltd have applied (ref. [1]) to ONR for the approval of a modification (ref. [2]) to transport package design DPR 200.
2. This report presents the basis of the regulatory decision by ONR as Great Britain CA for the transport of Class 7 (radioactive material) dangerous goods to approve the modification. The statutory duty is given to ONR through The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (CDG) 2009 (ref. [3]).

# Background

## The Package

1. The package is used to transport encapsulated high energy gamma sterilisation sources to and from irradiation plants and manufacturing sites. The key safety concern is due to the high permitted activity; up to 8.51 PBq (8.51 × 1015 Bq) of 60Co may be transported in each package.
2. The packaging outer components consist of a shield assembly and an energy absorbing pallet. The flask is a stainless steel, lead shielded, finned cylinder with a conventional plug type closure in the top and thermal insulation built into its upper and lower corners. The closure has a vent point and the cavity has a drain tube to allow the flask to be operated in ponds as well as in cells. The cylindrical cavity holds the encapsulated radioactive material in a basket.

## Regulatory History

1. Our first regulatory approval [4] of the DPR 200 package design was in April 2022; CoA GB/4120/B(U) (ref. [5]) was issued.
2. This approval was supported by two inspections: An inspection (ref. [6]) to ensure the adequacy of the management arrangements; and, a compliance inspection (ref. [7]) to ensure that Synergy Health Sterilisation UK Ltd will operate the package in accordance with the relevant regulations.

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

1. The modification consists of three minor design changes, the most significant of which is an additional seal specification, required due to supply chain issues. The other design changes are not safety significant and relate to minor changes to seal test points and design drawings (to aid fabrication and correct a minor mistake).
2. I agreed a regulatory permissioning plan with the our CA permissioning lead. In accordance with this plan and ONR transport guidance (ref. [8]), a targeted and proportionate assessment of the modification was undertaken, considering the recent regulatory activity with Synergy Health Sterilisation UK Ltd.
3. Typically, for a Category B modification, criticality, radiation shielding, safety case requirements (SCR) and criticality assessments are undertaken to support the regulatory decision.
4. This package is non-fissile and there is no requirement for criticality support.
5. It was determined during the planning stage that the modification will not impact the 2022 regulatory judgment regarding the radiation shielding regulatory requirements and as such, there is no requirement to include a radiation shielding assessment.
6. Considering the recent regulatory engagement with Synergy Health Sterilisation UK Ltd (a comprehensive assessment of the DPR 200 transport package design in 2022 with supporting inspections (refs. [6] [7]), we decided that an SCR assessment would not be required to support this regulatory judgement. Regulatory intelligence from the 2022 approval will support our judgement: 1. There were no significant issues identified in the GB/4120/B(U) inspections and as such, no reason to suggest that Synergy Health Sterilisation UK Ltd will not implement the modification safely and in compliance with the relevant regulations; 2. Synergy Health Sterilisation UK Ltd have a positive history of compliance (there have been no incidents or regulatory issues raised since the approval); and, 3. There are no significant design changes being made that will impact the judgements of our previous SCR assessment.
7. The only assessment required to support the regulatory decision is mechanical engineering, and the scope of the assessment targeted documental evidence to support the claim that the new seal specification was an improvement to the original specification.

## Engineering Assessment

1. Technical assessment note (ref. [9]) reports our engineering assessment of this modification.
2. The engineering assessor targeted documental evidence to support the claim that the new seal specification was an improvement to the original specification.
3. A review of the seal material review report and a laboratory test report was undertaken. No regulatory queries were raised.
4. Our mechanical engineering assessment concluded that the applicant has supplied documentary evidence supporting the claim that the alternative seal can deliver the same function as the original, without undermining the safety claims, arguments and evidence in the PDSR, and that the CA should approve the design modification.

# Matters Arising from ONRs Work

1. There are no matters arising from our assessment of this design modification application.

# Conclusions

1. Based on the supporting mechanical engineering assessment and the recent regulatory intelligence of the applicant and package, I conclude that the modification to the DPR 200 PDSR meets the relevant statutory requirements.

# Recommendations

1. I recommend that the CA approves the modification to the DPR 200 transport package design by endorsing the modification sheet (ref. [2]) supplied within the application.

# References

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| [1] | ONRW-2019369590-3137, Notification of Application. |
| [2] | ONRW-2019369590-5008, SR-066: DPR 200 MOD #1 Approval. |
| [3] | The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (CDG) 2009. (SI 2009 No. 1348). |
| [4] | GB/4120/B(U) Rev.0 Project Assessment Report, CM9: 20223899. |
| [5] | GB/4120/B(U) Rev. 0 Certificate of Approval, CM9: 2021/89225. |
| [6] | ONR-TD-IR-21-031, STERIS Management System Inspection, CM9: 2021/73077. |
| [7] | ONR-TD-IR-21-032, STERIS Compliance Inspection, CM9: 2021/83566. |
| [8] | ONR Guide TRA-PER-GD-001 Revision 3, ONR Transport Permissioning Process Guide, CM9: 2021/14609. |
| [9] | ONRW-2126615823-1507, Mechanical Engineering Assessment – GB/4120/B(U) package modification 001. |