Transport Permissioning (SVC4340879)

Assessment of the Renewal Submission for the GB/3605D/B(U)-96 Package Design for the Transport of Tritium

Project Assessment Report ONR-TD-PAR-17-008
Revision 0
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EXECUTIVE SUMMARY

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This report summarises the basis of the regulatory decision by the Office for Nuclear Regulation (ONR) as GB Competent Authority (CA) for Class 7 (radioactive material) dangerous goods, to issue Certificate of Approvals (CoA), GB/3605D/B(U)-96, for the GB/3605D transport package to GE Healthcare Limited.

Permission Requested

The Applicant, GE Healthcare Limited, has written to ONR to request CA approval of the GB/3605D package design. The application was made under The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009. These regulations transpose into GB law the international standards ADR and RID for transport of dangerous goods by road and rail. Regarding the transport by sea and air the applicable regulations are respectively the International Maritime Dangerous Goods and the technical instructions of the International Civil Aviation Organization (ICAO). These regulations in turn are based on the IAEA Regulations for the Safe Transport of Radioactive Material, currently SSR-6 supported by advisory material in SSG-26. The package will be transported by road, rail, air and sea.

Background

The GB/3605D package is used for the transport of commercial and medical tritium. Its main user, Ontario Power Generation (OPG), operates in Canada, the United States and the UK. The customers include luminescence emergency exit signs and landmine markers providers. The tritium is also used as a tracer in biomedical research.

This package design was approved by ONR as a Type B(U) in March 2012. In March 2017, a 6-month extension of the certificate was granted by ONR at the request of the Applicant. In October 2017, in response to a challenge arising from ONR assessment, GE Healthcare updated the package design by changing the grade of the containment bolting material.

Assessment work carried out by ONR in consideration of this request

ONR carried out a detailed programme of work that involved assessment of the Package Design Safety Report (PDSR), its claims, arguments, supporting documentation and evidence. ONR assessment involved engineering, shielding and a safety case requirements review. Taking a proportionate and targeted sampling approach, our assessments of the safety submission has focused on the changes between the 2012 and 2017 applications and on aspects of the package design that the ONR assessors considered to require particular attention.

ONR challenged the safety demonstration of the containment bolts. In response to this challenge, the Applicant has changed the material of the bolts along with the provision of new calculations, which ONR has judged adequate.

A full radiation shielding and dose-rate assessment against the requirements of SSR-6 regulations has been carried out. ONR has considered that the calculations and reasoned arguments used in the Applicant's safety case provide adequate justification of compliance with the shielding and dose-rate requirements of SSR-6.

Other queries have been raised with the Applicant related to the management system and were adequately addressed.

Matters arising from ONR's work

There are no outstanding technical or regulatory matters that would contradict the totality of the package safety case for the GB/3605D package that would preclude the issue of a certificate of approval.

Conclusions

ONR is satisfied with the claims, arguments and evidence presented within the PDSR and the supporting analyses and evidence for the GB/3605D package. ONR is satisfied that the totality of the package safety case and subsequent restrictions placed on the certificate of approval demonstrate that the package can be transported safely and in compliance with regulatory requirements.

Recommendations

Issue of the GB/3605D/B(U)–96 certificate of approval for transporting tritium by road, rail, air and sea.

LIST OF ABBREVIATIONS

ACT	Accident Conditions of Transport
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CA	Competent Authority
CoA	Certificate of Approval
HOW2	(Office for Nuclear Regulation) Business Management System
IAEA	International Atomic Energy Agency
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
NCT	Normal Conditions of Transport
ONR	Office for Nuclear Regulation
OPG	Ontario Power Generation
PAR	Project Assessment report
PDSR	Package Design Safety Report
RCT	Routine Conditions of Transport
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SCR	Safety Case Requirement
UK	United Kingdom

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1 PERMISSION REQUESTED

1. GE Healthcare submitted an application [8] requesting GB competent authority approval of the GB/3605D package for the carriage of tritium for transport in the UK. An illustration of the package is provided in Annex 1.

2. This application has been made under The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 [1]. These regulations transpose into GB law the international standards ADR [2] and RID [3] for transport of dangerous goods by road and rail. Regarding the transport by sea and air the applicable regulations are respectively the International Maritime Dangerous Goods (IMDG) [4] and the technical instructions of the International Civil Aviation Organization (ICAO) [5]. These regulations in turn are based on the IAEA Regulations for the Safe Transport of Radioactive Material currently SSR-6 [6] supported by advisory material in SSG-26 [7].

2 BACKGROUND

3. This package is used for the transport of commercial and medical tritium. Its main user Ontario Power Generation (OPG) operates in Canada, the United States and the UK. The customers include luminescence emergency exit signs and landmine markers providers. The tritium is also used as a tracer in biomedical research.

4. This package design was approved by ONR as a Type B(U) package [19] in March 2012. The package was assessed against the requirements of ADR, RID, IMDG and ICAO that were current at the time.

5. In March 2017, a 6-month extension of the certificate [20] was granted by ONR at the request of the Applicant. In October 2017, in response to challenge arising from ONR assessment, GE Healthcare updated the package design by changing the grade of the containment bolting material. A new version of the Package Design Safety Report (PDSR) [9] was submitted at this time.

3 ASSESSMENT WORK CARRIED OUT BY ONR IN CONSIDERATION OF THIS REQUEST

6. ONR carried out a programme of work that involved assessment of GE Healthcare's PDSR [8 and 9] for the GB/3605D package i.e. the claims, arguments, supporting documentation and evidence. The assessments were undertaken in line with the relevant requirements of the ONR HOW2 Business Management System (BMS) [13] and its associated guidance.

7. Our assessment involved engineering, shielding and a safety case requirements review. The assessments focused on the changes between the 2012 and 2017 applications and on aspects of the package design that the ONR assessors considered to require particular attention. The key findings and conclusions for each assessment are summarised below.

8. The consolidated assessment issues that ONR assessment identified and the responses to these from GE Healthcare are detailed in the shielding assessment [15], engineering assessment [14] and associated safety case requirement assessment [16]. The regulatory assessment issues raised with GE Healthcare and their responses are detailed in the ONR package application assessment form [17].

3.1 ENGINEERING ASSESSMENT

9. A thorough ONR engineering assessment in 2012 concluded that the design met the regulatory requirements of SSR-6 [4] for a Type B(U)-96 package.

10. The current engineering assessment [14] has therefore taken cognisance of the 2012 assessment and has focused on aspects considered to be of major importance for the package safety.

11. The engineering assessor challenged the validity [17] of the Applicant's calculations of the stresses in the bolts.

12. In response to this challenge, the Applicant changed the material of the bolts which enabled the bolt tightening torque to be increased and therefore provided better lid sealing function.

13. Along with this change the Applicant submitted a new set of calculations which adequately addressed the queries raised.

14. The ONR assessor has judged that an adequate engineering case has been presented by GE Healthcare and that the regulatory requirements of SSR-6 [4] have been met.

3.2 SHIELDING ASSESSMENT

15. No previous shielding and dose-rate assessment in support of approval for transport within the UK has been carried out for this package by the ONR TCA or its predecessor the Department for Transport (DfT) Radioactive Materials Transport (RMT). Therefore a full assessment against the requirements of SSR-6 [6] regulations has been carried out.

16. The scope of the ONR assessment covered the radiation shielding and dose-rate assessment of the package design under Routine, Normal and Accident Conditions of Transport, (RCT, NCT and ACT) and additional regulations for packages transported by air, as specified in paragraphs 619 to 621 of SSR-6 [6].

17. The calculations and reasoned arguments used in the Applicant's shielding analysis together with operational dose-rate survey measurements for the package have been considered in this assessment.

18. The ONR assessor considers that the Applicant's safety case for this package meets the shielding and dose-rate requirements of SSR-6 [6] under RCT, NCT and ACT.

3.3 SAFETY CASE REQUIREMENT ASSESSMENT

19. An SCR assessment addresses the non-engineering means of achieving compliance with the requirements of SSR-6, such as through instructions for the use, operation and maintenance of the approved package design.

20. The new contents and the modification in the PDSR have a direct implication on the operating instructions. The ONR assessor is satisfied that operating instructions in respect of the new bolts have been adequately specified by the Applicant in MGC_UKD_PQ_146 Version 4.0 [10].

21. Other queries have been raised with the Applicant related to the management system and were adequately addressed [11].

4 MATTERS ARISING FROM ONR'S WORK

22. There are no outstanding technical or regulatory matters that would contradict the totality of the package safety case for the GB/3605D design that would preclude the issue of the GB/3605D/B(U)-96 certificate of approval.

5 CONCLUSIONS

23. ONR is satisfied with the claims, arguments and evidence presented within the PDSR and supporting analyses and evidence for the GB/3605D package. ONR is satisfied that the totality of the package safety case and subsequent restrictions placed in the certificate of approval demonstrate that the package can be transported safely and in compliance with regulatory requirements.

6 RECOMMENDATIONS

24. Issue of the GB/3605D/B(U)–96 certificate of approval for transporting tritium by road, rail, air and sea.

REFERENCES

1. The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009, SI 2009 No1348 as amended by the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011, SI 2011 No 1885.

2. United Nations Economic Commission for Europe (UNECE), European Agreement concerning the International Carriage of Dangerous Good by Road (ADR) 2015 Edition.

3. Intergovernmental Organisation for International Carriage by Rail (OTIF), Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2015 edition.

4. International Maritime Organization (IMO) - International Maritime Dangerous Goods (IMDG) Code 2014 Edition incorporating Amendment 37-14 (until end of December 2017) or International Maritime Dangerous Goods (IMDG) Code 2016 Edition incorporating Amendment 38-16

5. International Civil Aviation Organization (ICAO) - Technical Instructions for the Safe Transport of Dangerous Goods by Air 2017-2018 Edition

6. IAEA Safety Standards for Protecting People and the Environment, Specific Safety Guide No SSR-26 “Regulations for the Safe Transport of Radioactive Material”, 2012 Edition

7. IAEA Safety Standards for Protecting People and the Environment, Specific Safety Guide No SSG-26 "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material", 2012 Edition.

8. Document submission “GB/3605 (SVC4340879) - GB/3605D - Renewal application for GB/3605D/B(U)-96 - GE Healthcare Ltd - 18 January 2017” (TRIM 2017/26106)

9. Document submission “GB/3605 (SVC4340879) - GB/3605D - Documents update - GE Healthcare -23 October 2017” (TRIM2017/409347)

10. Document submission “Operating Instruction for Package Design Number 3605D” – MGC_UKD_PQ_146 Version 4.0, 19 October 2017

11. Email from GE Healthcare “GE Healthcare Management System Arrangements”, November 2017 (TRIM 2017/418878)

12. Pre-Job Brief for the Assessment of the GB/3605D Transport Package as applied for UK Approval by GE Healthcare (SVC4340879), dated January 2017. TRIM Record: 2017/113311

13. HOW2 – ONR Business Management System.

14. ONR-TD-AR-17-011 - GB/3605D (SVC4340879) - Engineering Assessment - October 2017. TRIM Record: 2017/251932.

15. ONR-COP-AR-16-035 - GB/3605D (SVC4340879) - Report- GB/3605D Shielding Assessment Report, TRIM Record: 2017/76208.

16. Safety Case Requirements Assessment for the GB/3605D Application. TRIM 2017/411363

17. Q1 Assessment Review for the GB/3605D Transport Package as applied for UK Approval by GE Healthcare (SVC4340879), February 2017. TRIM Record: 2017/74271.

18. GE Healthcare – email – Response to Q1 shielding question. TRIM 2017/379702

19. Certificate of Approval GB/3605D/B(U)-96 Issue 5, dated 28 March 2012 (TRIM 2017/111390)

20. Certificate of Approval GB/3605D/B(U)-96 Issue 6, dated 31 March 2017 (TRIM 2017/107847)

Figure 1
GB/3605D Transport Package Illustration