



U.S. Department
of Transportation

Pipeline and
Hazardous Materials
Safety Administration

East Building, PHH-23
1200 New Jersey Ave, SE
Washington, D.C. 20590

COMPETENT AUTHORITY CERTIFICATION FOR A
TYPE B(U)
RADIOACTIVE MATERIALS PACKAGE DESIGN
CERTIFICATE USA/0596/B(U)-96, REVISION 6
REVALIDATION OF UNITED KINGDOM COMPETENT AUTHORITY
CERTIFICATE GB/3605D/B(U)-96

The Competent Authority of the United States certifies that the radioactive material package design described in this certificate satisfies the regulatory requirements for a Type B(U) package as prescribed in the regulations of the International Atomic Energy Agency¹ and the United States of America².

1. Package Identification - U. K. Design No. 3605D.
2. Package Description and Authorized Radioactive Contents - as described in United Kingdom Certificate of Competent Authority GB/3605D/B(U)-96, Revision 7 (attached).
3. General Conditions -
 - a. Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation. The user shall prepare the package for shipment in accordance with the documentation and applicable regulations.
 - b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Office of Engineering and Research, (PHH-23), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington D.C. 20590-0001.
 - c. This certificate does not relieve any consignor or carrier from compliance with any requirement of the Government of any country through or into which the package is to be transported.

¹ "Regulations for the Safe Transport of Radioactive Material, 2012 Edition, No. SSR-6" published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

² Title 49, Code of Federal Regulations, Parts 100-199, United States of America.

CERTIFICATE USA/0596/B(U)-96, REVISION 6

- d. Records of Management System activities required by Paragraph 306 of the IAEA regulations¹ shall be maintained and made available to the authorized officials for at least three years after the last shipment authorized by this certificate. Consignors in the United States exporting shipments under this certificate shall satisfy the applicable requirements of Subpart H of 10 CFR 71.
4. Marking and Labeling - The package shall bear the marking USA/0596/B(U)-96 in addition to other required markings and labeling.
5. Expiration Date - This certificate expires on December 31, 2022.

This certificate is issued in accordance with paragraph(s) 810 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the February 6, 2018 petition by GE Healthcare, Arlington Heights, IL, and in consideration of other information on file in this Office.

Certified By:



William Schoonover
Associate Administrator for Hazardous
Materials Safety

March 21, 2018
(DATE)

Revision 6 - Issued to revalidate U. K. Certificate of Approval of
Package Design GB/3605D/B(U)-96, Rev. 7.



CERTIFICATE OF APPROVAL OF PACKAGE DESIGN FOR THE CARRIAGE OF RADIOACTIVE MATERIAL

This is to certify that for the purposes of the Regulations of the International Atomic Energy Agency

- The Competent Authority of Great Britain in respect of inland surface transport, being the Office for Nuclear Regulation;
- 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;
- 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

approve the package design specified in Section 1 of this certificate, as submitted for approval by GE Healthcare (see Section 5)

as: Type B(U)

by: road, rail, sea and air.

Packaging identification: 3605D

Packages manufactured to this design meet the requirements of the regulations and codes on page 2, relevant to the mode of transport, subject to the following general condition and to the conditions in the succeeding pages of this certificate.

In the event of any alteration in the composition of the package, the package design, the management system(s) associated with the package or in any of the facts stated in the application for approval, this certificate will cease to have effect unless the Competent Authority is notified of the alteration and the Competent Authority confirms the certificate notwithstanding the alteration.

Expiry Date: This certificate cancels all previous revisions and is valid until the end of 31 December 2022 (see Section 5).

COMPETENT AUTHORITY IDENTIFICATION MARK: GB/3605D/B(U)-96

Signature:

Date of Issue: 22 December 2017

David Ian Barlow, Superintending Inspector
Head of GB Competent Authority, Land Transport of Radioactive Material
Office for Nuclear Regulation
Redgrave Court, Merton Road
Bootle, Merseyside
L20 7HS

on behalf of the Office for Nuclear Regulation; and the Secretary of State for Transport; the Civil Aviation Authority; and the Department of Agriculture, Environment and Rural Affairs - Northern Ireland.

This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.

REGULATIONS GOVERNING THE TRANSPORT OF RADIOACTIVE MATERIALS

INTERNATIONAL

International Atomic Energy Agency (IAEA)

SSR-6 Regulations for the Safe Transport of Radioactive Material 2012 Edition

United Nations Economic Commission for Europe (UNECE)

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2017 Edition

Intergovernmental Organisation for International Carriage by Rail (OTIF)

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2017 Edition

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

International Civil Aviation Organization (ICAO)

Technical Instructions for the Safe Transport of Dangerous Goods by Air 2017-2018 Edition

UNITED KINGDOM

ROAD

GREAT BRITAIN ONLY:

The Energy Act 2013 (2013 c. 32); The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009 No. 1348); The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011 (SI 2011 No. 1885); The Energy Act 2013 (Office for Nuclear Regulation) (Consequential Amendments, Transitional Provisions and Savings) Order 2014 (SI 2014 No. 469)

NORTHERN IRELAND ONLY:

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010, SR 2010 No 160; The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations (Northern Ireland) 2011, No 365

RAIL

GREAT BRITAIN ONLY:

The Energy Act 2013 (2013 c. 32); The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009 No. 1348); The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011 (SI 2011 No. 1885); The Energy Act 2013 (Office for Nuclear Regulation) (Consequential Amendments, Transitional Provisions and Savings) Order 2014 (SI 2014 No. 469)

SEA

British registered ships and all other ships whilst in United Kingdom territorial waters:

The Merchant Shipping Act 1995 (1995 c. 21); The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 (SI 1997 No. 2367); Merchant Shipping Notice MSN 1875 (M) The Carriage of Dangerous Goods and Marine Pollutants in Packaged Form: Amendment 38-16 to the International Maritime Dangerous Goods (IMDG) Code

AIR

The Air Navigation Order 2016 (SI 2016 No. 765); The Air Navigation (Dangerous Goods) Regulations 2002 (SI 2002 No.2786); The Air Navigation (Dangerous Goods) (Amendment) Regulations 2017 (SI 2017 No.28)

1. DESIGN SPECIFICATION

Package Design

- 1.1 The package design specification shall be in accordance with 'GE Healthcare Ltd Type B Design Safety Report Index Package Design Number 3605D', TAD3605D, Issue 15, dated 20 October 2017, and modifications to the package design approved by the authorities named on page 1 of this certificate under the established modifications procedure.

Design Drawings

- 1.2 The design is specified in the following drawings.

Design No.	Title (number of components)	Drawing / Drawing List	Issue
3605	Outer Steel Drum with Cork Spacers (One)	DL 25180 and PGM 865	J 7
3055	Intermediate Containment Pot (One)	DL22310	O
0035 (Mk3)	Inner Stainless Steel Pots 'Tritium Bed' (One)	DL23205	F
0035 (Mk4)		DL23549	G
0035 (Mk5)		DL27816	B

Package Description and Materials of Manufacture

- 1.3 Package design number 3605D comprises a zinc or nickel coated steel drum with a stainless steel clamp band and cork insulation and packing. The 3055 inner stainless steel pot acts as the containment system for a 0035 stainless steel pot which is a vessel for containing tritium as solid uranium tritide. See Appendix 1 for package illustration.

Package Dimension and Weights

- 1.4 Nominal Dimensions: 325mm diameter x 405mm high (see section 5 for package illustration).
1.5 Maximum authorised gross weight: 20.7 kg.

Authorised Contents

- 1.6 The authorised radioactive contents are:
- Tritium gas adsorbed on pyrophoric uranium in a stainless steel vessel.
 - The maximum activities of the authorised contents are 4 PBq of tritium and 6 MBq of depleted uranium.
 - The maximum heat loads of the authorised contents are 3.65 W of tritium and 4 μ W of depleted uranium.

Containment System

- 1.7 The containment system is defined by the 3055 Intermediate Containment Pot provided with its containment seal and the closure system consisting of 6 M4 stainless steel bolts.

2. USE OF PACKAGE

Information Provided in Safety Report on Use of Packaging

- 2.1 The packaging shall be used, handled and maintained in accordance with the requirements of MGC_UKD_PQ_146 Version 4 dated 18 October 2017.

Actions Prior to Shipment

- 2.2 Administrative controls shall ensure that the contents are in accordance with section 1 of this certificate, and that the consignor and consignee hold a copy of the instructions on the use of the packaging.
- 2.3 The package is not required to reach thermal equilibrium prior to shipment.

Emergency Arrangements

- 2.4 Before shipment takes place, suitable emergency plans will have been drawn up, copies of which shall be supplied to the GB Competent Authority on demand.
- 2.5 Within Great Britain, if the consignor's own, or other approved emergency plans, cannot be initiated for any reason, then the police shall be informed immediately and requested to call NAIR (National Arrangements for Incidents involving Radioactivity).

3. MANAGEMENT SYSTEMS

- 3.1 The management system(s) assessed as adequate in relation to this design by the authorities named on page 1 of this certificate, at the date of issue, are as specified in 'GE Healthcare Ltd Type B Design Safety Report Index Package Design Number 3605D', TAD3605D, Issue 15, dated 20 October 2017 referred to in Section 1 above, and comprise the following:
- GE Healthcare Global Quality Management System, GEHC_GQM Revision 11 (DOC0041547); and
 - any other quality assurance programmes for design; testing; manufacture; documentation; use; maintenance and inspection; and transport and in transit storage operations, providing they comply with national or international standards for quality assurance agreed as acceptable by the authorities named on page 1 of this certificate.
- 3.2 No alteration may be made to any management system confirmed as adequate in relation to this design, unless:
- a) the authorities named on page 1 of this certificate have confirmed the amended management system is adequate prior to implementation or use; or
 - b) the alteration falls within the agreed change control procedures set out in the management system(s).
- 3.3 Other management systems for design, testing, manufacture, documentation, use, maintenance, inspection, transport and in-transit storage operations may be used providing they comply with international, national or other standards for management systems agreed as acceptable by the authorities named on page 1 of this certificate.

4. ADMINISTRATIVE INFORMATION

Packaging Serial Numbers

- 4.1 For the purpose of compliance with ADR / RID, the owner of the packaging shall be responsible for informing ONR of the serial number of each packaging manufactured to this design.

Additional Technical Data / Information

- 4.2 At the time of compilation of this design approval certificate, The Ionising Radiations Regulations 1999, SI 1999 No 3232 and Approved Code of Practice apply, with regard to radiation protection, to all modes of transport and The Dangerous Substances in Harbour Areas Regulations 2016, SI 2016 No 721, apply in GB Ports, and The Dangerous Substances in Harbour Areas Regulations (Northern Ireland) 1991 SI 1991 No 509 apply in NI Ports.

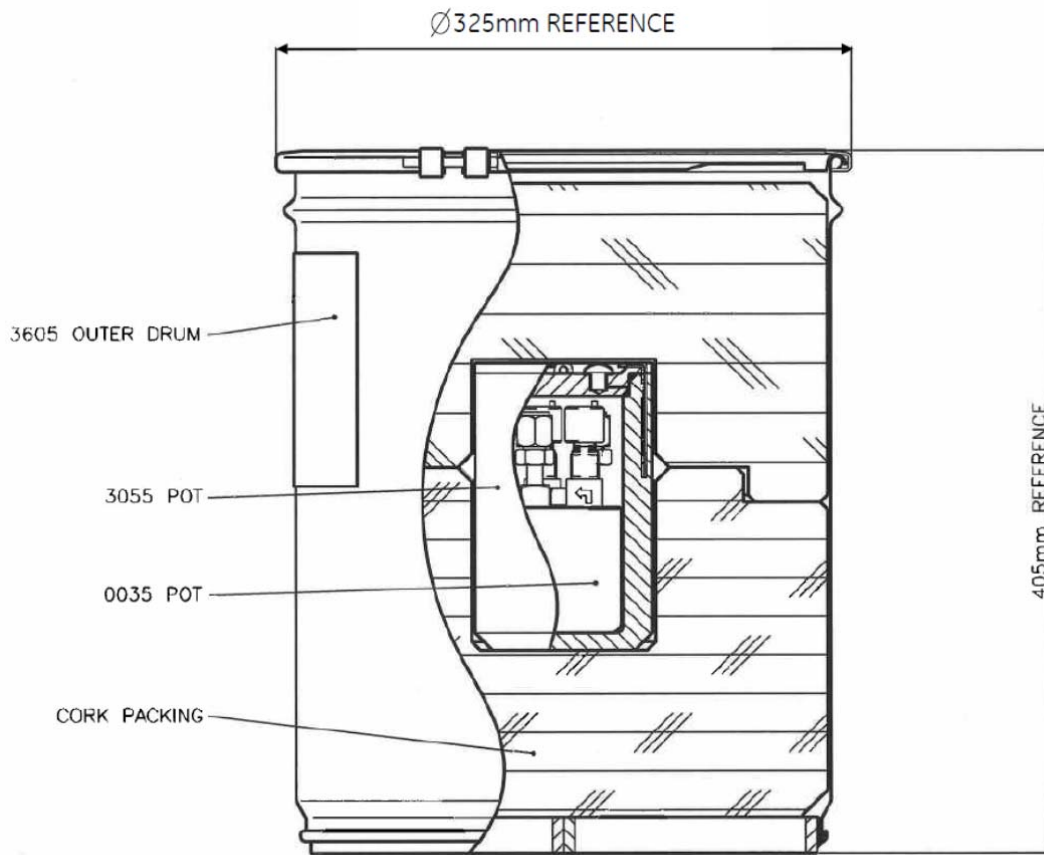
5. CERTIFICATE STATUS

Design approval issued to:

GE Healthcare Ltd
The Grove Centre
White Lion Road
Amersham
Buckinghamshire HP7 9LL

Issue / Revision Number	Date of Issue	Date of Expiry	Reason for Revision
1	25 September 2005	30 September 2006	First issued under new regulations
2	25 September 2005	30 September 2006 Extended by letter to 31 April 2007	Minor typographical changes.
3	23 March 2007	31 March 2012	Renewal on expiry of an extension to the previous certificate.
4	18 April 2007	31 March 2012	Issued to correct an error in section 2.1 a) of the issue 3 certificate.
5	28 March 2012	31 March 2017	5-yearly renewal
6	31 March 2017	30 September 2017	6 months extension
7	22 December 2017	31 December 2022	5-yearly renewal

APPENDIX 1 – PACKAGE ILLUSTRATION





U.S. Department of
Transportation

**Pipeline and
Hazardous Materials
Safety Administration**

East Building, PHH-23
1200 New Jersey Ave, SE
Washington, D.C. 20590

CERTIFICATE NUMBER: USA/0596/B(U)-96

ORIGINAL REGISTRANT(S) :

GE Healthcare
3350 N. Ridge Avenue
Arlington Heights, IL, 60004
USA

Moravek, Inc.
2770 Salk Avenue
Richland, WA, 99352
USA

American Radiolabeled Chemicals, Inc.
101 ARC Dr.
St. Louis, MO, 63146
USA

ViTrax Company
ViTrax Company
660 S. Jefferson St.
#E
Placentia, CA, 92870
USA

University of Rochester
Laboratory for Laser Energetics
250 East River Road
Rochester, NY, 14623-1299
USA

Schlumberger
300 Schlumberger Drive
MD-121
Sugar Land, TX, 77478
USA

Canadian Nuclear Laboratories
286 Plant Road

Chalk River, Ontario, K0J 1J0
Canada

PerkinElmer Life and Analytical Sciences
549 Albany Street
Boston, MA, 02118
USA