



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) , REVISION 7**

**REVALIDATION OF UNITED KINGDOM COMPETENT AUTHORITY  
CERTIFICATE GB/3605D/B(U)**

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 Agency<sup>1</sup> and the United States of America<sup>2</sup> The package design is approved for use within the United States for import and export shipments made in accordance with applicable international and domestic transport regulations.

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), Revision 8 (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.

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<sup>1</sup> "Regulations for the Safe Transport of Radioactive Material, 2018 Edition, No. SSR-6" published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

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

**CERTIFICATE USA/0596/B(U) , REVISION 7**

- 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.
  - d. Records of Management System activities required by Paragraph 306 of the IAEA regulations<sup>1</sup> 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) in addition to other required markings and labeling.
5. Expiration Date - This certificate expires on December 31, 2027. Previous editions which have not reached their expiration date may continue to be used.

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 September 26, 2022 petition by Croft Associates Limited, Abingdon, Oxfordshire, UK, and in consideration of other information on file in this Office.

Certified By:



William Schoonover  
Associate Administrator for Hazardous  
Materials Safety

October 13, 2022  
(DATE)

Revision 7 - Issued to revalidate U. K. Certificate of Approval of Package Design GB/3605D/B(U)-96, Rev. 8 which updates to the 2018 IAEA regulations and transfers ownership of design to Croft Associates.

GB/3605D/B(U) (Rev.8)

## **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 Croft Associates Ltd (see Section 5)

as: Type B(U)

by: road and rail in Great Britain; and 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.

Commencement and Expiry Date: This certificate is valid from 1 January 2023 until the end of 31 December 2027 (see Section 5).

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

Signature:



Date of Issue: 22 September 2022

Gavin Smith, Superintending Inspector  
Office for Nuclear Regulation  
Redgrave Court, Merton Road  
Bootle, Merseyside  
L20 7HS

on behalf of the Office for Nuclear Regulation; 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 2018 Edition

### United Nations Economic Commission for Europe (UNECE)

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)  
2021 Edition

### Intergovernmental Organisation for International Carriage by Rail (OTIF)

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)  
2021 Edition

### International Maritime Organization (IMO)

International Maritime Dangerous Goods (IMDG) Code 2020 Edition incorporating  
Amendment 40-20

### International Civil Aviation Organization (ICAO)

Technical Instructions for the Safe Transport of Dangerous Goods by Air 2021-2022  
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 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)

### **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 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 1906 (M) The Carriage of Dangerous Goods and Marine Pollutants: Amendments to

International Standards, Including Amendment 40-20 to the IMDG Code and amendments to the IBC Code and BCH Code

***AIR***

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

## 1. DESIGN SPECIFICATION

### Package Design

- 1.1 The package design specification shall be in accordance with Design Safety Report for Safdrum Package Design No. 3605D, DSR GB/3605D/B(U) Issue B, dated 10 August 2022, 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
3605D	Drawing list for packaging design No 3605D	Drawing list (DL-2C-8296)	A
3605	Drawing list for Drum Design No 3605	Drawling List (DL-2C-8297)	
3055	Drawing list for CV Design No 3055	Drawling list (DL-2C-8298)	
0035 mk3	Drawing list for CV Inner Design No 0035 mk3	Drawling list (DL-2C-8299)	
0035 mk4	Drawing list for CV Inner Design No 0035 mk4	Drawling list (DL-2C-8300)	
0035 mk5	Drawing list for CV Inner Design No 0035 mk5	Drawling list (DL-2C-8301)	

### Package Description and Materials of Manufacture

- 1.3 Safdrum 3605D is a Type B(U) package design consisting of a zinc or nickel coated carbon steel outer drum (3605), an internal stainless steel Containment Vessel (CV) (design number 3055) and an inner stainless steel confinement vessel (design number 0035. See Appendix 1 for package illustration.

### Package Dimension and Weights

- 1.4 Nominal dimensions: 325mm diameter x 405mm high
- 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 4.04  $\mu$ W of depleted uranium.

## Containment System

- 1.7 The 3055 CV is fabricated from stainless steel consisting of two parts, a body and closure lid. The containment interface between the closure lid and body is maintained by a double O-ring seal closure design. The closure lid is secured/fastened using 6 x M4 bolts..

## 2. USE OF PACKAGE

### Information Provided in Safety Report on Use of Packaging

- 2.1 The packaging shall be used and handled in accordance with Package and Handling Instructions for Package Design No 3605D, CPI 166, Issue B, dated 8 August 2022.
- 2.2 The packaging shall be maintained in accordance with Serviceability Checks for Safdrum Packaging Design No GB/3605D, CSP 095, Issue A, dated 11 February 2022.

### Actions Prior to Shipment

- 2.3 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 certificate and instructions on the use of the packaging.
- 2.4 Pre-shipment leakage testing of the 3055 CV is required after loading with contents and before shipment in accordance with the packing and handling instructions CPI 166, Issue B dated 8 August 2022. The required leakage testing is a test on the closure seals with a pass rate of  $5 \times 10^{-5} \text{ Pa.m}^3 \cdot \text{s}^{-1}$  SLR ( $5 \times 10^{-4} \text{ bar} \cdot \text{Cm}^3 \cdot \text{s}^{-1}$  SLR).

### Emergency Arrangements

- 2.5 Before shipment takes place, suitable emergency plans must be made, copies of which shall be supplied to the GB Competent Authority on demand.
- 2.6 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.

## 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 Design Safety Report for Safdrum Package Design No. 3605D, DSR GB/3605D/B(U) Issue B, dated 10 August 2022 referred to in Section 1 above and comprise the following:
- Design Safety Report for Safdrum Package Design No. 3605D, DSR GB/3605D/B(U) Issue B, dated 10 August 2022, section 1.5.7.
- 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.

## 5. CERTIFICATE STATUS

### Design approval issued to:

Croft Associates Ltd  
 F4 Culham Science Centre  
 Abingdon  
 Oxfordshire  
 United Kingdom  
 OX14 3DB

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
8	22 September 2022 [Commencement 1 January 2023]	31 December 2027	5-yearly renewal

# APPENDIX 1 – PACKAGE ILLUSTRATION

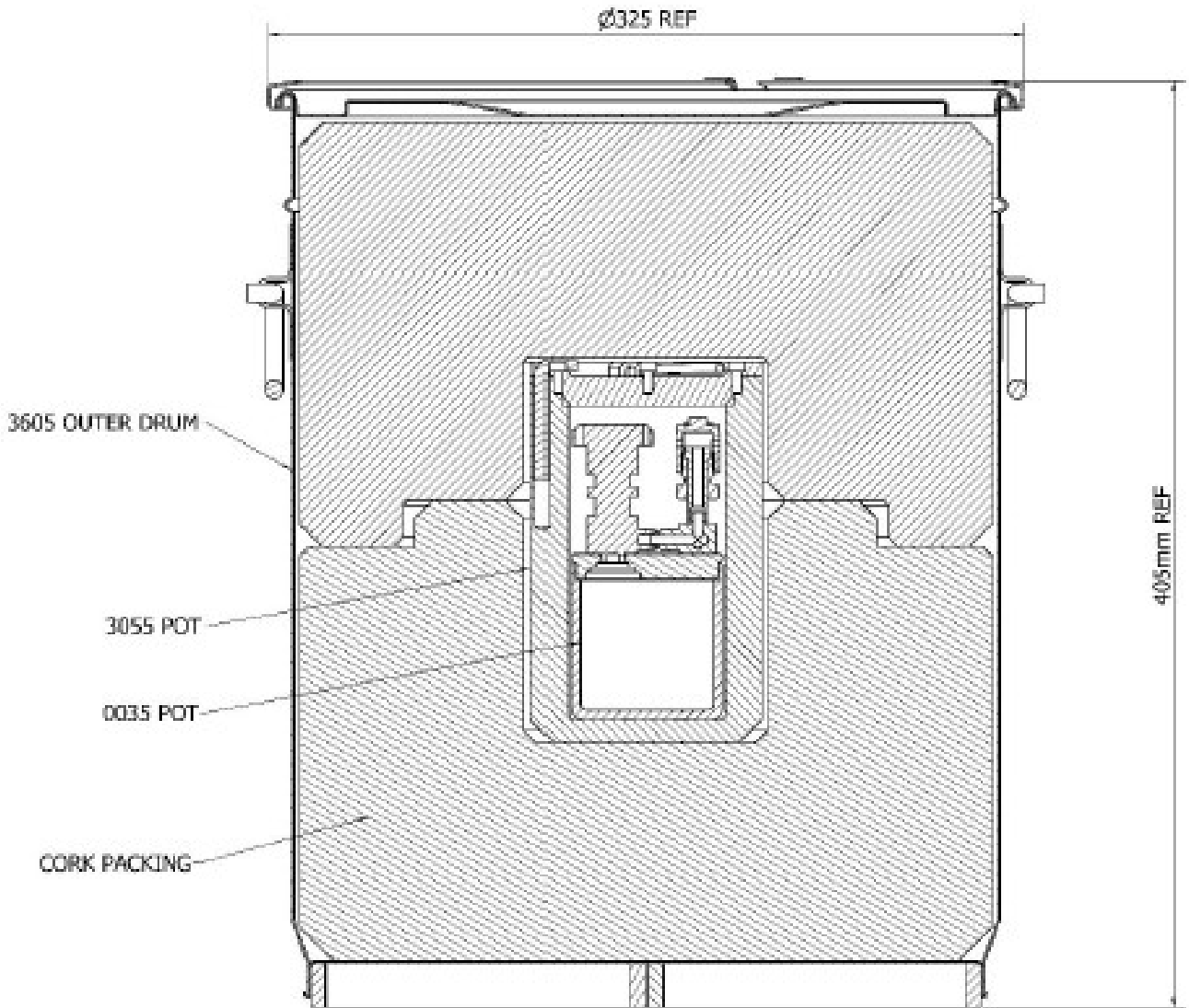


Figure 1 - Section through Safdrum 3605D Full assembly



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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  
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USA

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577 Mercury Lane  
Brea, CA, 92821  
USA

American Radiolabeled Chemicals, Inc.  
101 ARC Drive  
Saint Louis, MO, 63146  
USA

ViTrax Company  
ViTrax Company  
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#E  
Placentia, CA, 92870  
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