



U.S. Department of Transportation

COMPETENT AUTHORITY CERTIFICATION FOR A TYPE B(U)

RADIOACTIVE MATERIALS PACKAGE DESIGN CERTIFICATE USA/6788/B(U), REVISION 15

Pipeline and Hazardous Materials Safety Administration

REVALIDATION OF UNITED KINGDOM COMPETENT AUTHORITY CERTIFICATE GB/2799E/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 Agency¹ and the United States of America² 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 2799E Safkeg.
- 2. Package Description and Authorized Radioactive Contents as described in United Kingdom Certificate of Competent Authority GB/2799E/B(U), Revision 8 (attached).
- 3. <u>General Conditions</u>
 - 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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¹ "Regulations for the Safe Transport of Radioactive Material, 2018 Edition, No. SSR-6 (Rev. 1)" published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

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

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- 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 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. Special Conditions -

- a. The Model No. 2799E containment boundary, which is provided by the Model No. 2812 containment can, must be tested to demonstrate that the leak rate does not exceed 1 x 10-8 Pa m3 s-1 standardized leak rate (or 1 x 10-7 std cm3/s) at the following intervals: (1) within the 12-month period prior to shipment; and (2) upon replacement of the seals.
- b. Prior to each shipment, the seals of the Model No. 2812 containment can must be demonstrated to prevent leakage in excess of 5 x 10-5 Pa m3 s-1 standardized leak rate (or 5 x 10-4 ref cm3/sec).
- 5. $\underline{\text{Marking}}$ and $\underline{\text{Labeling}}$ The package shall bear the marking $\underline{\text{USA}/6788/B}$ (U) in addition to other required markings and labeling.
- 6. Expiration Date This certificate expires on May 31, 2028. Previous editions which have not reached their expiration date may continue to be used.

CERTIFICATE USA/6788/B(U), REVISION 15

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 August 17, 2023 petition by Croft Associates Limited, Abingdon, Oxfordshire, UK, and in consideration of other information on file in this Office.

Certified By:

William Schoonover

August 31, 2023 (DATE)

Associate Administrator for Hazardous Materials Safety

Revision 15 - Issued to revalidate, for non-fissile and fissile excepted contents, United Kingdom Certificate of Approval No. GB/2799E/B(U), Rev 8.



GB/2799E/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: air, road, rail, sea and inland waterway.

Packaging identification: SAFKEG Package design No 2799E

Packages manufactured to this design meet the requirements of the regulations and codes on pages 3 and 4, 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 May 2028 (see Section 5).

COMPETENT AUTHORITY IDENTIFICATION MARK: GB/2799E/B(U)

Signature: Fractile on . Date of Issue: 29 June 2023

Geoff Frackelton, Head of Transport Competent Authority

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.

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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

<u>United Nations Economic Commission for Europe (UNECE)</u>

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2021 Edition (until end June 2023) or Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2023 Edition

Intergovernmental Organisation for International Carriage by Rail (OTIF)

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2021 Edition (until end June 2023) or Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2023 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 2023-2024 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

AIR

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

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1. DESIGN SPECIFICATION

Package Design

1.1 The package design specification shall be in accordance with Design Safety Report for SAFKEG Design No 2799E, DSR 2799E/B(U)-96 Issue M, dated 20 July 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		
2799E	DRAWING LIST FOR DESIGN No 2799E PACKAGINGS – ALL BUILDS	DL-1C-5407	F		
And Innermost Packaging Arrangement 1					
	Bayer Contents (2799E) Licensing 0C-7598 Drawing		А		
Or Innermost Packaging Arrangement 2					
	Bayer Contents (2799E) Licensing Drawing	0C-7863	Α		
	Wheaton 3.0ml Glass Vial W986277		С		
Or Innermost Packaging Arrangement 3					
	Bayer Contents 2799E (Zr Vial option) Licensing Drawing	I 0C-8099 A			
	Zirconium Vial	N3D020399A356	В		

Package Description and Materials of Manufacture

- 1.3 The packaging consists of an outer double skin insulated keg, an insulating cork liner, a re-sealable containment can, an inner lead shielding pot and aluminium spacers. The outer keg is made of stainless steel filled with insulating phenolic resin foam and with a flat stainless-steel lid attached by eight stud/nut arrangements. The inner containment can and lid are manufactured from stainless steel, closed by a threaded retaining ring and sealed with a double EPDM O-ring. See Appendix 1 for package illustration.
- 1.4 There are three acceptable designs of innermost packaging arrangements. The contents are held centrally within the containment vessel by aluminium spacers and are shielded by a lead pot. The innermost packaging parts identified in arrangement 1 are not interchangeable with those of packing

arrangements 2 and 3. The lead pot, aluminium spacers and aluminium can are interchangeable between Innermost Packing Arrangement 2 and 3.

Package Dimension and Weights

- 1.5 Nominal dimensions: 425mm diameter x 540 mm high
- 1.6 Maximum authorised gross weight: 67.5 kg

Authorised Contents

- 1.7 The authorised radioactive contents for Innermost Packing Arrangement 1 are:
 - 20 GBq of Actinium 227 as a solid salt,
 - daughter products and
 - trace amounts (< 1%) of other radionuclides due to the production method.
- 1.8 The authorised radioactive contents for Innermost Packing Arrangement 2 and 3 are:
 - 20 GBg of Actinium 227 and 1 GBg of Actinium 225 as a solid salt,
 - daughter products and
 - trace amounts (< 1%) of other radionuclides due to the production method.

Restriction on Contents

1.9 The package is designed to carry a maximum heat load of 10W.

Containment System

- 1.10 The containment system consists of:
 - Containment Vessel (CV) design No 2812 The containment Vessel
 Design No. 2812, the CV lid and the inner O-ring seal provides absolute
 containment for the radioactive contents. A second (outer) O-ring is used
 to facilitate leakage testing. The CV lid is retained by a single screw
 threaded ring (M143.5 x 4.0).
 - Keg Design No. 2799 The keg (Design No. 2799) holds and provides impact and thermal protection of the 2812 CV (Design No. 2812). The keg is fitted with a flat lid that is secured by eight M12 studs and nuts. These bolted closures form the positive fastening device of the keg closure.

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 Croft Associates Ltd. Packing and Handling Instructions CPI 013 Issue V.

2.2 The packaging shall be maintained in accordance with Croft Associated Ltd. Serviceability Procedure CSP 006 Issue K.

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.

Supplementary Operational Controls

2.4 None required.

Emergency Arrangements

- 2.5 Before shipment takes place, adequate emergency arrangements 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 SAFKEG Design No 2799E, DSR 2799E/B(U)-96 Issue M, dated 20 July 2022, referred to in Section 1 above, and comprise the following:
 - Croft Associates Ltd Quality Management System.
- 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

Related Approvals

4.1 Not applicable.

Shipment Approval

4.2 Not applicable.

Packaging Serial Numbers

4.3 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.

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5. CERTIFICATE STATUS

Design approval issued to:

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

Issue / Revision Number	Date of Issue	Date of Expiry	Reason for Revision
4	18 June 2001	31 March 2004	Renewal as GB/2799E/B(U)F-85.
1	24 June 2004	30 June 2007	Design approval issued under new regulations. Fissile content removed and minor amendments/clarification.
2	5 March 2008	30 June 2010	Renewal with minor changes (1 year extension issued on 21 June 2010).
3	30 June 2011	30 June 2016	Renewal.
4	29 June 2016	31 Dec 2016	Short Term Certificate with limitations on contents.
5	11 July 2017	31 July 2022	Renewal for Ac-227 only.
6	6 September 2018	31 July 2022	Inclusion of Croft Modification CN048
7	10 February 2020	31 July 2022	Inclusion of Croft Modification CN066
8	29 June 2023	31 May 2028	Renewal

APPENDIX 1

FIGURE 1 - KEG AND CONTAINMENT VESSEL

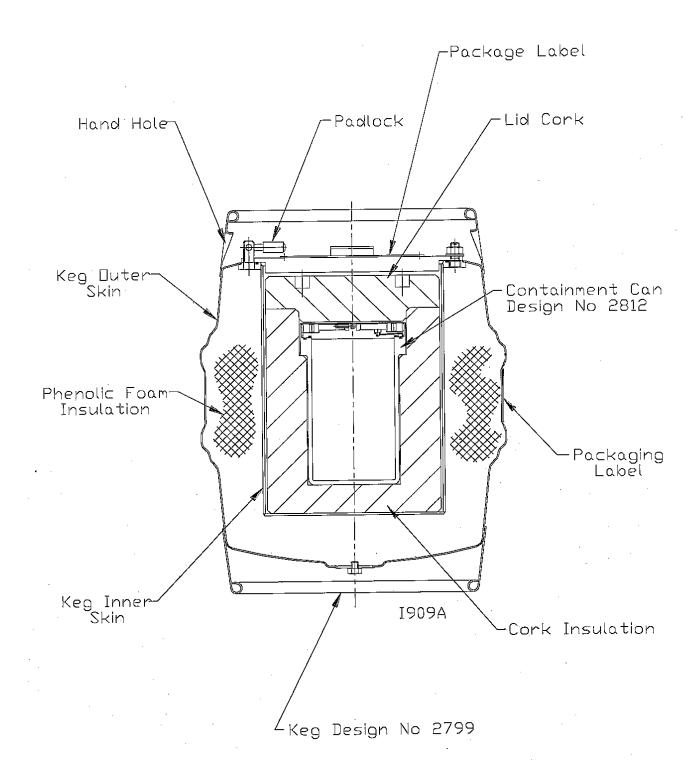


FIGURE 2 - INNERMOST PACKAGING ARRANGEMENT 1

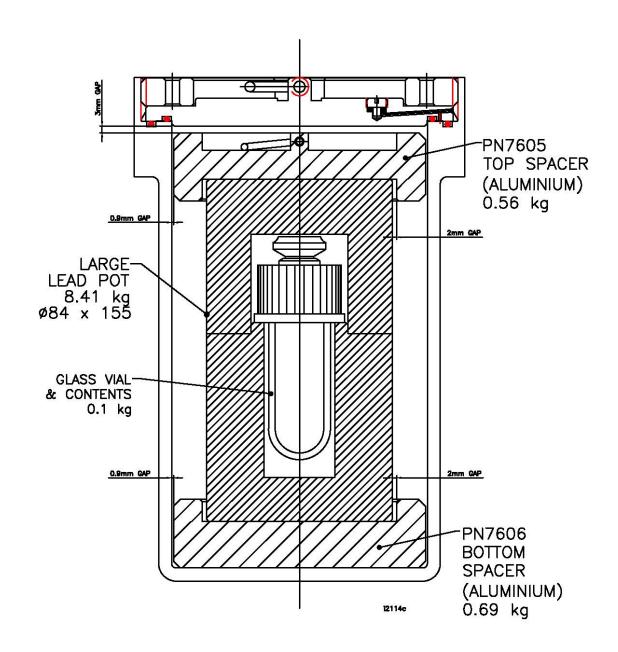


FIGURE 3 - INNERMOST PACKAGING ARRANGEMENT 2

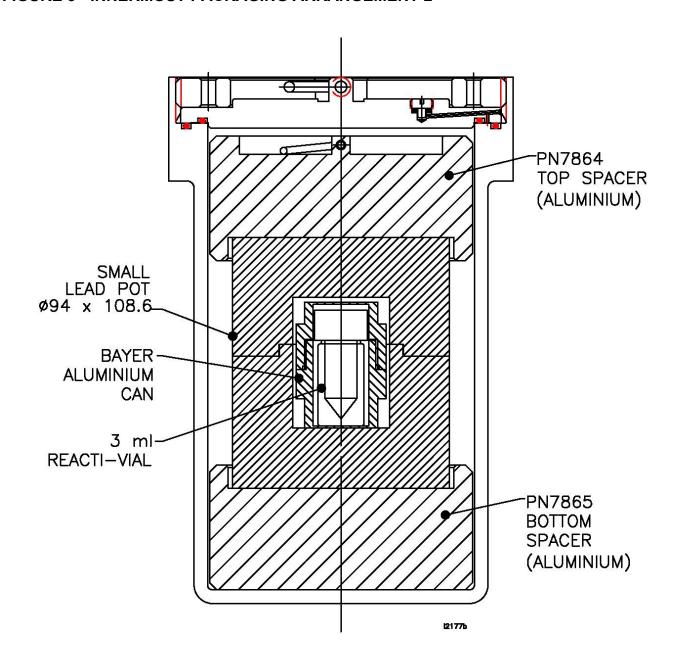
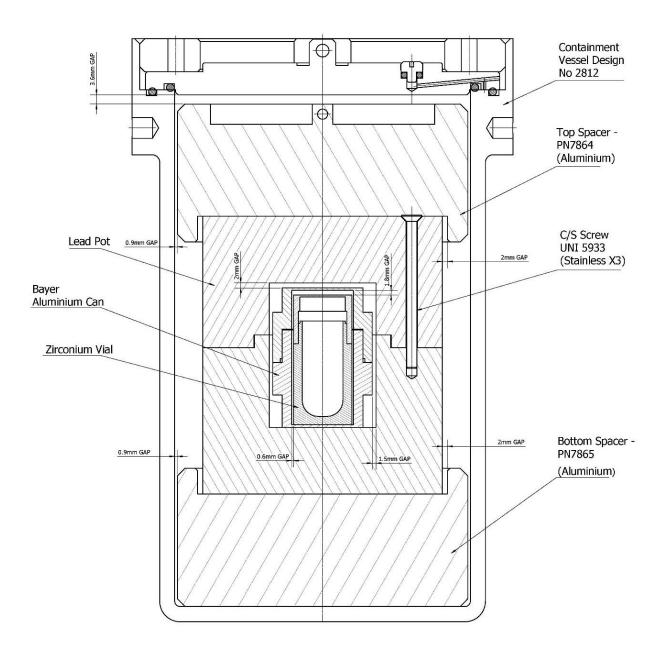


FIGURE 4 - INNERMOST PACKAGING ARRANGEMENT 3



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U.S. Department of Transportation

Pipeline and Hazardous Materials Safety Administration

CERTIFICATE NUMBER: USA/6788/B(U)-96

ORIGINAL REGISTRANT(S):

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