



U.S. Department
of Transportation
**Pipeline and
Hazardous Materials
Safety Administration**

400 Seventh Street, S.W.
Washington, D.C. 20590

**COMPETENT AUTHORITY CERTIFICATION
FOR A TYPE B(U)
RADIOACTIVE MATERIALS PACKAGE DESIGN
CERTIFICATE USA/0545/B(U)-96, REVISION 2**

**REVALIDATION OF UNITED KINGDOM COMPETENT AUTHORITY
CERTIFICATE GB/3605C/B(U)-96**

This certifies that the radioactive material package design described is hereby approved for use within the United States for import and export shipments only. Shipments must be made in accordance with the applicable regulations of the International Atomic Energy Agency¹ and the United States of America².

1. Package Identification - U. K. Design No. 3605C.
2. Package Description and Authorized Radioactive Contents - as described in United Kingdom Certificate of Competent Authority GB/3605C/B(U)-96, Revision 1 (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 Hazardous Materials Technology, (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, 1996 Edition (Revised), No. TS-R-1 (ST-1, Revised)," published by the International Atomic Energy Agency(IAEA), Vienna, Austria.

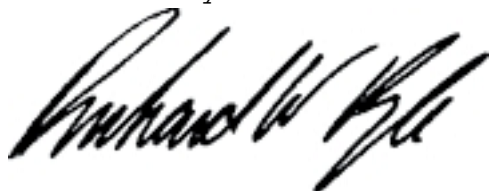
² Title 49, Code of Federal Regulations, Parts 100-199, United States of America.

CERTIFICATE USA/0545/B(U)-96, REVISION 2

- d. Records of Quality Assurance activities required by Paragraph 310 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 and consignees in the United States exporting or importing shipments under this certificate shall satisfy the requirements of Subpart H of 10 CFR 71.
4. Marking and Labeling - The package shall bear the marking USA/0545/B(U)-96 in addition to other required markings and labeling.
5. Expiration Date - This certificate expires on September 30, 2007.

This certificate is issued in accordance with paragraph 808 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the December 21, 2004 petition by GE Healthcare, Arlington Heights, IL and in consideration of other information on file in this Office.

Certified By:



Robert A. McGuire
Associate Administrator for Hazardous Materials Safety

Sep 21 2006
(DATE)

Revision 2 - Issued to revalidate United Kingdom Certificate of Approval No. GB/3605C/B(U)-96, Issue 1.



Reference: GB/3605C/B(U)-96

Issue 1

Page 1 of 8 Pages

Certificate of Approval of Package Design for the Carriage of Radioactive Materials

THIS IS TO CERTIFY that the Secretary of State for Transport being, for the purposes of the Regulations of the International Atomic Energy Agency, the Competent Authority of Great Britain in respect of inland surface transport and of the United Kingdom of Great Britain and Northern Ireland in respect of sea and air transport and the Department of the Environment for Northern Ireland being the Competent Authority of Northern Ireland in respect of inland surface transport, have approved the Package design as specified in section 1 of this certificate, as applied for by Amersham plc (see section 6)

as Type B(U)

by road, rail, sea and air

Packaging identification: 3605C

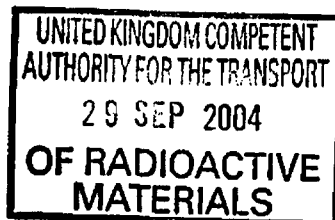
Packages manufactured to this design meet the requirements of the regulations and codes on page 2, relevant to the mode of transport, subject to the following general condition and to the conditions in the succeeding pages of this certificate.

In the event of any alteration in the composition of the package, the package design, the quality assurance programme(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 is valid until the end of September 2007

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

E. J. Morgan-Warren
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Transport Radiological Adviser
Department for Transport
Great Minster House
76 Marsham Street
London SW1P 4DR



*On behalf of the Secretary of State for Transport,
and the Department of the Environment for 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 AND CODES OF PRACTICE GOVERNING THE TRANSPORT OF RADIOACTIVE MATERIALS

INTERNATIONAL

International Atomic Energy Agency (IAEA)

TS-R-1. Regulations for the Safe Transport of Radioactive Materials 1996 Edition (Revised)

International Maritime Organisation (IMO)

International Maritime Dangerous Goods (IMDG) Code (Amdt. 31-02)

International Civil Aviation Organisation (ICAO)

Technical Instructions for the Safe Transport of Dangerous Goods by Air. 2003-2004 Edition

United Nations Economic Commission for Europe (UNECE)

European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). 2003 Edition

Intergovernmental Organisation for International Carriage by Rail (OTIF)

Convention concerning International Carriage by Rail (COTIF) Appendix B. Uniform Rules concerning the Contract for International Carriage of Goods by Rail (CIM) Annex 1 Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). 2003 Edition

UNITED KINGDOM

ROAD

GREAT BRITAIN ONLY.

The Radioactive Material (Road Transport) (Definition of Radioactive Material) Order 2002, SI 2002 No. 1092;

The Radioactive Material (Road Transport) Regulations 2002. SI 2002 No. 1093.

The Radioactive Material (Road Transport) (Amendment) Regulations 2003, SI 2003 No 1867.

NORTHERN IRELAND ONLY.

The Radioactive Substances (Carriage by Road) Regulations (Northern Ireland) 1983, SR 1983 No 344; The Radioactive Substances (Carriage by Road) (Amendment) Regulations (Northern Ireland) 1986, SR 1986 No 61.

RAIL

GREAT BRITAIN ONLY.

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment regulations 2004, S I 2004 No 568

SEA

British registered ships. All other ships whilst in United Kingdom territorial waters. The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997, SI 1997 No 2367; Merchant Shipping Notice No MSN 1772(M), "The Carriage of Dangerous Goods and Marine Pcllutants in Packaged Form - Amendment 31-02 to the International Maritime Dangerous Goods (IMDG) Code".

AIR

The Air Navigation Order 2000, SI 2000 No 1562. The Air Navigation (Dangerous Goods) Regulations 2002, SI 2002 No 2786.

1. PACKAGE DESIGN SPECIFICATION

The Package Design Specification shall be in accordance with Amersham plc Safety Report reference TAD 3605C issue 2 dated 27 August 2004 and modifications to the package design approved by the authority named on page 1 of this certificate under the established modifications procedure.

1.1 Specification of Packaging

Design No.	Title / No. of Components	Drawing List	Issue
3605	Outer / Steel Drum with Cork Spacers / One	DL 25126 and PGM 855	H
3055 (C)	Intermediate / Stainless Steel Pot / One		6
W1 or W6 or Q1	Inner / lead Pots / up to 6		

[(C) = Containment System]

1.2 Permitted Contents

1.2.1 Nuclides or mixtures of nuclides listed in the table below.

Radionuclide	Maximum quantity	Maximum Activity
Actinium-227	<1 g	90.0 GBq
Americium-241	8 g	1.0 TBq
Americium-243	135 g	1.0 TBq
Curium-242	<1 g	7.7 TBq
Curium-244	<1 g	2.0 TBq
Lead-210	18 g	50.0 TBq
Neptunium-237	2.7 kg	70.5 GBq
Plutonium-238	2 g	1.0 TBq
Plutonium-240	118 g	1.0 TBq
Polonium-210	<1 g	8.8 TBq
Promethium-147	22 g	750.0 TBq
Protactinium-231	228 g	400.0 GBq
Radium-226	<1 g	3.75 GBq
Samarium-151	385 g	375 TBq
Strontium-90	<1 g	1.05 TBq
Thorium-228	<1 g	1.0 TBq
Thorium-230	1336 g	1.0 TBq

1.2.2 Mixtures of these contents may be carried provided the sum of the proportion of each nuclide does not exceed one.

1.3 Restrictions on Contents

1.3.1 The activity shall not exceed 1000 A₂.

1.3.2 The heat shall not exceed 7.5 watts

1.3.3 The weight of the contents of the 3055 pot shall not exceed 2.7 kg

1.4 Package Dimensions and Weights

- a) Nominal Dimensions: 325mm diameter x 405mm high (see section 5 for package illustration)
- b) Maximum authorised gross weight: 21.9 kg

2. USE OF PACKAGE

2.1 Use of packaging

- a) The packaging shall be used, handled and maintained in accordance with the requirements of GB.PQ.162.E Version 2 dated 24 June 2004.

2.2 Actions prior to shipment

- a) 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.
- b) The package is not required to reach thermal equilibrium prior to shipment.

2.3 Emergency Arrangements

a) Road, Rail and Ports in GB

(i) RADSAFE member

In the event of an emergency the procedures set out in RADSAFE (the nuclear industry transport emergency plan) shall apply. The police shall be informed that RADSAFE has been initiated.

(ii) Non RADSAFE member

Before shipment takes place, the consignor shall have drawn up suitable emergency plans, copies of which shall be supplied to the UK Competent Authority on demand. In the event of an emergency these emergency plans shall be initiated and the police informed.

b) Sea

In the event of an emergency, the procedure set out in the IMDG Code as quoted on

page 2 of this certificate shall apply.

- c) If RADSAFE, 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 the local NAIR (National Arrangements for Incidents involving Radioactivity) establishment.

3. QUALITY ASSURANCE

3.1 Quality assurance programmes applicable to this design are:

- a) Amersham plc. Transport Safety Arrangements and
- b) any other quality assurance programmes associated with the design, manufacture, testing, documentation, use, maintenance and inspection, and for transport and in-transit storage operations, which must also comply with national or international standards for quality assurance which are acceptable to the authority named on page 1 of this certificate.

3.2 No alterations shall be made to the quality assurance programmes associated with this design and approved by the authority named on page 1 of this certificate unless that alteration has the prior approval of said authority, or it falls within the agreed change control procedures of that programme.

3.3 No quality assurance programme shall be used at any stage of the design, manufacture, testing, documentation, use, maintenance and inspection, and for transport and in-transit storage operations, unless said programme forms part of or is the quality assurance programme approved by the authority named on page 1 of this approval certificate.

3.4 During the conversion process from the previously approved 0666AW package to this 3605C design, using the inspection procedure GB.PQ.126.E Version 1, the serial numbers or batch numbers of the previously used components must be recorded and related to any new serial numbers assigned in order to maintain traceability to original manufacture records.

4. ADMINISTRATIVE INFORMATION

4.1 Other related certificates (alternative radioactive contents)

- a) This certificate forms the base approval of this design. Other related UK certificates using the 3605 outer are shown below: -

Certificate Reference & Issue	Certificate Type	Expiry Date
GB/3605D/B(U)-96 Issue 2	Design	30 September 2006

The list in 4.1(a) was complete at the time of compilation of this design approval certificate. Other related certificates may exist.

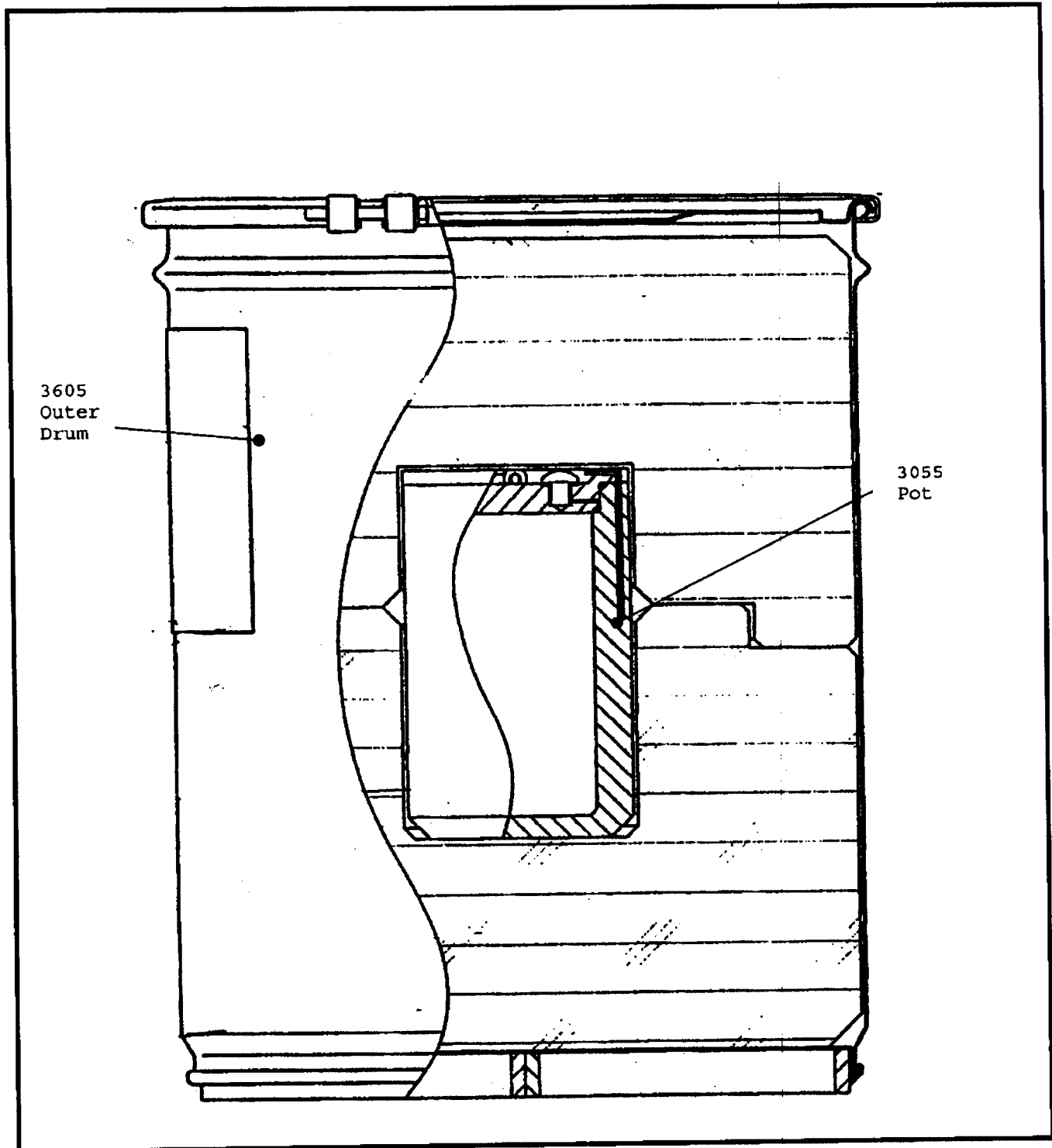
4.2 Additional Technical Data / Information

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 1987, SI 1987 No 37, apply in UK Ports

4.3 Renewal of Certificates

- a) If the period of validity is required to be extended, application shall be made at least six weeks in advance of expiry.

5. PACKAGE ILLUSTRATION



6. CERTIFICATE STATUS

Design Approval issued to:-
Amersham plc
Amersham
Buckinghamshire HP7 9NA

Issue No.	Date of Issue	Date of Expiry	Reason for Revision
GB/3605C/B(U)-96 Issue 1	As stamp on front page	End of September 2007	First issue under new regulations