U.S. Department
of Transportation

**Pipeline and
Hazardous Materials
Safety Administration**

**East Building, PHH-23
1200 New Jersey Avenue Southeast
Washington, D.C. 20590**

**COMPETENT AUTHORITY CERTIFICATION
FOR A TYPE B(U)
RADIOACTIVE MATERIALS PACKAGE DESIGN
CERTIFICATE USA/0596/B(U)-96, REVISION 4**

**REVALIDATION OF UNITED KINGDOM COMPETENT AUTHORITY
CERTIFICATE GB/3605D/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 Agency[1] and the United States of America[2].

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, Issue 5 (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/0596/B(U)-96, REVISION 4

d. Records of Quality Assurance activities required by Paragraph 310 of the IAEA regulations[1] 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 March 31, 2017.

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 April 16, 2012 petition by GE Healthcare, Arlington Heights, IL, and in consideration of other information on file in this Office.

Certified By:

for Dr. Magdy El-Sibaie
Associate Administrator for Hazardous Materials Safety

May 10 2012
(DATE)

Revision 4 - Issued to revalidate U. K. Certificate of Approval of Package Design GB/3605D/B(U)-96, Issue 5.

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

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 Secretary of State for Energy and Climate Change;**
- **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**
- **The Competent Authority of Northern Ireland in respect of road transport, being the Department of the Environment (Northern Ireland)**

approve the package design as specified in section 1 of this certificate, as applied for by GE Healthcare (see section 6)

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 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 Health and Safety Executive (Office for Nuclear Regulation) is notified of the alteration and the Health and Safety Executive (Office for Nuclear Regulation) confirms, on behalf of the relevant Competent Authority, the certificate notwithstanding the alteration.

Expiry Date: This certificate is valid until the end of March 2017.

COMPETENT AUTHORITY IDENTIFICATION MARK:

GB/3605D/B(U)-96

UNITED KINGDOM COMPETENT AUTHORITY FOR THE TRANSPORT
28 MAR 2012
OF RADIOACTIVE MATERIALS

George Sallit, Deputy Chief Inspector
Health and Safety Executive (Office for Nuclear Regulation)
4N.2 Redgrave Court
Merton Road
Bootle
Merseyside L20 7HS

on behalf of the Secretary of State for Energy and Climate Change; the Secretary of State for Transport; the Civil Aviation Authority; 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.

Serial No. 12/012

REGULATIONS GOVERNING THE TRANSPORT OF RADIOACTIVE MATERIALS

INTERNATIONAL

International Atomic Energy Agency (IAEA)
TS-R-1 Regulations for the Safe Transport of Radioactive Materials 2009 Edition.

International Maritime Organisation (IMO)
International Maritime Dangerous Goods (IMDG) Code Amendment 35-10

International Civil Aviation Organisation (ICAO)
Technical Instructions for the Safe Transport of Dangerous Goods by Air 2011-2012 Edition.

United Nations Economic Commission for Europe (UNECE)
European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2011 Edition

Intergovernmental Organisation for International Carriage by Rail (OTIF)
Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) 2011 Edition

UNITED KINGDOM

ROAD
GREAT BRITAIN ONLY.
The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009, SI 2009 No 1348 as amended by the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011, SI 2011 No 1885.

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 Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009, SI 2009 No 1348 as amended by the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011, SI 2011 No 1885.

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 1828 M, "The Carriage of Dangerous Goods and Marine Pollutants in Packaged Form - Amendment 35-10 to the International Maritime Dangerous Goods (IMDG) Code".

AIR
The Air Navigation Order 2009, SI 2009 No 3015. The Air Navigation (Dangerous Goods) Regulations 2002, SI 2002 No 2786. The Air Navigation (Dangerous Goods) (Amendment) (No. 2) Regulations 2011, SI 2011 No 1454

1. PACKAGE DESIGN SPECIFICATION

The Package Design Specification shall be in accordance with GE Healthcare Ltd Safety Report reference BU3605D Issue 9 dated 02 March 2012, 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 Design

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 (C)	Intermediate / Stainless Steel Pot / One	DL22310	O
0035 (Mk 3) or 0035 (Mk 4) or 0035 (Mk 5)	Inner / Tritium Pots / One	DL23205 DL23549 DL27816	F G B

[(C) = Containment System)]

1.2 Authorised Contents

a) Tritium gas adsorbed on pyrophoric uranium in a stainless steel vessel.
b) The maximum activities of the authorised contents are 4 PBq of tritium and 6 MBq of depleted uranium.
c) The maximum heat loads of the authorised contents are 3.65 W of tritium and 4 μW of depleted uranium

1.3 Containment System

The containment system is defined by the components and drawings identified above in Section 1.1.

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: 20.7 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 MGC_UKD_PQ_146.E Version 2 dated 01 August 2011.

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) 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.

b) 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 the local NAIR (National Arrangements for Incidents involving Radioactivity) establishment.

2.4 Ambient temperature range for package design

a) -40°C to +38°C (surface transport); -40°C to +55°C (air transport)

3. QUALITY ASSURANCE

3.1 The quality assurance programmes assessed as adequate in relation to this design by the authority named on page 1 of this certificate, at the date of issue, are as specified in GE Healthcare Ltd Safety Report reference BU3605D Issue 9 dated 02 March 2012, and comprise the following:

a) GE Healthcare Global Quality Management System; and

b) 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 Any quality assurance programmes not made available for assessment by the authority named on page 1 of this certificate prior to the date of issue of this certificate and applicable to any stage of design; testing; manufacture; documentation; use; maintenance and inspection; and transport and in-transit storage operations, must, prior to their implementation or use, be submitted to and confirmed as adequate by the authority named on page 1 of this certificate.

3.3 No alteration may be made to any quality assurance programme(s) confirmed as adequate in relation to this design, unless:

a) the prior approval of the authority named on page 1 is obtained; or

b) the alteration falls within the agreed change control procedures set out in the programme(s).

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/3605C/B(U)-96 Issue 3	Design	30 September 2013

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

a) 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 GB Ports, and The Dangerous Substances in Harbour Areas Regulations (Northern Ireland) 1991 SI 1991 No 509 apply in NI Ports.

4.3 Shipment Approval

a) Not applicable.

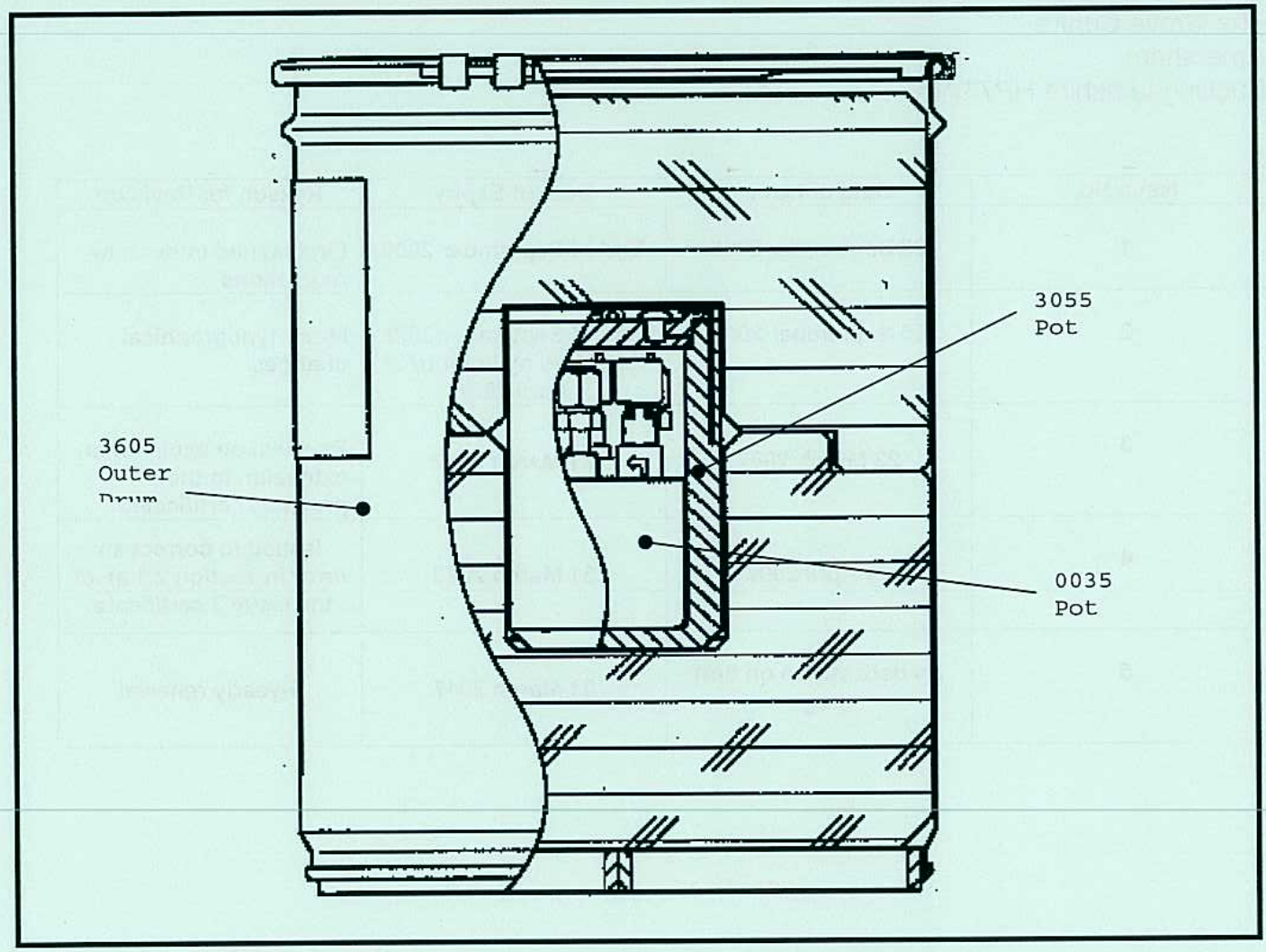
4.4 Non-fissile or fissile excepted

a) Not applicable.

4.5 Packaging Serial Numbers

a) For the purpose of compliance with ADR / RID, the owner of the packaging shall be responsible for compliance with ADR / RID 6.4.23.15.

5. PACKAGE ILLUSTRATION



6. CERTIFICATE STATUS

Design Approval issued to:-

GE Healthcare Ltd
The Grove Centre
Amersham
Buckinghamshire HP7 9NA

Issue No.	Date of Issue	Date of Expiry	Reason for Revision
1	25 September 2005	End of September 2006	First issued under new regulations
2	25 September 2005	End of 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	As date stamp on first page	31 March 2017	5-yearly renewal

U.S. Department
of Transportation

**Pipeline and
Hazardous Materials
Safety Administration**

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

CERTIFICATE NUMBER: USA/0596/B(U)-96, Revision 4

ORIGINAL REGISTRANT(S):

Mr. Michael A. Bernardo
Senior HazMat Transportation Specialist
GE Healthcare
3350 N. Ridge Avenue
Arlington Heights, 60004
USA

REGISTERED USER(S):

Robert Todd
Shipping Manager
Moravek Biochemicals, Inc.
Moravek Biochemicals, Inc.
577 Mercury Lane
Brea, 92821
USA

Regis A. Greenwood, CHP
Radiation Safety Officer
American Radiolabeled Chemicals, Inc.
101 ARC Drive
Saint Louis, 63146
USA

Robert Fazio
President
ViTrax Company
ViTrax Company
660 S. Jefferson St.
#E
Placentia, 92870
USA

Thomas L. Morgan
Radiation Safety Officer
University of Rochester
University of Rochester
601 Elmwood Ave., Box HPH
Rochester, NY 14624

Mr. Raymond Dickes
Radiation Safety Officer
Schlumberger
200 Gillingham Lane
Sugar Land, 77478
USA

Mr. Mike Godin
RAM Transport Specialist
AECL
Chalk River Laboratories
Chalk River
, K0J 1J0
CANADA

Mr. Jonathon Archer-Barnard
Alternate RSO
Moravek Biochemicals, Inc.
577 Mercury Lane
Brea, 92821
USA

Mr. Michael Fama
PerkinElmer Life and Analytical Sciences
549 Albany Street
Boston, 02118
USA

Mr. Kajal Nandy
Radiation Safety Officer
Moravek Biochemicals, Inc.
2770 Salk Avenue
Richland, 99352
USA

Ms. Bernie MacDonald
AECL
Nuclear Materials Mgmt and Transport
Chalk River Laboratories
Chalk River, Ontario K0J 1J0
Canada

Ms. Yvonne Andrews
RAM Transportation Specialist
AECL
Chalk River Laboratories
Chalk River, K0J1J0
CANADA

Dr. Walter Shmayda
Senior Scientist, RSO for LLE
University of Rochester
Laboratory for Laser Energetics
250 East River Road
Rochester, NY 14623-1299

Thomas Bracke
RSO
Schlumberger
Princeton Technology Center
20 Wallace Road
Princeton Junction, NJ 08550

Surendra Gupta, Ph.D.
President
American Radiolabeled Chemicals, Inc.
101 ARC Dr.
St. Louis, MO 63146