



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

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

**COMPETENT AUTHORITY CERTIFICATION
FOR A TYPE B(U)
RADIOACTIVE MATERIALS PACKAGE DESIGN
CERTIFICATE USA/0269/B(U), REVISION 10**

REVALIDATION OF UNITED KINGDOM COMPETENT AUTHORITY CERTIFICATE GB/0666AY/B(U)

This certifies that the radioactive materials package design described below 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. 0666AY
2. Packaging Description and Authorized Radioactive Contents - as described in United Kingdom Certificate of Competent Authority GB/0666AY/B(U), Issue 9 (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 in accordance with the endorsed certificate.
 - b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Office of Hazardous Materials Technology, (DHM-23), Research and Special Programs 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.
4. Marking and Labeling - The package shall bear the marking USA/0269/B(U) in addition to other required markings and labeling.
5. Expiration Date - This certificate expires on January 31, 2004. On April 1, 2001, this certificate supersedes, in its entirety, all previously issued revisions of USA/0269/B(U).

1 "Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1973 Revised Edition, as amended," published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

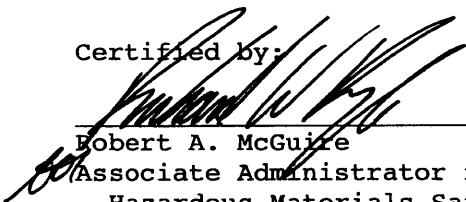
2 Title 49, Code of Federal Regulations, Parts 100 - 199, United States of America.

CERTIFICATE USA/0269/B(U), REVISION 10

This certificate is issued in accordance with paragraph 806 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the petition and information dated January 15, 2001 submitted by Nycomed Amersham, Arlington Heights, IL, and in consideration of other information on file in this Office.

Certified by:

MAR - 7 2001



Robert A. McGuire
Associate Administrator for
Hazardous Materials Safety

(DATE)

Revision 10 - Issued to correct revalidation number of previous issue (incorrectly issued Revision 9 for the second time).



Reference GB/0666AY/B(U)

Issue 9

Page 1 of 8 Pages

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

1. **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 described in paragraphs 2-4 of this certificate as submitted, for approval, by Nycomed Amersham plc, Amersham, Bucks.

as Type B(U) (see paragraph 7)

for the transport of tritium gas

by all modes of transport

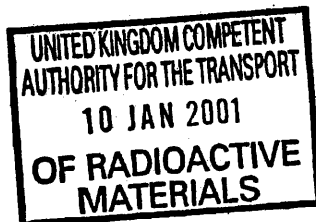
Packages manufactured to this design meet the requirements of the regulations and codes on page 2, relevant to the mode of transport, subject to the following general condition and to the conditions in the succeeding pages of this certificate.

In the event of any alteration in the composition of the package, the package design 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.

This Certificate Cancels all Previous Issues and is valid till 31 January 2004.

COMPETENT AUTHORITY IDENTIFICATION MARK:

GB/0666AY/B(U)



Transport Radiological Adviser
Department of the Environment,
Transport and the Regions
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*

REGULATIONS AND CODES OF PRACTICE GOVERNING THE TRANSPORT OF RADIOACTIVE MATERIALS

INTERNATIONAL

International Atomic Energy Agency (IAEA) Safety Series No 6 Regulations for the Safe Transport of Radioactive Materials 1985 Edition (As Amended 1990).

International Maritime Organisation (IMO). International Maritime Dangerous Goods Code -- Class 7 Radioactive Substances.

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

ROAD

GREAT BRITAIN ONLY. The Radioactive Material (Road Transport)(Great Britain) Regulations 1996 SI No 1350: The Ionising Radiations Regulations 1999 SI No 3232: and Approved Code of Practice.

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.

EUROPE ONLY. European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), Class 7.(ed 1999).

RAIL

GREAT BRITAIN ONLY. The Packaging, Labelling and Carriage of Radioactive Material by Rail Regulations (RAMRail) 1996 (SI 1996 No 2090): Approved Requirements for the packaging, labelling and carriage of radioactive material by rail 1996 Edition. The Carriage of Dangerous Goods (Classification, Packaging and Labelling) and Use of Transportable Pressure Receptacles Regulations (CDGCPL) 1996 (SI 1996 No 2092). The Carriage of Dangerous Goods (Amendment) Regulations 1999 (SI 1999 No 303).

EUROPE ONLY. Convention concerning the International carriage by rail (COTIF), Appendix B, Uniform Rules concerning the International Carriage of Goods by Rail (CIM), Annex 1, Regulations concerning the International carriage of dangerous goods by rail (RID), Class 7.(ed 1999).

SEA

British registered ships. All other ships whilst in United Kingdom territorial waters. The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 SI No 2367: Merchant Shipping Notice No M 1620, "The Carriage of Dangerous Goods and Marine Pollutants in Packaged Form on Ships".

PORT: UK ONLY.

AIR

UK ONLY. The Air Navigation (No 2) Order 1995 SI No 1970: The Air Navigation (Dangerous Goods) Regulations 1994 SI No 3187 and Amendments 1996 SI No 3100 and 1998 SI No 2536. International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air.

NOTES

1. Attention is drawn to the labelling and marking requirements of Section IV of the 1985 Edition of the IAEA Regulations, one provision of which is that the outside of each package shall be clearly and durably marked with the Competent Authority's Package Design Identification Mark.

2. Any questions relating to this Certificate should be addressed to:--

*The Transport Radiological Adviser,
Department of the Environment, Transport and the Regions,
Great Minster House
76 Marsham Street, London SW1P 4DR.
Telephone 020 7944 5795.
Fax 020 7944 2187.*

3. This Certificate does not relieve the consignor from compliance with any requirements of this Government or any other Government of any country through or into which the package may be transported.

2. SPECIFICATION OF PACKAGING

Item No.	Packaging	Design Number	Quantity per Assembly
1	Outer	0666	One
2	Intermediate	3055	One
3	Inner	0035/3, or 0035/4	One One

The containment system comprises item Nos. 2 & 3.

Package Design Details

Design No.	Title	Drawing List	Issue
0666	Steel Drum with Three Cork Spacers)	1
	Stainless Steel pot)	
3055	Tritium pots) PGM 913	
) dated	
0035/3 or 0035/4) 9-2-95	

The Package Design Specification shall be in accordance with Nycomed Amersham plc document WD19 - BU 0666AY - Revision 4, Application for Approval of Package Design 0666AY dated September 1986, and PGM 902, Issue 1 dated 30 January 1995.

3. PERMITTED CONTENTS

Tritium gas adsorbed on pyrophoric uranium in a stainless steel vessel.

4. RESTRICTIONS ON CONTENTS

The maximum activity of the permitted contents may be up to 2 PBq of tritium.

5. INSTRUCTIONS ON THE USE OF THE PACKAGE

- a. Inspection of the containment pot, Design No. 3055, shall be carried out in accordance with Nycomed Amersham plc Quality Control Procedure QCP 021 Issue 5: Integrity Checks on Containment Pot Design No. 3055, Drawing No A22310.

- b. Inspection and maintenance shall be carried out in accordance with Nycomed Amersham's Quality Control Procedures for Transport Containers:-

QCP002 Issue 10 General Maintenance Procedures for Reusable Containers.

- c. Handling and operating instructions for the package (HPI 13 Issue C) shall be provided to the consignee.

6. ACTION PRIOR TO DESPATCH

- a. The Package shall be handled and packed in accordance with :

HPI 13 Issue C - Handling and Packing Instructions for Tritium Transport Design No. 0666AY.

- b. All nuts and bolts shall be checked for tightness.

- c. All locking wires and security seals shall be checked and replaced as necessary.

7. GRANDFATHERING PROVISIONS

Packages to this design may continue to be used subject to multilateral approval in accordance with the requirements of paragraph 714 of the 1985 Edition of the IAEA Regulations for the Safe Transport of Radioactive Material (SS6).

No Supplementary Operational Controls are required.

8. QUALITY ASSURANCE

- (a) Quality Assurance (QA) programmes applicable to this Design are;

i) Nycomed Amersham plc Transport Safety Arrangements; and

ii) All other Quality Assurance programmes associated with the manufacture, modification, use, maintenance and transport of this package not invoked or associated with (i). These must comply with National and International Standards for Quality Assurance which are acceptable to the United Kingdom Competent Authority (or other appropriate National Competent Authorities when international package movements occur outside the jurisdiction of the UK Competent Authority).

- (b) Failure to comply with any of the provisions of sub-paragraphs (a)(i) and (ii) above may render this certificate invalid.

9. RESTRICTIONS ON SHIPMENT

Road in GB If, for any reason, the vehicle is subject to a speed restriction of less than 20 mph the carrier shall instruct the driver of the vehicle that before crossing any automatic half-barrier railway crossing, he shall notify the railway signalman of his intention to cross and await the signalman's instructions.

10. LABELLING, MARKING AND PLACARDING

Labelling and marking of packages and the placarding of vehicles shall be in accordance with the regulations listed on page 2 of this approval certificate.

11. EMERGENCY ARRANGEMENTS

(a) Road/Rail, Ports and Airports in GB

RADSAFE member

In the event of an emergency the procedures set out in RADSAFE, the nuclear industry's emergency plan, shall apply.

The police shall be informed that RADSAFE has been initiated.

Non RADSAFE member

Before shipment takes place suitable emergency plans shall have been drawn up by the consignor 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.

If RADSAFE or the consignor's 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.

b) Rail in GB (non-RADSAFE member)

The procedure to be followed should an emergency occur is set out in Railtrack publication GO/RM3053 "Working Manual for Rail Staff, Part 3, Handling and Conveyance of Dangerous Goods" (Pink Pages).

c) Sea

In the event of an emergency the procedure set out in Section 9 of Class 7 of IMDG Code, quoted on page 2 of this approval certificate, shall apply.

12. ADMINISTRATIVE ARRANGEMENTS

A. The Consignor shall be responsible for fulfilling the conditions set out in any Competent Authorities' certificates of approval associated with the shipment of this package and for compliance with the administrative requirements of paragraphs 446-459 of the 1985 Edition of the IAEA Regulations.

B. Competent Authority Approval Certificates

Copies of Competent Authority certificates of approval associated with the shipment of this package must be available at places of loading, unloading transshipment.

C. Notification of Despatch

In the event of the activity of the contents exceeding 1000 TBq or 3×10^3 A₁ or A₂ (as appropriate), whichever is the lower, the following notification procedure shall apply:

(i) Before the shipment the consignor shall give prior notice, at least 48 hours, to the following:

(a) The Transport Radiological Adviser
Department of the Environment, Transport and the Regions
Great Minster House
76 Marsham Street
LONDON SW1P 4DR

Telephone: 020 7944 5795 Fax 020 7944 2187.

(b) The Competent Authorities of those countries concerned with the shipment. These authorities will normally require to be notified at least 7 days in advance.

(c) The consignee.

(d) The port/airport authority concerned (as appropriate).

(e) All other persons specified as notifiable in the relevant regulations.

(ii) The information passed to the addressees above shall include the following:

(a) sufficient information to enable the identification of the package, including all applicable certificate numbers and identification marks;

(b) details of the journey and timings;

(c) the name and nationality of the vessel/the flight number (as appropriate).

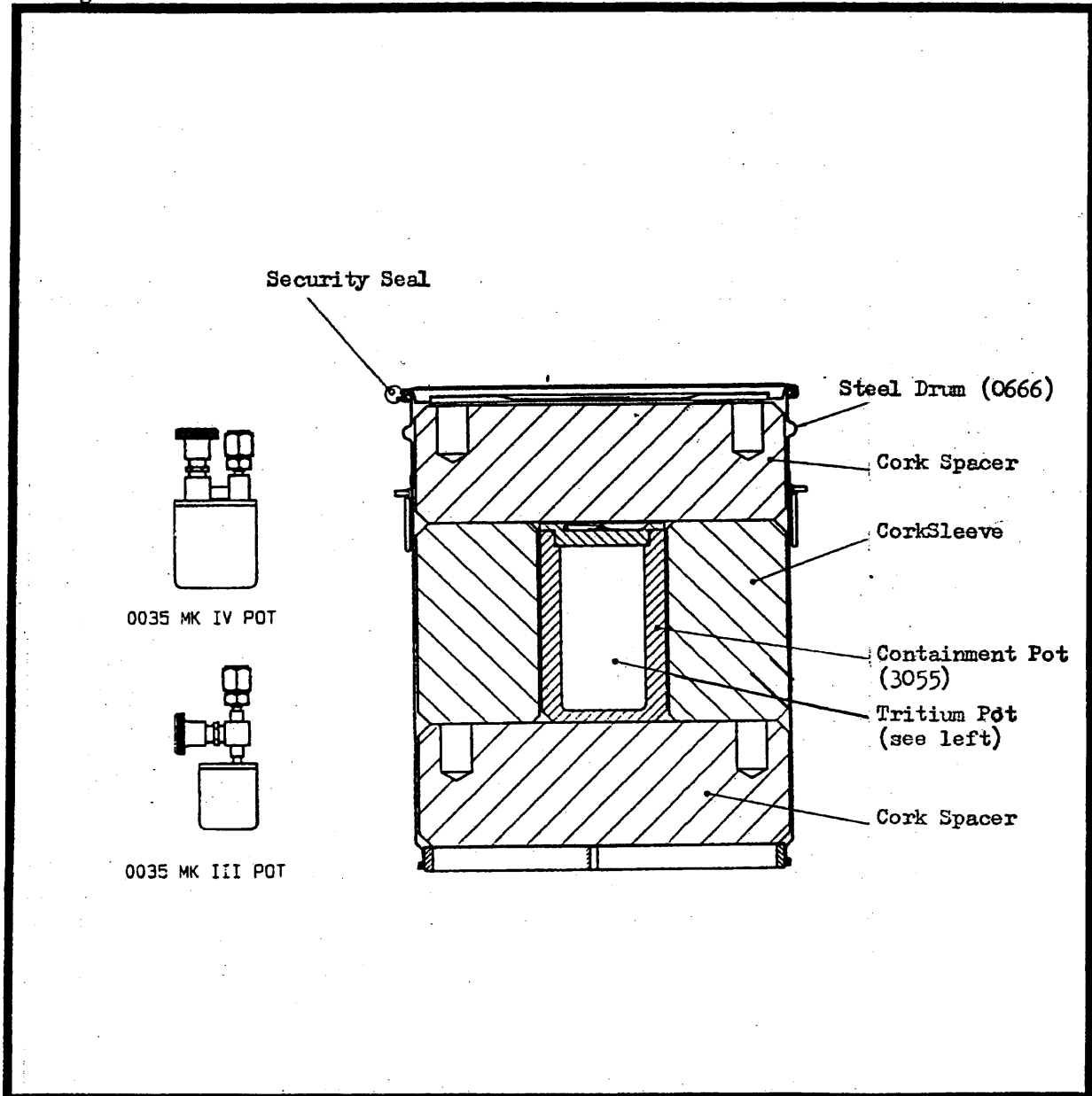
D. Serial Numbers

The Competent Authority must be informed by the owner or operator, of the serial numbers applied to all packages covered by this Certificate.

13. RENEWAL OF CERTIFICATES

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

Package Illustration



Description of Package, Dimensions and Weights

Packaging: Steel drum containing cork spacers and a tritium pot inside a stainless steel pot.

Dimensions: 327 mm diameter x 403 mm

Gross Weight: 20.5 kg