



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/0562/B(U)-96, REVISION 9**

**REVALIDATION OF SOUTH AFRICAN COMPETENT AUTHORITY
CERTIFICATE ZA/NNR 1005/B(U)-96**

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.

1. Package Identification - ZA/NNR/1005/B(U)-96 (Beatrice).
2. Package Description and Authorized Radioactive Contents - as described in South African Certificate of Competent Authority ZA/NNR 1005/B(U)-96, Revision 3 (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.
 - 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, 2012 Edition, No. SSR-6" 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/0562/B(U)-96, REVISION 9

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. Prior to each shipment, the inner cavity liner, including the cavity liner welds, must be visually inspected to assure that there is no visible evidence of cracks, pinholes or other defects.

b. In accordance with the attached South African certificate, this certificate cannot be used until January 2, 2018.

5. Marking and Labeling - The package shall bear the marking USA/0562/B(U)-96 in addition to other required markings and labeling.

6. Expiration Date - This certificate expires on January 2, 2023.

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 28, 2017 petition by NTP Radioisotopes, Pretoria, South Africa, South Africa, and in consideration of other information on file in this Office.

Certified By:



November 17,
2017

William Schoonover
Associate Administrator for Hazardous
Materials Safety

(DATE)

Revision 9 - Issued to revalidate South Africa Certificate of Competent Authority ZA/NNR/1005/B(U)-96 Revision 03, dated September 4, 2017.



CERTIFICATE NO. ZA/NNR/1005/B(U) – 96
REVISION 03
PACKAGE DESIGN APPROVAL

This is to certify that the National Nuclear Regulator, being, for the purpose of the International Atomic Energy Agency, the Competent Authority in the Republic of South Africa, in respect of the transport of radioactive material, has re-certified the Certificate of Package Design Approval, as described herein, as having met the requirements for Type B(U) packages as described in the International Atomic Energy Agency, Safety Standards Series No. SSR-6, Regulations for the Safe Transport of Radioactive Material, 2012 Edition, Vienna 2012.

1. CERTIFICATE

Effective Date : 02 January 2018

Expiry Date : 02 January 2023

2. COMPETENT AUTHORITY

National Nuclear Regulator
Eco Glades Office Park
Eco Glades 2
Block G
420 Witch Hazel Avenue
Centurion
South Africa

**3. THIS CERTIFICATE IS ISSUED ON THE BASIS OF THE APPLICATION
SUBMITTED BY**

Name and Address of Applicant:

NTP Radioisotopes SOC Ltd, on behalf of South African
Nuclear Energy Corporation Limited (Necsa) SOC Ltd
Church Street West
Pelindaba
Republic of South Africa

4. TITLE AND IDENTIFICATION OF REPORTS

4.1 Reports

- Document No. NTP-SAR-0002 (Rev 4): Safety Analysis Report: "Beatrice" Transport Package: ZA/NNR 1005/B(U)-96
- Licencing Submission NIL39-NAR-0087: Safety Analysis Report: "Beatrice" Transport Package ZA/NNR 1005/B(U)-96

4.2 Drawings

The Package is fabricated in accordance with the following drawings-

Drawing no	Revision	Description
I:E 144:000	N	Container ZA/NNR/1005 Transport Container – Assembly
I:D 144:002	G	Liner
I:C 144:003	H	Top Liner
I:B 144:004	F	Bottom Liner
I:C 144:010	L	Inner Cover
I:C 144:011	J	Inner Cover – Top Plate
I:C 144:012	E	Inner Cover – Bucket
I:B 144:013	G	Inner Cover – Inner Cover Liner
I:B 144:014	G	Inner Cover – Lifting Eye
I:B 144:015	G	Inner Cover – Clevis
I:D 144:020	M	Inner Container
I:D 144:021	G	Inner Container – Outer Casing
I:C 144:022	G	Inner Container – Uranium Shield
I:D 144:023	M	Inner Container – Inner Casing
I:B 144:024	E	Inner Container – Bottom Spacer
I:B 144:025	H	Inner Container – Top Spacer
I:D 144:030	K	Top Cover
I:B 144:031	E	Top Cover – Lifting Eye
I:B 144:032	F	Top Cover – Clevis
I:B 144:033	E	Top Cover – Bolt
I:D 144:040	K	Outer Casing
I:B 144:041	H	Outer Casing – Identification Plate
I:D 218:001	R6	IPC Mk II (Forged)

5. PACKAGE IDENTIFICATION

The Package is identified by the Model Number:

ZA/NNR/1005/B(U) – 96

6. PACKAGE DESCRIPTION

The Package Assembly (See Figure 1) consists of a Stainless Steel Inner Container, which is placed inside a Stainless Steel Outer Casing. The Stainless Steel Inner Container is sealed by two "O"-rings that serve as outer containment barrier. Solid depleted uranium is used to provide shielding in the Inner

Container. A Cork Liner, situated between the Inner Container and the Outer Casing, serves as a thermal protective envelope during a fire and also serves to cushion the internals from mechanical shocks.

A cavity inside the Inner Container Shield contains an Inner Product Container fitted with an "O"-ring, which serves as the primary containment for this package. The transport package schematic is detailed in Figure 2.

The product is placed inside a product bottle into this Inner Product Container.

Dimensions (approximate) of the Package:

Outer container: Ø286 x 374mm
 Inner container: Ø178 x 238mm (Cavity Ø50 x 103mm)
 Inner product container: Ø49 x 102mm

Weights (approximate) of the Package:

Outer container: 126 kg
 Inner container: 85 kg
 Depleted Uranium: 74 kg

7. AUTHORISED CONTENTS

The maximum authorised contents of the Beatrice package is given in the table below-

Radionuclide	Activity	Form	Formulation	Product Bottle	Volume (Max)
⁹⁹ Mo	1500 Ci (55.50 TBq)	Solid	MoO ₃ powder	Stainless Steel/ Glass	-
	1500 Ci (55.50 TBq)	Liquid	NaOH solution	Stainless Steel	40ml
	320 Ci (11.84 TBq)	Liquid	NaOH solution stabilised with NH ₄ NO ₃	Stainless Steel	40ml
	660 Ci (24.42 TBq)	Liquid	NaOH solution stabilised with NaOCl	Stainless Steel	20ml
	900 Ci (33.30 TBq)	Liquid	NaOH solution stabilised with NaNO ₃ or H ₂ O ₂	Stainless Steel	20ml
¹³¹ I	250 Ci (9.25 TBq)	Liquid	NaOH solution with or without reducing agent	Glass	20ml
¹⁹² Ir	4000 Ci (148.0 TBq)	Solid	Ir-metal	Stainless Steel	-

8. CONDITIONS FOR USE OF THE PACKAGING

The maintenance required on this transport package is described in the handling instructions. NTP-SOP-9010 Rev 3 (or such future revisions as accepted by the competent authority): *Handling Instructions for the ZA/NNR 1005/B(U)-96 "Beatrice" Transport Package* and in essence entails the following:

- 8.1 The on-condition replacement of the "O" – rings of the Inner Container.
- 8.2 Replacement of "O" – ring of the Inner Product Container before every shipment of radioactive material.
- 8.3 Replacement of the Inner Product Container after every shipment of liquid I-131, if any leakage from the product bottle into the Inner Product Container has occurred or is suspected.
- 8.4 The coating of all screws with copper grease before every shipment to prevent galling.
- 8.5 The pressure testing of the Inner Product Container every 3 years.

9. NOTIFICATION

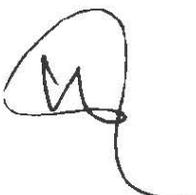
- 9.1 The owner of a package, manufactured in accordance to the design covered by this Certificate, shall forward the packaging serial number to the competent authority.
- 9.2 Should a package be disposed of or change ownership, then this change must be notified to the competent authorities.
- 9.3 Accordingly, the party relinquishing ownership of a package shall forward the name of the new owner to the competent authority.
- 9.4 The consignor of a package compliant with the design covered by this Certificate, shall check that the package bears a serial number, as well as a Model Number, as identified in Section 5 above.

10. MODE(S) OF TRANSPORT

The package described by this Certificate may be transported by all modes of transport.

11. SPECIFICATIONS OF QUALITY ASSURANCE PROGRAMME

- 11.1 A quality assurance system as described in document NTP-PRG-0100 must be applied to the design, manufacture, controls and tests of the packaging.



11.2 All packaging must be periodically inspected and as necessary, repaired and maintained in good condition so that they continue to comply with the relevant requirements and specifications, even after repeated use.

12. GENERAL CONDITIONS

12.1 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.

12.2 This certificate does not relieve the consignor or carrier from the compliance with any requirements of the government of any country through or into which the package will be transported.

13. MARKING AND LABELS

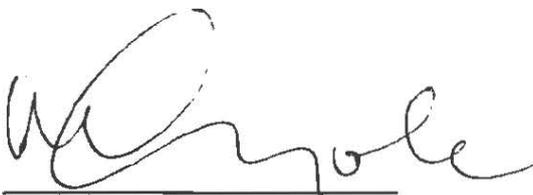
The package must bear the marking ZA/NNR/1005/B(U)-96 in addition to any other required markings and labelling.

14. RELEVANT REGULATIONS

International Atomic Energy Agency Safety Standards Series No. SSR-6, Regulations for the Safe Transport of Radioactive Material, 2012 Edition, Vienna 2012.

15. EXPIRY DATE

This certificate expires at midnight on 02 January 2023.



M B TYOBKA
CHIEF EXECUTIVE OFFICER

04/07/2017
DATE:

National Nuclear Regulator
P O Box 7106
CENTURION
0046



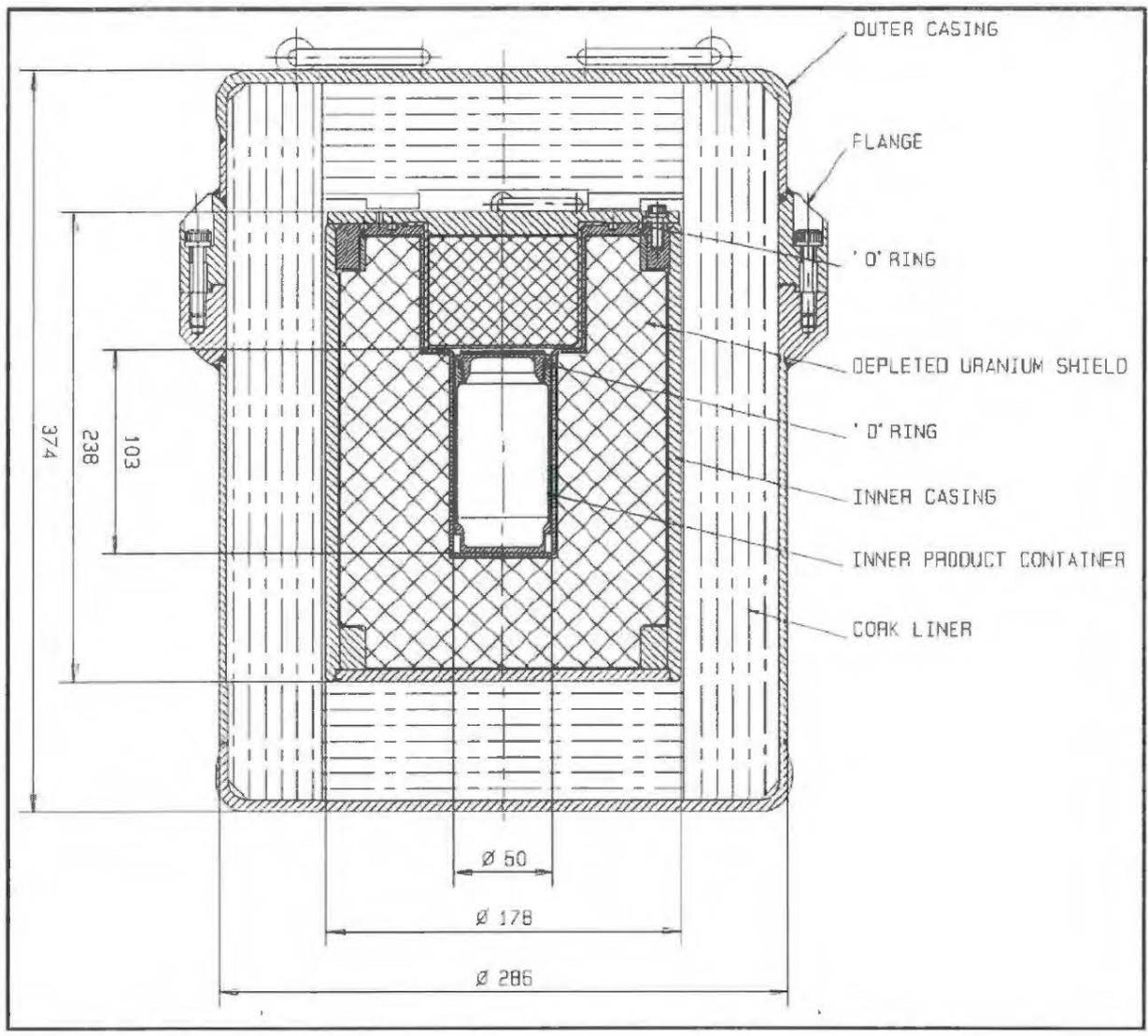


Figure 1: Beatrice Package Outline Drawing

[Handwritten signature]

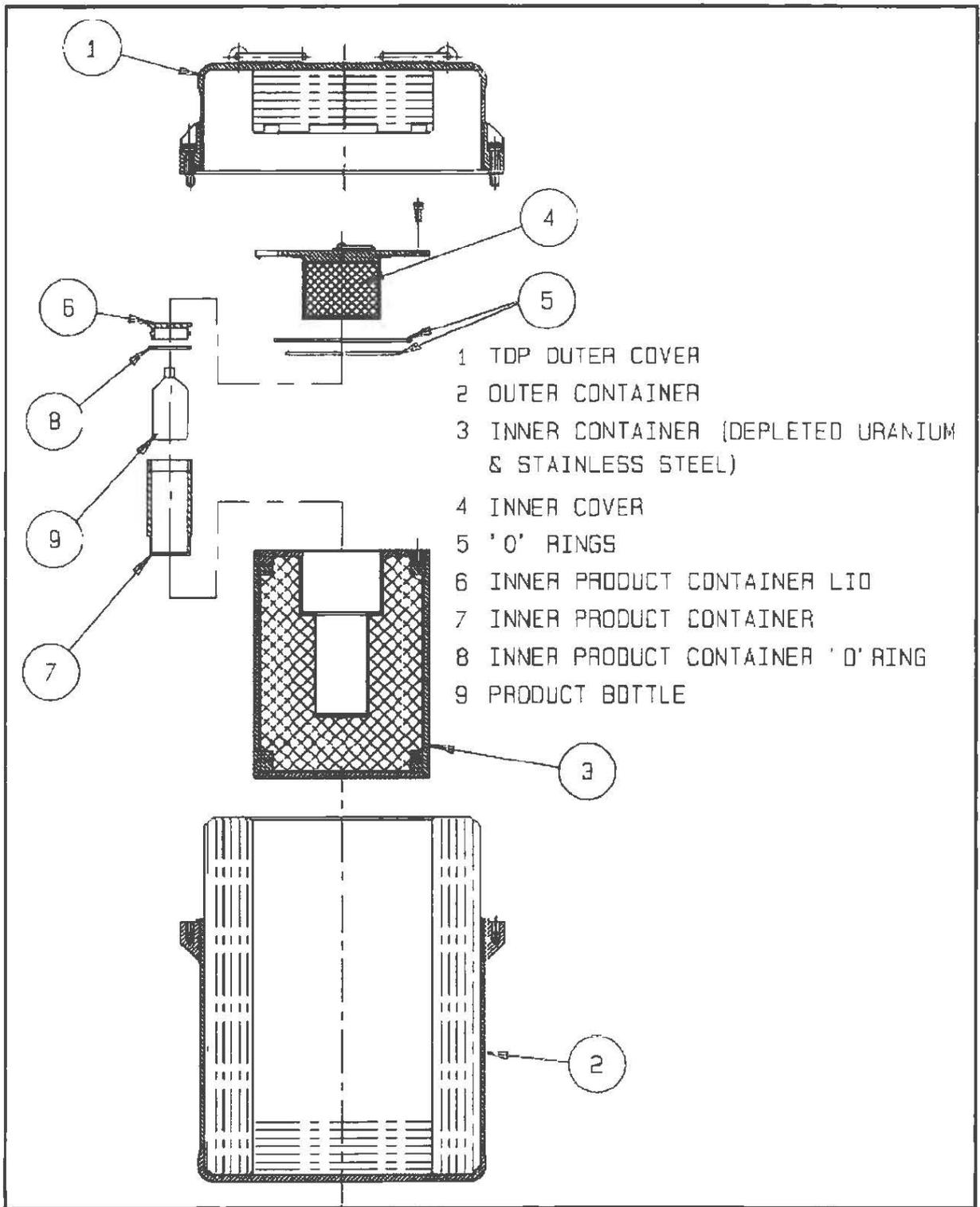


Figure 2: Schematic of Beatrice Package

[Handwritten signature]



U.S. Department of
Transportation

**Pipeline and
Hazardous Materials
Safety Administration**

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

CERTIFICATE NUMBER: USA/0562/B(U)-96

ORIGINAL REGISTRANT(S) :

Mallinckrodt Nuclear Medicine, LLC
Mallinckrodt Nuclear Medicine, LLC
2703 Wagner Place
Maryland Heights, MO, 63043
USA

IRE
Avenue de L'Esperance 1
B-6220
Fleurus, XX,
Belgium

Mallinckrodt Medical BV
Westerduinweg 3, 1755 LE
P.O. Box 3
1755 ZG
Petten, NL,
The Netherlands

University of Missouri-Columbia
1513 Research Park Drive
Columbia, MO, 65211
USA

NTP Radioisotopes
P.O. Box 582
Pretoria 0001, South Africa,
South Africa