

DOE Docket Manager note December 4, 2025: The DOT letter is addressed to Dr. James Shuler, who retired December 1, 2023. The DOT database auto-generates these form letters. DOT has subsequently updated the DOE contact in their database from Shuler to Christopher Cable (EM-4.24).



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

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

December 03, 2025

Dr. James M. Shuler
Manager, Packaging Certification Program
Department of Energy
U.S. Department of Energy
1000 Independence Ave, SW
EM-60
Washington, DC, 20585
USA

Dear Dr. James M. Shuler,

As your December 2, 2025 letter requested, Department of Energy has been registered as a user of IAEA Certificate of Competent Authority USA/0562/B(U)-96 for the ZA/NNR/1005/B(U)-96 (Beatrice). This certificate, which revalidates the South African Certificate of Competent Authority No.NNR 1005 authorizes the transport of the package from the point of entry to final destination in the United States, from point of origin in the United States to point of exit, and through the United States.

A copy of the certificate is enclosed. All future revisions of the certificate will be forwarded to Department of Energy at James.Shuler@em.doe.gov.

Sincerely,

A handwritten signature in blue ink, reading "Lad Falat".

Lad Falat, Director
Sciences and Engineering Division
Office of Hazardous Materials Safety



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 10**

**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. 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 - 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 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 Engineering and Research, (PHH-23), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington D.C. 20590-0001.

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 10

- 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. 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, 2023.

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, 2028. Previous editions which have not reached their expiration date may continue to be used.

CERTIFICATE USA/0562/B(U)-96, REVISION 10


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 27, 2022 petition by NTP Radioisotopes, Pretoria, South Africa, South Africa, and in consideration of other information on file in this Office.

Certified By:



December 13, 2022

(DATE)

 William Schoonover
Associate Administrator for Hazardous
Materials Safety

Revision 10 - Issued to revalidate South Africa Certificate of Competent Authority ZA/NNR/1005/B(U)-96 Revision 5, dated September 21, 2022.



CERTIFICATE NO. ZA/NNR/1005/B(U) – 96

REVISION 05

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 certified the package design, as described herein, and which is intended to contain the authorised radioactive materials described herein, as having met the regulatory 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, 2018 Edition, Vienna 2018.

1 CERTIFICATE

Effective Date: 02 January 2023

Expiry Date: 02 January 2028

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

The safety case for the package design comprises the following reports –

	Document Number	Rev	Date	Title/Description
(i)	NTP-SAR-0002	5	23-02-2022	SAFETY ANALYSIS REPORT: "BEATRICE" TRANSPORT PACKAGE: ZA/NNR 1005/B(U)-96
(ii)	RRT-NTP-REP-18001	01	15-06-2018	DOSE RATE AND HEATING RATES IN NTP BEATRICE PACKAGE
(iii)	MES-MEC-REP-0053	2.0	22-02-2012	Thermal analysis of Beatrice transport container
(iv)	NTP-SOP-9010	6	18-02-2022	Handling Instructions for the ZA/NNR 1005/B(U)-96 "BEATRICE" Transport Package
(v)	NTP-REP-12/09		13-02-2012	HANDLING INVESTIGATION: ZA/NNR 1005/B(U)-96 "BEATRICE" TRANSPORT PACKAGE
(vi)	RRT-MCNP-00-2		11-04-2000	DOSE RATE FOR THE O-RING ON A STAINLESS STEEL CANISTER
(vii)	Beatrice recertification 01	5	19-09-2003	Pressure build-up analysis for liquid isotopes in Beatrice transport container
(viii)	NTP-REP-12/51		22-02-2012	DESIGN REPORT FOR THE IPC MK II
(ix)	R04-00/2.1	2.1	07-12-2000	Molybdenum Transport Container Thermal Analysis
(x)	NTP-REP-12/08		22-02-2012	STACKING INVESTIGATION: ZA/NNR 1005/B(U)-96 "BEATRICE" TRANSPORT PACKAGE
(xi)	NTP-VLG-03/57		15-09-2003	REPORT ON PENETRATION TEST ON THE BEATRICE TRANSPORT PACKAGE
(xii)	IPC-REP-166-2	0	04-10-1998	FIRE TEST ON MOLYBDENUM TRANSPORT CONTAINER CONTAINER ZA-CNS-1005
(xiii)	IPC-REP-166/4	0	12-04-2000	FIRE TEST ON TRANSPORT CONTAINER: ZA/CNS-1005 BEATRICE
(xiv)	NTP-REP-18/363		18-06-2018	CONTAINMENT DESIGN ANALYSIS – BEATRICE AND JANE TRANSPORT PACKAGES
(xv)	IPC-REP-166-1	0	06-10-1998	DROP TEST ON MOLYBDENUM TRANSPORT CONTAINER CONTAINER ZA-CNS-1005
(xvi)	IPC-REP-166/3	0	13-04-2000	DROP TEST ON TRANSPORT CONTAINER: ZA/CNS-1005 BEATRICE
(xvii)	NTP-REP-18/280		14-06-2018	STRUCTURAL ASSESSMENT OF THE BEATRICE AND JANE TRANSPORT PACKAGES
(xviii)	MES-MEC-REP-0117	1.0	12-06-2018	Ageing Effect on Thermal Conductivity of Beatrice Container Test Report

4.2 Drawings

The Package is fabricated in accordance with the following drawings –

	Drawing Number	Rev	Date	Description
(i)	I:E 144:000	N	03-02-2012	Assembly
(ii)	I:D 144:002	G	13-02-2012	Liner
(iii)	I:C 144:003	H	13-02-2012	Top Liner
(iv)	I:B 144:004	F	13-03-2012	Bottom Liner
(v)	I:C 144:010	L	13-02-2012	Inner Cover
(vi)	I:C 144:011	J	13-02-2012	Top Plate
(vii)	I:C 144:012	E	13-02-2012	Bucket
(viii)	I:B 144:013	G	13-02-2012	Liner
(ix)	I:B 144:014	G	13-02-2012	Lifting Eye
(x)	I:B 144:015	G	13-02-2012	Clevis
(xi)	I:D 144:020	M	13-02-2012	Inner Container
(xii)	I:D 144:021	G	13-02-2012	Outer Casing
(xiii)	I:C 144:022	G	13-02-2012	Uranium Shield
(xiv)	I:D 144:023	M	13-02-2012	Inner Casing
(xv)	I:B 144:024	E	13-02-2012	Bottom Spacer
(xvi)	I:B 144:025	H	13-02-2012	Top Spacer
(xvii)	I:D 144:030	K	13-02-2012	Top Cover
(xviii)	I:B 144:031	E	13-02-2012	Lifting Eye
(xix)	I:B 144:032	F	13-02-2012	Clevis
(xx)	I:B 144:033	E	13-02-2012	Bolt
(xxi)	I:D 144:040	K	13-02-2012	Outer Casing
(xxii)	I:B 144:041	H	13-02-2012	Identification Plate
(xxiii)	I:D 218:001	R6	18-07-2016	IPC MK II

5 PACKAGE IDENTIFICATION

5.1 The Package is identified by the Model Number:

ZA/NNR/1005/B(U) – 96

6 PACKAGE DESCRIPTION

6.1 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 an 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 serves to cushion the internals from mechanical shocks.

6.2 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.

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

6.4 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

6.5 Weights (approximate) of the Package:

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

7 AUTHORISED CONTENTS

7.1 The maximum authorised contents of the Beatrice package are given in the table below –

Radionuclide	Activity	Form	Formulation	Product Bottle	Volume
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 6 (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.

- 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 or Loctite Food Grade Anti-Seize Lubricant 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 with 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 that is 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

- 10.1 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 fabrication, testing and usage 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 the transport package must have in their 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

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

14 RELEVANT REGULATIONS

14.1 International Atomic Energy Agency Safety Standards Series No. SSR-6, Regulations for the Safe Transport of Radioactive Material, 2018 Edition, Vienna 2018.

15 EXPIRY DATE

This Certificate expires at midnight on 02 January 2028.



21/09/22

D KGOMO
ACTING CHIEF EXECUTIVE OFFICER

DATE:

National Nuclear Regulator
P O Box 7106
CENTURION
0046

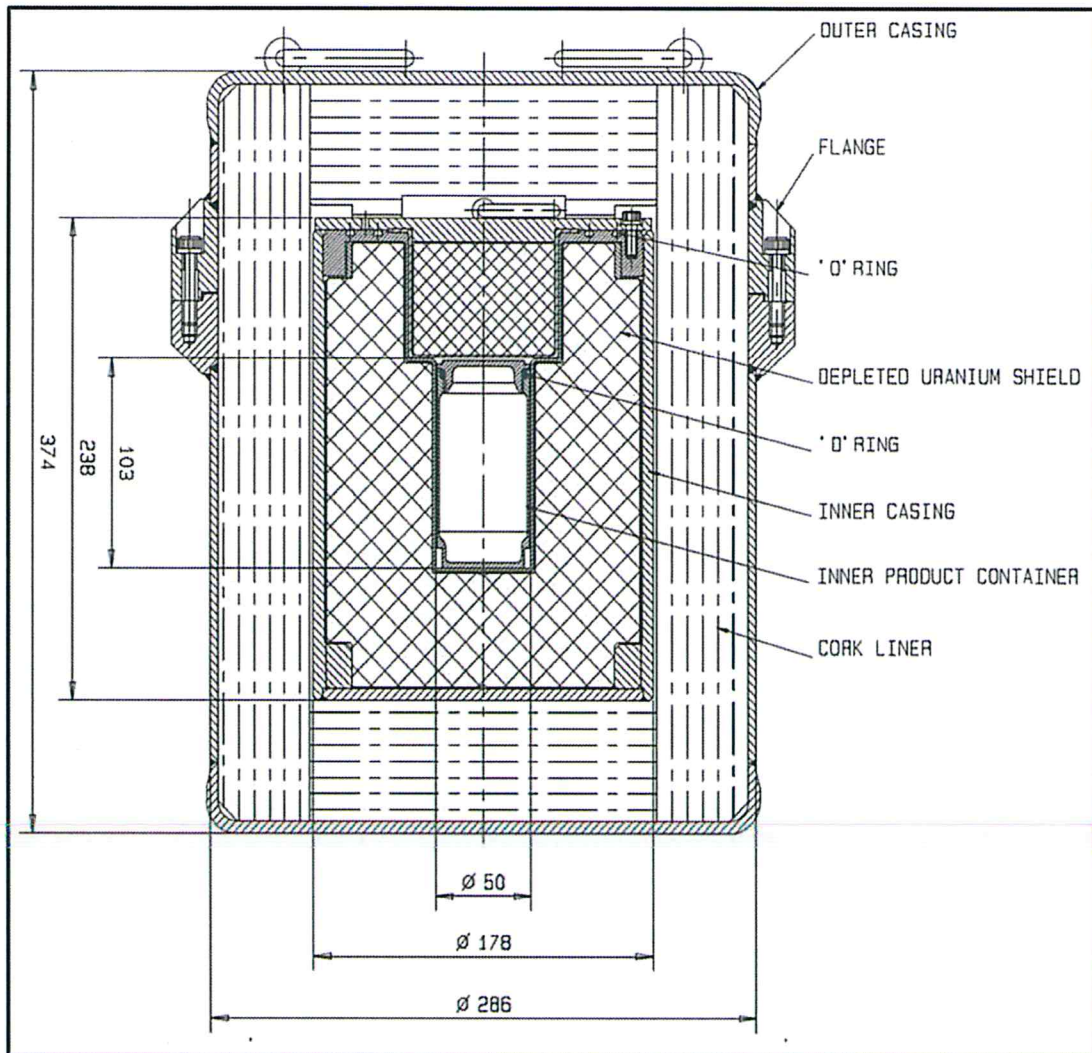


Figure 1: Beatrice Package Outline Drawing

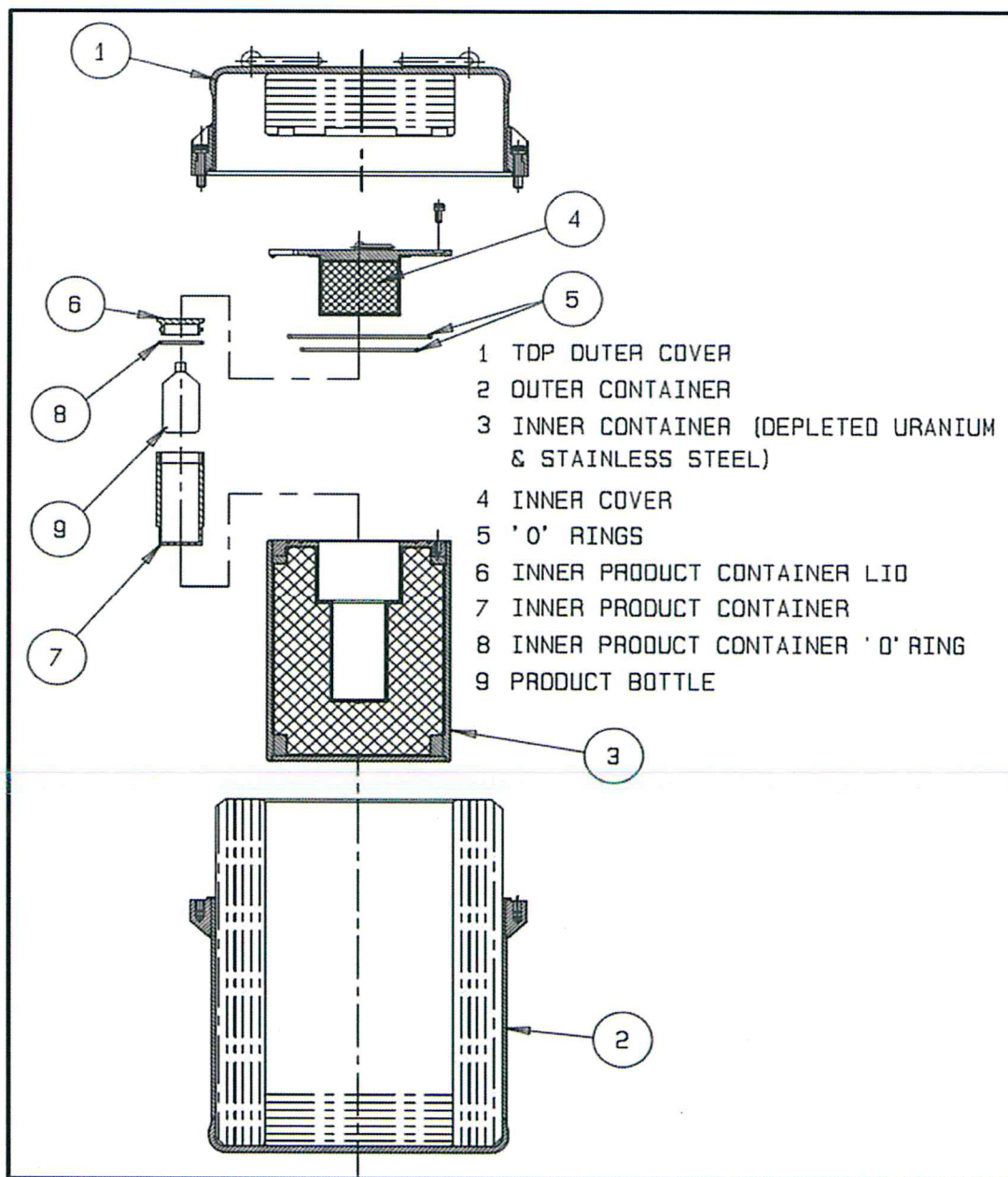


Figure 2: Schematic of Beatrice Package



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) :

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Mallinckrodt Nuclear Medicine, LLC
2703 Wagner Place
Maryland Heights, MO, 63043
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P.O. Box 582
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