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

U.S. Department of Transportation

Pipeline and Hazardous Materials Safety Administration

COMPETENT AUTHORITY CERTIFICATION FOR A TYPE B(U) RADIOACTIVE MATERIALS PACKAGE DESIGN CERTIFICATE USA/0697/B(U), REVISION 11

REVALIDATION OF CANADIAN COMPETENT AUTHORITY CERTIFICATE CDN/2078/B(U)

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 Agency[1] and the United States of America[2] 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 - F-458/F-245, F-458/F-247, F-458/F-251, F-458/F-251 MKII, F-458/F-318 and F-458/F-448.

2. Package Description and Authorized Radioactive Contents - as described in Canadian Certificate of Competent Authority CDN/2078/B(U), Revision 11 (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.

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[1] "Regulations for the Safe Transport of Radioactive Material, 2018 Edition, No. SSR-6, Revision 1" published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

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

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 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. Special Conditions -

a. For shipments of radioactive material not in special form:

(i) The radioactive material must be packaged in a leakproof insert.

(ii) The maximum decay heat is 6.1 watts per package.

(iii) The leakproof inset O-ring must be tested to demonstrate a leakage rate not more than 1E-7 ref-cm^3/s prior to use. This test may be performed prior to loading the contents in the leakproof insert.

(iv) Radioactive iodine is limited to a quantity of 30 A_2 per package.

(v) After loading and prior to shipment of Sr-90 or Mo-99, the seals of the leakproof insert must show no leakage when tested to a sensitivity of at least 1E-3 ref-cm^3/s.

b. The shipper must provide the consignee special instructions for safely opening the package. The instructions must give special consideration to any byproducts generated by the radiolysis of water.

c. The shipment of packagings containing any of the following isotopes is not authorized: Ra-223, Ra-224, Ra-225, Ra-226, Ra-228, Th-228, Th-229 and Ac-225.

5. Marking and Labeling - The package shall bear the marking USA/0697/B(U) in addition to other required markings and labeling.

6. Expiration Date - This certificate expires on October 31, 2027. Previous editions which have not reached their expiration date may continue to be used.

CERTIFICATE USA/0697/B(U), REVISION 11

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 August 8, 2025 petition by BWXT Medical Ltd, Ottawa, Ontario, and in consideration of other information on file in this Office.

Certified By:

for William Quade
Acting Associate Administrator for
Hazardous Materials Safety

September 12, 2025
(DATE)

Revision 11 - Issued to endorse Canadian Certificate of Competent Authority CDN/2078/B(U), Rev. 11, with the indicated conditions.

Certificate

CDN/2078/B(U) (Rev. 11)

Transport Package Design

The transport package design identified below is certified by the Canadian Nuclear Safety Commission pursuant to paragraph 21(1)(h) of the *Nuclear Safety and Control Act* and Subsection 10(1) of the *Packaging and Transport of Nuclear Substances Regulations*, 2015 and to the IAEA's *Regulations for the Safe Transport of Radioactive Material*, 2018 Edition.

REGISTRATION OF USE OF PACKAGES

All users of this authorization shall register their identity in writing with the Canadian Nuclear Safety Commission prior to the first use of this authorization and shall certify that they possess the instructions necessary for preparation of the package for shipment.

PACKAGE IDENTIFICATION

Designer:	**BWXT Medical Ltd.**
Make/Model:	**F-458/F-245; F-247; F-251; F-251 MKII; F-318 and F-448**
Mode of Transport:	**Air, Sea, Road, Rail**

IDENTIFICATION MARK

The package shall bear the competent authority identification mark **"CDN/2078/B(U)".**

PACKAGE DESCRIPTION

The packaging consists of a containment system, a shielding vessel and an outer container. The containment system consists of an F-242, F-248, F-256 or F-320 leak proof insert. The leak proof insert consists of a stainless-steel body and a lid that is screwed into place and sealed with an O-ring. The shielding consists of an F-251, F-251 MKII, F-318, F-245 or F-247 vessel made of depleted uranium encased in stainless-steel or an F-448 vessel made of lead encased in stainless-steel.

The outer container consists of a double-wall cylindrical stainless steel drum closed by a lid and six M10 stainless steel bolts. The void between the two walls is filled with polyurethane foam for thermal and impact protection. Two vent holes, closed by a plastic pipe thread plug are located on the body of the drum and two are located on the lid. An optional heat shield can be screwed to the top of the lid to prevent access to the top surface of the package.

The various packaging models are further shown on BWXT Medical Drawings Nos. F-458/F-245: F624501-002 (Issue G); F-458/F-247: F624701-002 (Issue G); F-458/F-251 and F-251 MKII: F625101-002 (Issue H); F-458/F-318: F631801-002 (Issue G) and F-458/F-448: F644801-002 (Issue G).

An illustration of the package is shown in the attached BWXT Medical Drawing No. F-545801-006 (Issue C).

The total mass of each package combination is as follows:

F-458/F-251 and F-458/F-251 MKII: 159 kg
F-458-F-318: 156 kg
F-458/F-245: 149 kg
F-458/F-247: 125 kg
F-458/F-448: 133 kg

Any modification to the package design must be submitted to the Canadian Nuclear Safety Commission for approval prior to implementation.

The configuration of the F-458 packaging is as follows:

Shape:	**Cylinder**	Shielding:	**Lead or Depleted Uranium**
Mass:	**n/a**	Outer Casing:	**Stainless Steel**
Length:	**n/a**	Height:	**494 mm**
Width:	**n/a**	Diameter:	**400 mm**

AUTHORIZED RADIOACTIVE CONTENTS

The radioactive contents for the various configurations of the F-458 Transport Package are listed in Appendix A attached.

MANAGEMENT SYSTEM

The management system for the design, manufacture, testing, documentation, use, maintenance and inspection of the package shall be in accordance with:

- BWXT Medical Document No. IS/QA 2663 Z000 (4)* "Radioactive Material Transport Package Quality Plan"
- BWXT Medical Document No. IS/QA 2677 C000 (2)* "Sealed Source Quality Plan"
- BWXT Medical Document No. IS/DS 1789 F458 (14) "Design, Manufacturing and Operating Specification for the F-458 Family of Transport Packages"
- Packaging and Transport of Nuclear Substances Regulations, 2015
- * or latest current revision

SHIPMENT

The preparation for shipment of the package shall be in accordance with:

- BWXT Medical Document No. IS/DS 1789 F458 (14) "Design, Manufacturing and Operating Specification for the F-458 Family of Transport Packages"
- Packaging and Transport of Nuclear Substances Regulations, 2015

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.

I. Tremblay
Designated Officer pursuant to paragraph 37(2)(a)
of the Nuclear Safety and Control Act

Appendix A

The authorized radioactive contents for the various configurations of the F-458 Transport Packages are listed in the following three tables:

Table 1: Package Configurations and Authorized Radioactive Contents for F-458/F-251* and F-458/F-318

Isotope	Package Configuration			Chemical and Physical Form
	F-251 or F-318 with F-248 insert	F-251 or F-318 with F-320 insert	F-251 with F-320 insert	
I-131	20 TBq	20 TBq	—	Solid
I-131	7.4 TBq	13 TBq	—	Aqueous NaOH solution or aqueous NaOH with up to 0.02 M Na_2SO_4
Mo-99/ Tc-99m	37 TBq	55.5 TBq	—	Solid or aqueous NaOH solution or aqueous NaOH with up to 1 M NH_4NO_3 or up to 0.4% NaOCl
Mo-99/ Tc-99m	—	21.5 TBq	—	Aqueous NH_4OH solution
Sr-90/ Y-90	18.5 TBq	18.5 TBq	—	Solid
Sr-90/ Y-90	6.4 TBq	11.1 TBq	—	Liquid in up to 1 N HCl
Y-90	18.5 TBq	18.5 TBq	—	Solid
Y-90	6.4 TBq	11.1 TBq	—	Liquid in up to 0.04 N HC1
Ra-223	—	—	1.3 TBq	Solid
Ra-224	—	—	22 GBq	Solid
Ra-225	—	—	1.5 TBq	Solid
Ra-226	—	—	42 GBq	Solid
Ra-228	—	—	26 GBq	Solid
Th-228	—	—	17 GBq	Solid
Th-229	—	—	0.5 TBq	Solid
Ac-225	—	—	1.3 TBq	Solid

* The term F-251 includes both the F-251 and F-251 MKII configurations.

Table 2: Package Configurations and Authorized Radioactive Contents for F-458/F-245 and F-458/F-247

Isotope	Package Configuration		Chemical and Physical Form
	F-245 with F-248 insert	F-247 with F-242 insert	
I-131	7,500 GBq	3,300 GBq	Solid or aqueous NaOH solution or aqueous NaOH with up to 0.2 M Na_2S0_4
Ir-192	—	37 TBq	Solid pellets
Mo-99/ Tc-99m	37 TBq	25 TBq	Solid or aqueous NaOH solution or aqueous NaOH with up to l M NH_4NO_3 or up to 0.4% NaOCl

Table 3: Package Configurations and Authorized Radioactive Contents for F-458/F-448 in F-256 Leakproof Insert

Isotope	Package Configuration		
	F-448/F-256	F-448/F-256/F-389	Chemical and Physical Form
I-125	7,400 GBq	7,400 GBq	Solid or aqueous NaOH solution
I-131	5,180 GBq	10,000 GBq	Solid or aqueous NaOH solution or aqueous NaOH with up to 0.02 M Na_2SO_4
Mo-99/ Tc-99m	555 GBq	1,110 GBq	Solid or aqueous NaOH solution or aqueous NaOH with up to 1 M NH_4NO_3 or up to 0.4% NaOCl
Y-90	16,000 GBq	—	Solid or liquid in up to 0.04 N HCl
Sr-90/Y-90	16,000 GBq	—	Solid or liquid in up to 1 N HCl

NOTES

Revision 5: January 23, 2013. Addition of Mo-99/Tc-99m in the form of NH_4OH solution to the authorized radioactive contents.

Revision 6: April 25, 2013. Certificate revised to reflect addition of an optional seating gasket.

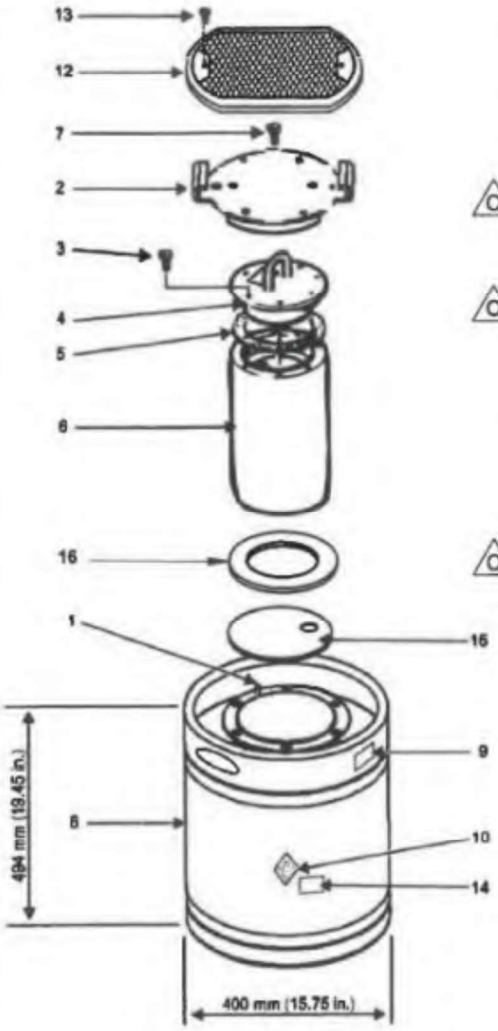
Revision 7: September 14, 2015. Certificate renewed.

Revision 8: May 31, 2019. Certificate revised. Designer changed from Nordion to BWXT. Addition of BWXT Document No. IS/QA 2663 Z000.

Revision 9: August 17, 2020. Certificate renewed. Nordion documents changed to BWXT documents.

Revision 10: June 28, 2021. Designer changed from BWXT ITG Canada Inc. to BWXT Medical Ltd.

Revision 11: July 31, 2025. Certificate revised to add Ra-223, Ra-224, Ra-225, Ra-226, Ra-228, Th-228, Th-229, and Ac-225, and to remove unused configurations from the authorized radioactive contents.



Parts List

1. Wire seal locating pin
2. Lid
3. 3/8-16UNC hex head cap screws, SAE J429, GR.5,(F-245, F-247, and F-251 - 4 pcs., F-448, F-251 MKII, and F-318 - 6 pcs.
4. Shielded Plug
5. Neoprene gasket
6. Shielding Vessel
7. (C) Lid screws, M10 X 1.5mm x 30mm long, stainless steel (6)
8. Stainless steel cylinder
9. Shipping container identification and radiation caution label (2)
10. Radioactive Category Labels (2): on two opposite sides
11. (C) Leakproof insert and radioactive contents
12. Heat shield
13. Hex head screw, M8 x 1.25mm x 16mm long, stainless steel (2)
14. UN Number Labels (2): one next to each of the radioactive category labels
15. Bottom Spacer disk (as required for F-245, F-247, F-448)
16. Optional gasket

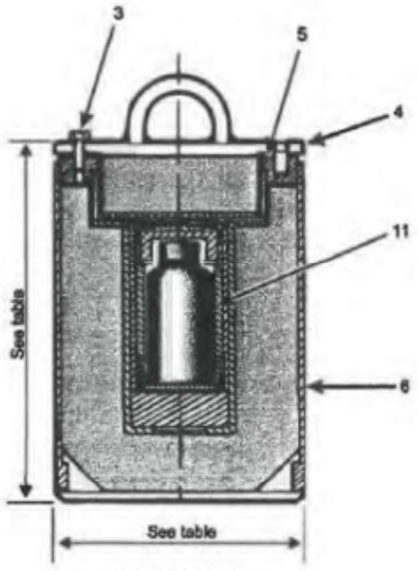
Notes

1. Meets IAEA Type B(U) requirements
2. (C) CNSC Certificate CDN/2078/B(U)
3. Prepare for shipment in accordance with IS/PP 1693 F458
4. Supplemental shielding inserts may be used in some configurations
5. Supplemental heat shield required for shipments of Ir-192 in excess of 150 TBq

(C)

Shielding Vessels & Inserts

Package Model Type	Package Total Weight (kg)	Shielding Vessel Diameter (mm)	Shielding Vessel Height (mm)	Leakproof Insert Type	Shielding Insert Type
F-458/F-251 F-458/F-251MkII	159	184	274	F-320 F-248	
F-458/F-318	156	171	268	F-320 F-248	
F-458/F-245	149	181	245	F-248	
F-458/F-247	125	165	218	F-242	
F-458/F-448	133	184	256	F-256	F-389



CROSS SECTION THROUGH ITEM 6

BWXT

TITLE

F-458 TRANSPORT PACKAGING

File: F545801-006	ISSUE C	-	CF 16160
CREATED 2013-02-19	REVISED 2025-03-05	Package No: F-458	
DRAWN RD	CHECKED ADC	APPROVED MD	SHEET 1 OF 1

U.S. Department of
Transportation

**Pipeline and
Hazardous Materials
Safety Administration**

**East Building, PHH-23
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CERTIFICATE NUMBER: USA/0697/B(U)-96

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