April 24, 2006

Mr. Richard W. Boyle
Radioactive Materials Branch
Office of Hazards Material Technology
U.S. Department of Transportation
400 Seventh Street, S.W.
Washington, DC 20590

SUBJECT: REVALIDATION OF CANADIAN PACKAGE DESIGN CERTIFICATE NO. CDN/2078/B(U)-96 FOR THE MODEL NOS. F-458/F-245, F-458/F-247, F-458/F-251, F-458/F-251 MK2, F-458/F-318, F-458/F-448 PACKAGES

Dear Mr. Boyle:

This is in response to your letter dated February 4, 2005, as supplemented September 12, November 4, December 15 and 20, 2005, and February 7, 2006, requesting our assistance in evaluating the Model Nos. F-458/F-245, F-458/F-247, F-458/F-251, F-458/F-251 MK2, F-458/F-318, and F-458/F-448 packages (F-458 family of transport packages), authorized by Canadian Package Design Certificate No. CDN/2078/B(U)-96, Rev. 0. In the December 20, 2005, submittal you requested our recommendation to revalidate Rev. 1 of the Canadian Certificate.

Based upon our review, the statements and representations in the MDS Nordion engineering assessment, as supplemented, and for the reasons stated in the enclosed Safety Evaluation Report, we recommend revalidation of Canadian Package Design Certificate No. CDN/2078/B(U)-96, Rev. 1, with the following additional conditions for Type B shipments only:

Condition No. 1: The leakproof insert O-ring must be tested to demonstrate a leakage rate not more than 1×10^{-7} ref-cm^3/s prior to use. This test may be performed prior to loading the contents in the leakproof insert.

Condition No. 2: This authorization is for consignments by MDS Nordion only.

Condition No. 3: All shipments of normal form radioactive material must be in leakproof inserts. The maximum heat load of normal form radioactive material in a leak proof insert is 6.1 Watts.

Condition No. 4: After loading and prior to each shipment of normal form Sr-90, the seals of the F-248, F-250, F-256, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least 1×10^{-3} ref-cm^3/s.

Condition No. 5: This authorization is limited to CDN/2078/B(U)-96, Rev. 1. Upon renewal of CDN/2078/B(U)-96 when it expires on October 31, 2007, the following conditions will apply:

a) MDS Nordion must demonstrate the package tie-downs meet the tie-down loads as described in Table V.2 of IAEA safety Guide No. TS-G-1.1 (ST-2), "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material."

b) After loading and prior to each shipment of normal form radioactive material, the seals of the F-242, F-248, F-250, F-256, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least $1x10^{-3}$ ref-cm^3/s.

Condition No. 6: The shipper must provide the consignee special instructions for safely opening the package under the presence of combustible gases.

If you have any questions regarding this matter, please contact me or Nancy Osgood of my staff at (301) 415-8500.

Sincerely,

/RA/

Robert A. Nelson, Chief
Licensing Section
Spent Fuel Project Office
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-3076
TAC No. L23814

Enclosure: Safety Evaluation Report

b) After loading and prior to each shipment of normal form radioactive material, the seals of the F-242, F-248, F-250, F-256, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least $1x10^{-3}$ ref-cm^3/s.

Condition No. 6: The shipper must provide the consignee special instructions for safely opening the package under the presence of combustible gases.

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SAFETY EVALUATION REPORT
F-458 Family of Transport Packages
Package Design Certificate No. CDN/2078/B(U)-96, Rev. 1
Docket No. 71-3076

SUMMARY

By letter dated February 4, 2005, the U.S. Department of Transportation (DOT) requested the U.S. Nuclear Regulatory Commission (NRC) staff's assistance in evaluating the Model Nos. F-458/F-245, F-458/F-247, F-458/F-251, F-458/F-251 MK2, F-458/F-318, and F-458/F-448 packages (F-458 family of transport packages), authorized by Canadian Package Design Certificate No. CDN/2078/B(U)-96, Rev. 0.

In response to a request for additional information, you provided supplemental information by letter dated September 12, 2005. MDS Nordion also provided an e-mail response to a request for additional information dated November 4, 2005, that was in reference to a conference call conducted October 27, 2005. As a result of our review, MDS Nordion requested the Canadian Nuclear Safety Commission revise the Canadian certificate. On December 15, 2005, MDS Nordion provided by e-mail Rev. 7 of the "Design, Manufacturing and Operating Specifications of the F-458 Family of Transport Packages ((IS/DS 1789 F458(7)." On December 20, 2005, you requested our recommendation to revalidate Rev. 1 of the Canadian Certificate No. CDN/2078/B(U)-96 (Canadian Certificate).

On January 19, 2006, a draft Safety Evaluation Report (SER) was sent to MDS Nordion that included two recommended conditions:

1. Prior to each shipment of normal form radioactive material, the seals of the F-248, F-250, F-242, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least $1x10^{-3}$ ref-cm^3/s.

2. Prior to each shipment of normal form Y-90 and Sr-90/Y-90 in the F-256 containment vessel, the seal must show no leakage when tested to a sensitivity of at least $1x10^{-3}$ ref-cm^3/s.

By letter dated February 7, 2006, you forwarded MDS Nordion's additional information and justification requesting the removal of the draft conditions requiring a pre-shipment leakage test.

Based upon our review, the statements and representations in the MDS Nordion engineering assessment, as supplemented, and for the reasons stated in this SER, the staff recommends that Canadian Package Design Certificate No. CDN/2078/B(U)-96, Rev. 1, be revalidated with the following conditions for Type B shipments only :

Condition No. 1: The leakproof insert O-ring must be tested to demonstrate a leakage rate not more than 1 x 10^{-7} ref-cm^3/s prior to use. This test may be performed prior to loading the contents in the leakproof insert.

Condition No. 2: This authorization is for consignments by MDS Nordion only.

Condition No. 3: All shipments of normal form radioactive material must be in leakproof inserts. The maximum heat load of normal form radioactive material in a leak proof insert is 6.1 Watts.

Condition No. 4: After loading and prior to each shipment of normal form Sr-90, the seals of the F-248, F-250, F-256, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least 1x10^{-3} ref-cm^3/s.

Condition No. 5: This authorization is limited to CDN/2078/B(U)-96, Rev. 1. Upon renewal of CDN/2078/B(U)-96 when it expires on October 31, 2007, the following conditions will apply:

a) MDS Nordion must demonstrate the package meets the accident tie-down loads as described in Table V.2 of IAEA safety Guide No. TS-G-1.1 (ST-2), "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material."

b) After loading and prior to each shipment of normal form radioactive material, the seals of the F-242, F-248, F-250, F-256, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least 1x10^{-3} ref-cm^3/s.

Condition No. 6: The shipper must provide the consignee special instructions for safely opening the package under the presence of combustible gases.

1.0 GENERAL INFORMATION

The F-458 is an outer drum for the F-251, F-251 MK2, F-318, F-247, F-245, and the F-448 shielding vessels. MDS Nordion notes that the F-458 is an integral part of the packaging and is therefore not considered an overpack according to the regulations but they use the term “overpack” in the Engineering Assessment as a matter of convenience.

1.1 Packaging

The F-458 family of transport packages consist of three major sub-assemblies:

(1) The containment. The radioisotope is contained in F-248, F-250, F-242, F-256, or F-320 leak proof insert or in a welded capsule that meets the requirements as special form radioactive material. The leak proof insert consists of a body and a cap that are threaded together and sealed with an O-ring.

(2) The shielding vessel. The special form source or leak proof insert is placed inside a F-251, F-251 MK2, F-318, F-247, F-245, or an F-448 shielding vessel. The F-251, F-251 MK2, F-318, F-247, and F-245 are primarily depleted uranium cylindrical vessels. The F-448 is a lead filled cylindrical vessel.

(Note: The F-368, F-336, F-174, F-286, and F-382 are also called “inserts” that provide additional shielding for Ir-192 shipments that are placed within the shielding vessel.)

(3) The fire shield. A double skinned stainless steel keg. The space between the double skins of the stainless steel keg is filled with closed cell polyurethane foam. The stainless steel keg with the integral fire shield is denoted as the F-458 “overpack.”

The maximum authorized transport weight of the heaviest configuration is 368 lbs (167 kg).

1.2 Contents

Appendix A of the Canadian Certificate includes the multiple packaging configurations, authorized contents, and the chemical and physical form authorized for each configuration.

The maximum authorized radioactive contents are summarized in Table 1.

Table 1: Maximum Authorized Contents

Isotope	Max. Contents
I-131	1000 Ci
Ir-192	8100 Ci
Mo-99/TC-99m	1500 Ci
Y-90 & Sr-90/Y-90	500 Ci
Co-60	7.4 Ci
I-125	200 Ci
Sb-124	1.2 Ci

2.0 STRUCTURAL

The NRC staff reviewed the structural aspects of the F-458 family of transport packages and evaluated them to be in accordance with the International Energy Atomic Agency TS-R-1, 1996 Edition, Amended 2003, (IAEA Transport Regulations).

The F-458 family of transport packages is a modular system of five leak-proof inserts or sealed capsules serving as the containment vessels which in turn are placed in one of six shielding vessels that may or may not include an additional shielding insert. This assembly is then placed into the F-458 that serves as the outer container. The F-458 contains the fireproofing insulation material within its double steel shell skins. Various combinations of these modules are used depending on the specific radioisotope and its form, quantity and characteristics to

make up the packaging. Table 1 of the Engineering Assessment, IS/TR 1791 F458(3), provides the maximum weights that can be obtained using each of the five shielding vessels and the other components in the combinations required for the various authorized radioisotope sources that can be transported in the packaging. The maximum transport weight is 368 lb (167 kg). The value used for the maximum design weight is 376 lb (171 kg). Drawing No. F-458, Issue 7, "F- 458 Transport Packaging," reflects the actual maximum weights for each of the six shielding vessel combinations that can be used for the F-458.

The following comments and conclusions are made with respect to the structural review of IAEA Transport Regulations, paras. 606 - 619, "General Requirements for All Packagings and Packages."

Paragraph 606: The F- 458 configuration is essentially a keg that can be easily and safely be transported and the lifting apertures in the outer container allow for lifting and securing the package during transport.

Paragraph 607: The F- 458 design provides for integral lifting apertures in the protruding upper portion of the shell structure that will not fail under proper lifting conditions and has been tested, without failure or measurable deformation, to a snatch load equivalent to 3g (three times the design weight) as reported in Appendix 10.2.

Paragraph 608: The F- 458 lifting apertures are visible and exposed during use and transport and no other features that could be used for lifting or securing the package during transport are available.

Paragraph 609: The F- 458 is designed and constructed so that there are no protruding external features and provides an external smooth-skinned stainless steel surface that is easy to decontaminate.

Paragraph 610: The F- 458 is designed to prevent the collection and retention of water on the stainless steel shell outer skin by drain holes.

Paragraph 611: The F- 458 utilizes no special attachments at the time of shipment.

Paragraph 612: The F- 458 utilizes all internal components that have been used for several years with the F-327 as the outer container and the various configurations have been utilized repeatedly without any observed adverse consequences as a result of vibration or any observed vibration resonance during routine transport. The lid and heat shield, if used when required, are provided with adequate machine screw bolting and torquing to maintain a secure package during transport.

Paragraph 613: Addressed in Materials Section.

Paragraph 614: The F-458 does not utilize valves in its design.

Paragraph 615: The F-458 design does account for the conditions of temperature and pressure that can be encountered during the routine conditions of transport. The specific conditions and resulting parameter values are discussed under paras. 618, 619 and 660.

Paragraph 616: The contents of the F-458 that is considered to have dangerous properties are the aqueous form of the radioisotopes that are generally solutions having dilute acids or bases. These aqueous solutions are contained within a separate receptacle resistive to the solutions

inside the leak-proof inserts which are themselves constructed of stainless steel that is subjected to routine inspections. The consequences of hydrogen gas generation have been addressed in Section 3.1 of this SER. The appropriate conditions have been adequately addressed.

Paragraph 617: Addressed in the Thermal Section.

Paragraph 618: The F-458 structural capabilities for adequate performance in the required temperature range will be maintained. The leak tightness under the required thermal range is addressed in the Materials, Containment, and Thermal sections.

Paragraph 619: The F-458 is designed to more than withstand an internal pressure that produces a maximum differential pressure of not less than the maximum normal operating pressure plus 95 kPa. The leakage capability under this condition is discussed in the Containment section.

With respect to IAEA Transport Regulations that address the requirements for Type B(U) packages and the structural aspects of those requirements of paras. 634 - 647, except as specified in 646 (a) and 650 - 664, the following comments and conclusions resulted from the review. Where a specific paragraph is not identified there was no structural implication for the requirement.

Paragraph 636: The two lifting apertures also serve as the tie-down attachment locations for the F-458 package. These apertures in the top skirt of the F-458 have been tested for independent loads of 3g in the vertical direction and 3g in the horizontal radial direction and shown to have no adverse impact on the structure. The accident tie-down loads have not been discussed or characterized. For transport in the United States the lifting aperture zones used as tie-down locations and the structure must withstand specified multi-directional loads without causing the structural materials to exceed the yield strength. The accident load is described as static loads applied at the center of gravity of the package equal to a horizontal load 10 times the weight of the package in the direction of travel with a transverse horizontal load of 5 times the weight of the package and a vertical load of 2 times the weight of the package. This loading condition for transport in the United States is described in Table V.2 of IAEA safety Guide No. TS-G-1.1 (ST-2), "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material."

Because of the medical necessity as described in Section 4 of this SER combined with the current level of assurance for the F-458 tie down attachments, staff recommends the following condition be included in the DOT certificate:

Included as part of Condition No. 5
Upon renewal of CDN/2078/B(U)-96 when it expires on October 31, 2007, MDS Nordion must demonstrate the package tie-downs meet the tie-down loads as described in Table V.2 of IAEA safety Guide No. TS-G-1.1 (ST-2), "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material."

Paragraph 637: Addressed in Thermal and Materials Sections.

Paragraph 638: The F-458 design and fabrication processes utilize recognized national standards for structural materials and the fabrication of the components.

Paragraph 643: See para. 619 regarding reduced ambient pressure considerations that have been incorporated in the structural design of the F-458.

Paragraph 644: See para. 614 regarding the use of no valves in the design of the F-458.

Paragraph 648: See para. 725 regarding the testing of the F-458 for use to transport liquids and gases.

Paragraph 660: The F-458 system has been tested in accordance with paras. 719 to 724 for normal conditions of transport and paras. 726 to 729 for accident conditions of transport under maximum normal operating pressure. The level of strains in the containment system will not attain values which would adversely affect the package in such a way that it would fail to meet the applicable requirements.

With respect to the IAEA Transport Regulations, Section VII, “Test Procedures,” the following comments and conclusions resulted from the review.

Paragraph 701: The F-458 family of transport packages was subjected to full scale testing to demonstrate compliance. Not all possible combinations of the various components that can be used in the modular system were tested. However, the logic for the combinations selected for testing was explained and staff agrees that the results would likely define the worst case response to compliance testing.

The testing program consisted of using the two heaviest shielding vessels (F-251 and F-318), nearly equal in weight, as they would cause the most distress in impact loadings. Three test specimens were used to demonstrate proper behavior during accident conditions of transport and had weight added to bring the total weight to the approximately 376 lbs (171 kg) design value. For the leak-proof insert the weakest one (F-320) based on the physical geometry was selected for the testing program. The test specimens utilized in the test program are considered to adequately represent the F-458 family of transport packages.

Paragraph 713: The F-458 testing program relative to the structural performance as described in Appendix 4 for the drop tests has included pretest inspections to identify any specimen non-conformance with respect to the design, defects in fabrication or manufacture, corrosion or other deterioration, and the damage or distortion of the packaging. These tests and inspections are identified in Sections 4.1 and 5.1 of Appendix 4 of the Drop Test Report as Fit Tests and Inspection/Dimensional Measurements.

Paragraph 717: The flat impact target for the drop tests was located at a facility at Chalk River Laboratories of Atomic Energy of Canada and consisted of an alloy steel plate approximately 4 in (10 cm) in thickness bearing on and attached to a large concrete cubic mass with a dimension of approximately 10 ft (3 m). The entire assembly is founded on solid bedrock at the Chalk River site. The target for the pin drop tests was a steel bar approximately 6 in (15 cm) in diameter and approximately 26 in (66 cm) long which was welded perpendicular to the center of a steel plate approximately 2 ft (60 cm) square and approximately 2.5 in (6.25 cm) thick. This assembly was attached to the steel plate of the flat impact target for the tests. These targets are acceptable for the testing program.

Paragraph 719: The tests performed on the F-458 family of transport packages included the free drop test, the stacking test and the penetration test for the normal conditions of transport. The water spray tests to be conducted prior to each of the other tests was not performed since the outer surfaces are stainless steel and there is a neoprene gasket or double O-ring seal

between the lid and the body of the F- 458 outer container. The thermal vents for the interior foam insulation under high temperature fire conditions are normally in a sealed condition with plastic pipe plugs. These design characteristics create a condition that no performance knowledge could be gained from such water spray tests. A single specimen with its actual weight was drop tested for the approximately 4 ft (1.2 m) test with the F- 458 in a horizontal orientation. A single specimen was tested for the stacking test.

Paragraph 722: The F-458/F-251 package weighing approximately 348 lb (158 kg) was tested with a free drop of 4 ft (1.2 m) on the side creating a line impact/contact with the flat target. Minor denting was observed on the outer container but no visible damage to the shield vessel or leak-proof insert. The test results are acceptable.

Paragraph 723: The F- 458 stacking test was conducted as reported in Appendix 10.1 with an equivalent of five times the design weight of 376 lb (171 kg) for a period of more than 24 hours without any observed buckling or other deformation of the F-458. The test results are acceptable.

Paragraphs 724 and 725(b) (Penetration Test): The F-458 dropped rod penetration test was performed with the approximately 1.25 in (3.2 cm) diameter steel rod with a hemispherical end and a mass of 13.2 lb (6 kg) falling a distance of approximately 67 in (1.7 m). Three surface positions were tested with the side impact away from the longitudinal weld seam or other stiffening creating the maximum dent depth of approximately 5 mm. There was no penetration of the stainless steel skin, damage to welds or the inner foam thermal barrier, and no effect on the inner containment system. Post-test radiation survey showed no changes. The test results are acceptable.

Paragraph 725(a) (Free Drop test): See Paragraph 727.

Paragraph 726: Cumulative effects of tests required under paras. 727 (Mechanical) and 728 (Thermal) were considered in the test program for accidental conditions of transport. Three specimens were involved in the required drop testing that resulted in a total of five approximately 30 ft (9 m) drops with a total of ten pin drops of approximately 3.3 ft (1 m). Various orientations of the F-458 were utilized during these tests with corner drops at 45 degrees.

Paragraph 727(a) and (b): The F-458 specimens were all tested with at least the same basic drop sequence of a pin drop test from 1 m onto the fixed pin as the first test, then a free drop test from 30 ft followed by another pin drop test from 1 m onto a fixed pin. One F-458 specimen (#5) was subjected to two 30 ft drop tests in series with one on the top and one on the bottom corner. Another specimen (#6) that underwent a single 30 ft free drop test received three additional pin drop tests beyond the final single basic pin drop test. The third specimen (#7) was subjected to two 30 ft drop tests in series with the first onto the top corner and the second on the side. This specimen was subjected to an extra pin drop after the final basic pin drop.

From the testing of specimen #5 there was no significant damage to the outer skin of the F-458, however upon disassembly after the four drops (two pin and two free drop) there was a length of the overpack cavity to flange weld cracking as a result of cap handle plate bending impact from the top drop. The thermal insulation remained intact, the shielding vessel was undamaged and the leak-proof insert remained leak-tight. The test results are acceptable.

From the testing of specimens #6 and #7 there was no significant damage to the F-458, the thermal insulation remained intact, the shielding vessel was undamaged, and the leak-proof insert remained leak-tight. The test results are acceptable.

Based on the testing program, the worst orientation with regard to the compression of the thermal insulation, was from the drop on the bottom corner from 30 ft. The most damaging condition for the lid was determined to be the top corner drop, which essentially propels the shielding vessel to behave like a ram or piston trying to force the lid off from the inside.

Paragraph 729: The F-458 was not subjected to an approximately 49 ft (15 m) water immersion test for a minimum of eight hours. Calculations were performed to determine the stress levels in the shielding vessel as the result of water pressure based on submergence in water to the prescribed depth. Stresses in the cylinder wall and the base head are within the stress allowables for the materials so there is no structural consequences from such a loading if it were to occur.

2.1 Materials Evaluation

The F-458 family of transport packages are designed to transport solid and liquid samples of medical radioisotopes, typically over periods of time less than a week. The samples are sealed in either a welded austenitic stainless steel capsul or leak proof austenitic stainless steel vessel sealed with a neoprene O-ring. The vessel is placed inside a shielding vessel consisting of either tungsten, or stainless steel encased depleted uranium or lead. Fire protection is provided by polyurethane foam encased in stainless steel.

During normal transport, all the materials will be used within their accepted operating temperature range. During a fire accident, MDS Nordion testing showed that the materials would perform as expected.

2.1.1 Contents

All contents will be non-fissile material. None of the authorized content is greater than $3000A_1$ or $3000A_2$ and therefore this cask meets para. 416 and can be shipped by air as specified in the request. The radionuclides Co-60, Ir-192, Y-90, Sr-90 and Sb-124 may be shipped as special form sealed sources. These sources are welded shut and need to be destroyed to open thus meeting para. 604.

2.1.2 Corrosion and Adverse Interactions

The materials used in the components are neoprene, depleted uranium, lead, tungsten, closed cell polyurethane foam, and austenitic stainless steel (304L). Only the 304L and neoprene will come in contact with the contents. The 304L and neoprene have excellent corrosion resistance to dilute acid and alkaline at low transport temperatures, < 200 F, and for short durations, < 48 hours.

The only reaction of concern is the generation of hydrogen due to the radiolysis of the aqueous sources. MDS Nordion testing at optimal ignition concentration indicated that at the maximum expected temperature in an accident fire, ignition would not occur, thus paras. 613 and 642 are met.

2.1.3 Containment

Neoprene has an operable temperature range of -55 °C to +149 °C. The maximum expected temperature is below 149 °C. Fire tests to 800 °C did not result in a high enough temperature at the seal site to cause failure of the neoprene seal. The seals are expected to maintain containment integrity over the full operational range and meet para. 618 for transport by air.

2.1.4 Shielding

Shielding of either depleted uranium metal or lead is encapsulated in stainless steel sheathing and thus meets this requirement for transport as an excepted package when empty. Other shielding is provided by tungsten. Paragraph 651(b) is met since the service temperatures are too low to cause deformation of these materials. Paragraph 520(b) is met requiring that the outer surface of all uranium structures be covered in an inactive metal sheath to transport empty.

2.1.5 Structural Stability

The cask and container are made 304L, 316, and 416 stainless steel and have no ductile/brittle transition in the -40 °C to +55 °C range. Polyurethane foams maintain their useful properties between -60 °C and 260 °C. Thus all the structural materials are capable of operating without a reduction in properties over the proposed operating temperature meeting paras. 618 and 651(b).

2.2 Evaluation Findings

Based on the information provided in MDS Nordion IS/TR 1791 F-458 (3) and referenced information that addresses the tests performed, calculations performed and evaluation performed, the F-458 family of transport packages, as presented, conforms to the structural and material discipline requirements of IAEA Transport Regulations.

3.0 THERMAL

The F-458 family of transport packages consists of a foam filled double skinned stainless steel cylinder with various internal shielding configurations. Shielding is mainly provided by depleted uranium but one configuration allows for the use of lead. The radioisotopes are either contained in a welded sealed capsule or a stainless steel insert closed via a threaded connection with or without a neoprene O-ring. The radioactive content is either a special form capsule, liquid, or solid. The heat load depends on the amount of specific radioactive isotope being shipped. However, the maximum heat load for the F-458 family of transport packages with depleted uranium shielding is 49.5 W for 300 TBq of Ir-192, and is only 5.5 W for the lead shielded packages. The maximum heat load for a leak proof insert with an O-ring is 6 W.

The thermal issues of concern in this submittal include: (1) the maximum package surface temperature and O-ring temperature for normal conditions of transport, (2) the material temperature limits of the O-ring and lead for the hypothetical accident fire test, and (3) any pressure buildup due to the fire test.

For the normal conditions of transport, the applicant performed a thermal test and an analysis of the package with the highest heat load (49.5 W for 300TBq of Ir-192). The analysis assumed convection and radiation on the outside surfaces of the package. It was

demonstrated that the 50 C limit on surface temperature was exceeded for this maximum heat load but was met for heat loads less than 25W (150 TBq of Ir-192). In response to staff's concerns, the applicant added guidance in their procedure, IS/DS 1789 F458(7) "Design, Manufacturing, and Operating Specification for the F-458 Family of Transport Packages," stating that for loadings of 150 TBq of Ir-192 or more, a supplemental heat shield is to be installed. The applicant further analyzed and demonstrated that for the other heat loads of the proposed content (limited to 6.1 W), that the O-ring temperature limit of 149 C was met as well as the surface temperature limit. Note that O-rings are not used for the inserts (F-368, F-336, F-174, F-286 and F-382) that are placed in the shielding vessels for heat loads greater than 6.1 W. Since this is not explicitly stated in IS/DS 1789 F458(7) "Design, Manufacturing, and Operating Specification for the F-458 Family of Transport Packages," staff recommends the following condition be included in the DOT certificate, "*The maximum heat load of normal form radioactive material in a leak proof insert is limited to 6.1 Watts."* (Included as Condition No. 3.)

The staff requested the applicant to define what special stowage provisions would be used if the package exceeded 15 W/m^2. In response, the applicant revised procedure IS/DS 1789 F-458(7) "Design, Manufacturing, and Operating Specification for the F-458 Family of Transport Packages," to require for loadings exceeding 115 TBq the following statement shall be added to the Shipper's Declaration for Dangerous Goods document (under the Additional Handling Information): "To allow for adequate air circulation for the safe dissipation of heat, do not cover with other materials." Even though the staff would have preferred an explicit separation distance from other shipped material, the applicant's additional statement above in combination with the relatively low heat load is acceptable because the system will meet the design basis boundary conditions of convective and radiative heat transfer.

For the hypothetical accident condition tests, the applicant performed a fire test of a F-458 with F-256 insert and F-113 shielding insert (not a part of the F-458 shielding family). The staff concluded that the F-113 lead shielding was acceptable for the thermal test under accident conditions in lieu of F-448 lead shielding proposed to be used with the F-458 family of transport packages because it was demonstrated to be similar in size and construction. Further, the applicant concluded that the tested package had no apparent lead melt and the O-ring was maintained below its design temperature of 149 C.

The fire test lasted slightly longer than the required 30 minutes but did not include the effects of internal heat load and did not consider the ambient temperature of 38 C (25 C was used). The fire test principally served as a benchmark for the ANSYS thermal code utilized in the analysis. Another ANSYS analysis was performed that did consider internal heat loads up to 6 W which corresponds to the maximum heat load for lead shielding and O-ringed stainless steel inserts and an ambient temperature of 38 C. The analysis had good correlation with the fire test results and demonstrated that the internal heat generation up to 6 W had no appreciable effect on the lead and O-ring (maximum temperature of 133 C). The staff concluded that the increased heat load up to 49.5 W would have negligible effect on the F-458 family of transport packages because of the lack of an O-ring on the shielding inserts, no lead shielding is used above 6.1 W, and the depleted uranium shielding is compatible with the predicted temperatures.

The applicant also evaluated the maximum pressures within the inserts for the normal conditions of transport and the fire hypothetical accident condition. Consideration was given to radiolytic decomposition, temperature effects, and auto ignition of explosive hydrogen mixtures. Reasonable analytical and empirical evidence was provided that demonstrated that the pressure rating of 4.9 MPa (715 psig) for the inserts was not exceeded for the aforementioned conditions.

3.1 Flammable Gas Generation

Flammable gas generation was previously addressed by MDS Nordion for the Model No. F-327/F-448 package in a DOT revalidation request submitted by DOT to the NRC on March 19, 2004.

In that submittal, as written in Staff's Safety Evaluation Report, "the applicant performed laboratory experiments to accurately replicate the composition of combustible and non-combustible gases that would be generated inside the F-256 leakproof insert during transport. The applicant evaluated the probability of having potential sources of ignition inside the combustible mixture, and of reaching the mixture's auto-ignition temperature during hypothetical fire accident conditions. The applicant conservatively demonstrated that the mixture would not reach its auto-ignition temperature under normal or accident conditions of transport. The applicant also performed experiments to evaluate the performance of the containment vessel with the ignition of the combustible mixture inside the vessel. The results show that, even under a worst-case mixture of gases, the pressure transient resulting from the hydrogen combustion will not exceed the maximum design pressure specified for the F-256 leakproof insert. The applicant also demonstrated that the amount of energy released in the combustion and its resulting temperature transient is not sufficient to significantly increase the temperature inside the leakproof insert or to thermally affect the stainless steel walls of the leakproof insert. Therefore, the applicant concluded that containment would be maintained under both normal and accident conditions even if hydrogen combustion inside the insert occurs."

The applicant further presented the flammable gas generation analysis in a public meeting dated May 17, 2005, and stated that the worst-case flammable gas generation analysis performed for the F-256 leakproof insert bounds the F-458 family of transport packages. The staff agrees with the applicant's assessment of the performance of the package and concludes that it will maintain containment of its radioactive contents under normal and accident conditions, including during a possible ignition and combustion of a flammable gas mixture.

3.2 Evaluation Findings

Based on review of the statements and representations in the application, the staff concludes that the thermal design has been adequately described and evaluated, and the thermal performance of the package meets IAEA Transport Regulations.

4.0 CONTAINMENT

The containment system for the F-458 family of transport packages forms a separate unit of the package. When the radioisotope is encapsulated as a special form sealed source, the sealed capsule is the containment. Otherwise, the F-248, F-250, F-242, F-256, or F-320 leak proof insert provides containment. The leak proof insert consists of a stainless steel body and cap that are threaded together and sealed with an O-ring. The following is a list of the authorized combinations that form the containment boundaries:

1. F-458/F-245 (F-245 is a depleted uranium shielding vessel) with an F-248 leak proof insert.

2. F-458/F-245 with F-336 shielding insert.

3. F-458/F-247 (F-247 is a depleted uranium shielding vessel) with an F-242 leak proof insert.

4. F-458/F-251 (F-251 is a depleted uranium shielding vessel) with an F-248 leak proof insert.

5. F-458/F-251 with an F-320 or F-250 leak proof insert.

6. F-458/F-251 or F-458/F-251 MK2 with an F-368 shielding insert with special form containment boundary.

7. F-458/F-318 (F-318 is a depleted uranium shielding vessel) with an F-248 leak proof insert.

8. F-458/F-318 with an F-320 leak proof insert.

9. F-458/F318 with an F-368 shielding insert with special form containment boundary.

The applicant demonstrated, by performing a helium leak test on the most limiting leak proof insert (the F-320), that the package will maintain a leakage rate not to exceed $1x10^{-7}$ ref-cm^3/s, under both normal and hypothetical accident transport conditions. This leakage rate is defined as leak-tight in ANSI N14.5 - 1997, "American National Standard for Radioactive Materials - Leakage Tests on Packages for Shipment."

The F-458 family of packages are designed, manufactured, inspected, and maintained in accordance with MDS Nordion Document No. IS/DS 1789 F458 (7). They are prepared for shipment in accordance with MDS Nordion Document No. IS/DS 1789 F458 (7). All newly manufactured leak proof inserts must pass a helium leak test (HLT) and a hydrostatic pressure test. Additionally, all inserts must pass an HLT or a vacuum liquid bubble test and a hydrostatic leak test annually. Sealed sources are subjected to leak tests and contamination tests prior to shipment.

However, MDS Nordion does not perform a pre-shipment leakage test consistent with ANSI N14.5 - 1997, Section 7.6. Staff, therefore, recommended the following conditions that were sent in a draft SER to MDS Nordion and DOT on January 19, 2006:

1. Prior to each shipment of normal form radioactive material, the seals of the F-248, F-250, F-242, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least $1x10^{-3}$ ref-cm^3/s.

2. Prior to each shipment of normal form Y-90 and Sr-90/Y-90 in the F-256 containment vessel, the seal must show no leakage when tested to a sensitivity of at least $1x10^{-3}$ ref-cm^3/s.

The applicant requested removal of these conditions based on their alternate method of containment verification and provided supporting documentation by letter dated February 7, 2006. The supporting justification included a discussion of: (1) regulatory testing, (2) containment assurance through design, manufacture and verification, (3) challenging seal performance, (4) MDS Nordion's operational experience, (5) the regulatory framework, (6) packaging contents, and (7) the necessity of medical isotopes in the U.S.

Regulatory Testing

Regulatory testing included drop and fire testing, followed by leak testing. None of the final leak tests showed any evidence of leakage. Staff agrees that the F-458 family of packages have met the requirements of regulatory testing.

Containment Assurance through Design, Manufacture and Verification

The applicant states that the containment is assured through a robust design of the leakproof inserts. The assembled leakproof inserts are visually inspected to ensure the cap is fully seated. Manufacturing quality of the leakproof inserts is assured via the engineering drawings and quality assurance. Leakproof inserts are given a thorough cleaning and visual examination after each shipment. On a yearly basis or if defects are suspected, detailed inspections are performed (including hydrostatic leak testing and helium leak testing). In 2003, helium leak testing replaced vacuum bubble leak testing as the primary method to validate leak-tightness.

The leak proof inserts are different sizes but the seal geometry for each is the same. Sealing is achieved by radial compression of an O-ring. A new, greased O-ring is installed prior to loading the leak proof insert and the O-ring is never re-used. The operator would be able to see if an O-ring was missing due to the visual contrast of black on stainless steel. Staff has verified the calculations of the minimum and maximum compression of the O-rings.

Challenging Seal Performance

The applicant states that the robustness of the O-ring seal has been assured by challenging seal performance. The applicant describes the additional testing of the O-rings under multiple scenarios including two different manufacturers' batches, using different operators, and improper insertion of the cap. All test results concluded no increase in leak rate even in less-than-optimal circumstances.

Staff agrees that the O-ring seal is robust, however, the applicant uses a new, greased O-ring for each shipment, and O-rings are never re-used. ANSI N14.5-1997 specifies that all containment boundary components, including seals, be tested annually to demonstrate the containment system can achieve the required leakage rate, as well as after the contents are loaded and the containment system is assembled. Since the applicant does not perform this pre-shipment leakage test, and since a new (untested) O-ring is used for each shipment, staff recommends the following condition be included in the DOT Certificate. The test specified in this condition is to assure that each new O-ring is capable of achieving a seal that is leak tight. This test corresponds to the annual leakage test specified in ANSI N14.5-1997.

Condition No. 1

The leakproof insert O-ring must be tested to demonstrate a leakage rate not more than 1×10^{-7} ref-cm^3/sec prior to use. This test may be performed prior to loading the contents in the containment vessel.

MDS Nordion's Operational Experience

The applicant provided information on operating experience and cited that "almost 10,000 shipments have been made using the leakproof inserts in the past five years without any complaint about loss of containment. During that same period, over 1300 vacuum bubble tests and more than 400 helium leak tests were successfully completed." Since this operating experience has been demonstrated by MDS Nordion, staff recommends the following condition be included in the DOT Certificate:

Condition No. 2

This authorization is for consignments by MDS Nordion only.

The Regulatory Framework

The applicant described the requirements of IAEA Transport Regulation para. 502 and its associated guidance, IAEA Safety Standards Series No. TS-G-1.1, para. 502.6.

A pre-shipment leakage test is accepted throughout the international community as the primary method to show compliance with IAEA Transport Regulations, para. 502. MDS Nordion, rather than performing a pre-shipment leakage test, chose to show compliance to IAEA para. 502 by an alternate means of assembly verification. The applicant states that their method is described in the IAEA guidance document, IAEA Safety Standards Series No. TS-G-1.1. MDS Nordion specifically uses the following in para. 502.6 as an example :

"First inspect and/or test comprehensively the complete containment system of an empty packaging. The radioactive contents may then be loaded into the packaging and only the closure components which were opened during loading need to be inspected and/or tested as part of the assembly verification."

The staff agrees that the regulations nor the guidance specifically require a leakage test of the containment system of a Type B package prior to shipment. However, based on the staff's evaluation of the design, package operations, and the quantity of radioactivity authorized for transport, the staff believes that the package should be leak tested prior to each shipment after loading. Included in the considerations by staff were the physical form of the contents (liquid), the high maximum normal operating pressure of the containment system, the high specific activity of the contents, and the relatively large quantity of radioactivity authorized for shipment. Therefore the staff recommends that shipments be allowed to continue without a pre-shipment leakage test for a limited period of time, as discussed below (Condition No. 5).

The staff also concludes that the compliance of the package with the requirements of para. 502 relies upon the physical integrity of the special form source or the containment provided by the leak proof insert. Therefore the staff recommends the following additional condition be included in the DOT certificate:

Condition No. 3

All shipments of normal form radioactive material must be in leakproof inserts. The maximum heat load of normal form radioactive material in a leak proof insert is 6.1 Watts.

Packaging Contents

On October 29, 2004, in staff's review of a separate revalidation of the Canadian Certificate No. CDN/1041/B(U)-85 for the Model No. F-327/F-448 package, staff did recommend to DOT approval of shipments made by MDS Nordion without performing a pre-shipment leakage test consistent with ANSI N14.5-1997 and accepted MDS Nordion's alternate method of containment verification. However, as stated in the associated SER, staff considered more than regulatory testing, assurance through design, manufacture and verification, and challenging seal performance:

"In addition to the information provided by the applicant, the staff considered other factors in its evaluation ... the maximum number of A_2 quantities that the package is authorized to transport is approximately 14. This is for I-131 (a maximum of 10 TBq per package, and an A_2 value of 0.7 TBq). For other radionuclides, the quantity of material is not more than two A_2 quantities. In addition, for I-131, the radioactive material is short-lived, with a half-life of approximately 8 days. The staff therefore recognizes that the radiological hazard of the package contents is

limited, even if the contents were to be released during transport. These factors give additional margins of safety and additional assurance that the package provides adequate safety."

In the application for Canadian Certificate No. CDN/2078/B(U)-96 used to ship the F-458 family of transport packages, MDS Nordion requested consideration of the limited radiological hazard present due to the short lived isotopes and short half lives. However, a significant increase in A_2 quantities and additional isotopes were requested as seen in the following Table:

Medical Isotopes	Half Life	Maximum Quantity of A_2s authorized in CDN/1041/B(U)-85	Maximum Quantity of A_2s requested in CDN/2078/B(U)-96
I-125	60 days	2.5	2.5
I-131	8 days	14	53
Mo-99/Tc-99m	2.7 days	2	93
Ir-192	74 days	0	500
Sr-90	28 years	0	62
Y-90	2.7 days	0	62

Because of the significant increase in the quantity of A_2s, the additional contents (Ir-192, Sr-90, and Y-90), and the 28 year half life of Sr-90, the radiological hazard of the package is no longer limited and there is no longer the additional assurance and additional margin of safety if the contents were to be released during transport.

The justification of a limited radiological hazard due to short half life does not apply to Sr-90, therefore, the staff recommends the following condition be included in the DOT certificate:

Condition No. 4:
After loading and prior to each shipment of normal form of Sr-90, the seals of the F-248, F-250, F-256, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least $1x10^{-3}$ ref-cm^3/s.

The Necessity of Medical Isotopes in the U.S.

The applicant described the medical necessity for I-131, Mo-99/Tc-99m, and Y-90 in the U.S. Staff agrees with the medical necessity of these isotopes. The applicant stated that pre-shipment leakage testing cannot be completed on a loaded leakproof insert outside a hot cell due to high radiation levels and that a pre-shipment leakage test is not practical to be completed within hot cells, due to the volatility of some of the products, the potential for increased contamination, and deterioration of the test equipment due to radiation.

Staff understands that because the F-458 family of transport packages was not designed to include a pre-shipment leakage test, imposing an immediate pre-shipment leakage test on the medical isotopes with short half lives may cause a significant burden on MDS Nordion and the bottleneck of the flow of medical isotopes into the U.S. This consideration combined with the

significant increase in A_2 values requested to be shipped in the F-458 family of transport packages, staff recommends the following condition to be included in the DOT certificate:

Condition No. 5
This authorization is limited to CDN/2078/B(U)-96, Rev. 1. Upon renewal of CDN/2078/B(U)-96 when it expires on October 31, 2007, the following condition will apply:

After loading and prior to each shipment of normal form radioactive material, the seals of the F-242, F-248, F-250, F-256, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least $1x10^{-3}$ ref-cm^3/s.

This time should allow MDS Nordion to develop a method of pre-shipment leakage testing of the package, without incurring significant additional radiation exposure.

5.0 SHIELDING

The F-458 outer drum is a replacement for the F-327 outer drum used for shipment of radioisotopes. The same shielding vessels and inserts used in the F-327 family of transport packages are used in the F-458 family of transport packages. The F-458 is similar in dimension to the F-327 and includes additional steel shielding to reduce radiation levels. The package consists of a foam filled double skinned stainless steel cylinder with various internal shielding configurations. The steel shielding in the F-458 overpack was substantially increased on the top, bottom, and sides of the package. Shielding is mainly provided by the depleted uranium in the shielding vessels, but one configuration allows for the use of lead. The radioisotopes are either contained in a welded sealed capsule or a stainless steel insert closed via a threaded connection with a neoprene O-ring. The radioactive content is either a special form capsule, liquid, or solid.

Based on the radiation levels observed for the previous F-327 package, significant additional shielding was added to the top, bottom and sides of the F-458 package to reduce the maximum radiation levels. Prototypes of the F-458 were manufactured with varying thickness of the shield ring. The prototypes were subjected to radiation testing. Based on these tests, the shielding was ultimately increased on the top from 1 mm to 7.5 mm of steel, on the sides from 1 mm to 31.5 mm, and on the bottom from 1 mm to 28 mm.

Based on the maximum activity of the various isotopes allowed for transport in the F-327 package, the maximum loadings of 300 TBq (~8100 Ci) of Ir-192 and both 55.5 TBq (1500 Ci) and 37 TBq (1000 Ci) of Mo-99 were tested and surveyed for the new F-458 package utilizing the F-251 and F-318 shielding vessels since they yielded the highest radiation levels in the F-327 package. The maximum surface radiation levels and the Transport Index were significantly lower in the F-458 package than the original F-327 package for these shielding vessels and well within IAEA Transport Regulations.

Staff noted that there are several different isotopes at various activities allowed for transport in the F-458 family of transport packages. The prototype analysis performed evaluated the effects of the additional shielding for the isotopes indicated above. The rest of the analysis uses the evaluation of the shielding analysis of the F-327 package for the other isotopes. This appears to be bounding since the additional shielding present on the F-458 package will similarly reduce the overall surface radiation levels for all transported isotopes. The test data obtained from the F-458 was added to the engineering assessments for the F-327 package for all allowable contents and appear to be conservative due to the additional shielding of the F-458

package. In addition, operating procedures for the F-458 package specify that radiation measurements are taken prior to each shipment to ensure that the package contents meet IAEA Transport Regulations.

For the hypothetical accident condition, the applicant performed a drop test of a F-458 with F-318 shielding vessel containing a bulk Ir-192 source with a total activity of 8000 Ci (~300 TBq) in a F-320 leakproof insert. The survey results of the top, bottom, and sides of the package indicated that the F-458 package met the maximum surface radiation levels and 1 meter radiation levels specified in IAEA Transport Regulations. This is the bounding case for all allowable contents of the F-458 package.

Staff concludes that the F-458 outer drum incorporates more radiation shielding then the F-327 outer drum and concludes that an adequate basis exists to support that the F-458 family of transport packages meets the requirements specified in IAEA Transport Regulations.

6.0 CRITICALITY

There are no fissile materials authorized for transport in the package, therefore criticality is not a concern.

7.0 PACKAGE OPERATIONS

The package operations will be made in accordance with MDS Nordion Document No. IS/DS 1789 F-458(7), “Design, Manufacturing and Operating Specification for the F-458 Family of Transport Packages.” This document requires a “Routine Inspection” of the F-458 family of transport packages prior to each shipment. This inspection includes:

- The F-458 overpack is inspected for contamination (inside and outside), damage (such as rust and severe dents), labels, the lid and associated bolts.
- The shielding vessels are inspected for contamination and damage. The screws securing the plugs are inspected for damage. The O-rings are replaced for model nos. F-448 and F-251 MK II. For all other models, the O-rings are inspected and replaced as necessary. The condition of the face of the shielding vessel and sealing face on the top plug are inspected for damage that may affect the gasket seal.
- The F-242, F-248, F-250, F-256, and F-320 leakproof inserts are inspected for damage and decontaminated as necessary. The lid shall thread freely onto the body without an O-ring. The sealing surfaces are inspected to be free of defects. A new O-ring is placed in the cavity for installation prior to the next use.

As also recommended in staff’s October 29, 2004, SER, and in accordance with 10 CFR 71.89, the shipper must ensure that any special procedures or instructions needed for safely opening the package have been provided to the consignee prior to delivery of the package to a carrier for transport. Therefore, recognizing the potential for combustible gases to be generated by radiolysis inside the leakproof inserts, the staff recommends that the approval be conditioned as follows:

Condition No. 6
The shipper must provide the consignee special instructions for safely opening the package under the presence of combustible gases.

8.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM

The acceptance tests are described in Appendix 6 of the Engineering Assessment in MDS Nordion Document No. IS/TR 1791 F458 (3) and in MDS Nordion Document No. IS/DS 1789 F458(7), "Design, Manufacturing and Operating Specification for the F-458 Family of Transport Packages."

Manufacturing Acceptance Tests include:

- Confirmation that the packaging was fabricated in accordance with the approved design and Quality Assurance Program.

- Pressure Test
  - All new leakproof inserts must pass a hydrostatic pressure test to a minimum gage pressure of 1070 kPa (155 psi) for a period of 5 minutes.
  - The leakproof insert shall not deform permanently, crack, or leak.
  - A leak test is performed after the pressure test.

- Leak Tests
  - Each F-248, F-250, F-256, and F-320 leakproof insert shall be leak tested using a method sensitive to $1x10^{-8}$ ref - cc/s. The leak rate shall be less than $1x10^{-7}$ ref-cc/s.
  - The stainless steel shell surrounding the depleted uranium in the F-245, F-247, and F-251 shielding vessels shall be leak tested using a method sensitive to $1x10^{-8}$ ref - cc/s. The leak rate shall be less than $1x10^{-7}$ ref-cc/s.
  - The F-245, F-247, and F-251 cavities shall be leak tested using a test sensitive to $1x10^{-4}$ ref-cc/s. The leak rate shall be less than $1x10^{-3}$ ref-cc/s.

- Radiation Survey
  - The shielding vessel shall be subjected to a radiation survey using I-131, Ir-192, or Mo-99 that produce a radiation field of at least 50 mR/h on the surface of the shielding vessel.
  - An additional radiation survey shall be completed with the shielding vessel installed in the F-458 overpack.
  - Extrapolated results to the maximum activity limit authorized in the Certificate must result in radiation fields no greater than 200 mR/h on the surface and 10 mR/h at 1 m from the surface of the package.

- Sealed sources are leak tested according to ISO 9978.

- Welding procedures and welder qualification shall be ASME Boiler and Pressure Vessel Code Section IX, or CSA Standard W59.

Maintenance and Inspection Procedures include:

- The F-458 family of transport packages shall be subjected to a routine inspection prior to each shipment already described in Section 7 of this SER and in Section 5.0 of MDS Nordion Document No. IS/DS 1789 F458(7), "Design, Manufacturing and Operating Specification for the F-458 Family of Transport Packages."

C The F-458 family of transport packages shall be subjected to annual, or a more frequent if necessary, detailed inspection.
  - The inside and outside of the F-458 overpack is inspected for rust and damage such as cracks, severe dents, perforation.
  - The shielding vessels, its internal threads, and associated plug screws and are inspected for damage, cracks, and ensure that the screws turn freely into the shielding vessel. The gasket or O-ring is inspected and replaced as necessary.
  - The F-242, F-248, F-250, F-256, and F-320 leakproof inserts are subjected to a hydrostatic pressure test to a minimum gage pressure of 1070 kPa (155 psi) for a period of 5 minutes and must show no permanent deformation, cracking, or leaking. A vacuum liquid bubble test is performed at the hydrostatic test to ensure no visible sign of leakage.
  - In the February 7, 2006, supplement, MDS Nordion states that in 2003, helium leak testing replaced the vacuum liquid bubble test as the primary leak-tightness validation method.

9.0 QUALITY ASSURANCE PROGRAM

MDS Nordion Quality Assurance Program consists of the "Radioactive material Transport Package Quality Plan", Appendix 6.3, and the "Sealed Source Quality Plan", Appendix 6.4, of the Engineering Assessment in MDS Nordion Document No. IS/TR 1791 F458 (3).

These plans establish a documented system of management controls that provide confidence in the quality of all associated work activities, including design, manufacture, testing, documentation, use, maintenance and inspection.

CONCLUSIONS

Based upon our review, the statements and representations in the MDS Nordion engineering assessment, as supplemented, and for the reasons stated in this Safety Evaluation Report, the staff agrees that the Model Nos. F-458/F-245, F-458/F-247, F-458/F-251, F-458/F-251 MK2, F-458/F-318, and F-458/F-448 transport packages, authorized by Canadian Package Design Certificate No. CDN/2078/B(U)-96, Rev. 1, meets the requirements of IAEA TS-R-1, 1996 Edition (As amended 2003). The staff recommends revalidation of this package design with the following additional conditions for Type B shipments only:

Condition No. 1: The leakproof insert O-ring must be tested to demonstrate a leakage rate not more than 1 x 10^{-7} ref-cm^3/s prior to use. This test may be performed prior to loading the contents in the leakproof insert.

Condition No. 2: This authorization is for consignments by MDS Nordion only.

Condition No. 3: All shipments of normal form radioactive material must be in leakproof inserts. The maximum heat load of normal form radioactive material in a leak proof insert is 6.1 Watts.

Condition No. 4: After loading and prior to each shipment of normal form Sr-90, the seals of the F-248, F-250, F-256, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least 1x10^{-3} ref-cm^3/s.

Condition No. 5: This authorization is limited to CDN/2078/B(U)-96, Rev. 1. Upon renewal of CDN/2078/B(U)-96 when it expires on October 31, 2007, the following conditions will apply:

a) MDS Nordion must demonstrate the package tie-downs meet the tie-down loads as described in Table V.2 of IAEA safety Guide No. TS-G-1.1 (ST-2), "Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material."

b) After loading and prior to each shipment of normal form radioactive material, the seals of the F-242, F-248, F-250, F-256, and F-320 containment vessels must show no leakage when tested to a sensitivity of at least $1x10^{-3}$ ref-cm^3/s.

Condition No. 6: The shipper must provide the consignee special instructions for safely opening the package under the presence of combustible gases.

Issued with letter to R. Boyle, Department of Transportation,
on April 24, 2006.