71-3076

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

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

FEB 7 2006

Mr. William Brach, Director
Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards (NMSS)
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Brach:

On February 4, 2005 I requested that you review Revision 0 of Canadian Package Design Certificate No. CDN/2078/B(U)-96 for the MDS Nordion Transport Packages 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 and make a recommendation concerning our revalidation of the certificate for import and export use. As a result of your ongoing review, MDS Nordion has sent us a report containing additional information on their pre-shipment assembly verification procedures.

In accordance with the Memorandum of Understanding between our Agencies, I request that you review the enclosed additional information. I am providing this in the form of two proprietary and two non-proprietary reports, with an affidavit to support the MDS Nordion request to withhold parts of this response from public disclosure.

Thank you for your assistance and please feel free to contact me or Fred Ferate if you need any further information. We can both be reached at 202-366-4545.

Sincerely,

Fred Ferate

for Richard W. Boyle, Chief
Radioactive Materials Branch
Office of Hazardous Materials
Technology

Enclosures

cc: MDS Nordion, Inc.

NMSS01

AFFIDAVIT

I, E. S. Martell, in my capacity as Senior, Vice President, Engineering, Development & Compliance, having been duly authorized to apply for withholding from disclosure of proprietary information by and on behalf of MDS Nordion, a division of MDS (Canada) Inc., ("MDS Nordion"), do depose and say:

1. I, E.S. Martell, am the Senior, Vice President, Engineering, Development & Compliance, of MDS Nordion.

2. The information contained in the attached document, to MDS Nordion's, letter to Dr. Fred Ferate dated February 2, 2006, are the property of MDS Nordion. This document contains proprietary information related to the design of the F-458/F-251, F-458/F-318, F-458/F-448, F-458/F-245 and F-458/F-247 transport packages.

3. MDS Nordion, has expended extensive funds and manpower in developing the aforementioned document and any release for disclosure of such information to third parties would enable and assist third parties to use the information to fabricate and register a similar transport package without incurring any development costs. This could compromise MDS Nordion's, ability to compete in the marketplace. Therefore, MDS Nordion, submits that parts of the attached document, "Additional Safety Information for the F-458 Family of Transport Packages," and the drawings F124501-029 rev M, F124501-030 rev N, F124501-004 rev S, F124701-026 rev H, F124701-009 rev K, F124701-028 rev F, F125101-022 rev L, F125101-025 rev H, F125101-024 rev D, F125101-031 rev A, F125601-001 rev H, F125601-003 rev J, F125601-004 rev J, F132001-001 rev G, F132001-002 rev D, F132001-003 rev D, to MDS Nordion letter to Dr. Fred Ferate dated February 2, 2006, should be withheld from public disclosure.

4. The information has been held in confidence by MDS Nordion, and any disclosure thereof for developmental purposes, has been accompanied by a confidentiality agreement protecting the trade secrets contained herein.

5. The information has been transmitted to and received by the Department of Transportation in the United States in confidence.

6. This information is not available in public sources.

7. The information contained in this affidavit is to the best of my knowledge true and correct.

Sworn before me this 2nd day of February 2006 in the City of Ottawa, Ontario, Canada.

Neil J. Gotfrit per:
Notary Public in and
for the Province of Ontario, Canada

E. S. Martell
Senior, V.P., Engineering, Development & Compliance
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MDS Nordion
Science Advancing Health

February 2, 2006

Dr. Fred Ferate
Hazardous Materials Technology
Research and Special Programs Administration
Office of Hazardous Materials Transportation
Radioactive Materials Branch
U.S. Department of Transport, Room 8430
400 7th Street, South West
Washington, D.C. 20590

Re: Request to remove conditions 1 & 2 in the Draft Safety Evaluation Report for the F-458 Family of Transport Packages, Certificate No. CDN/2078/B(U)-96, Rev1

Dear Dr. Ferate:

Further to the telephone discussions with Mr. Shawn Williams and his email of January 19, 2006, please find attached the report that provides information and justification for the removal of conditions 1 & 2 from the draft SER for the revalidation of Certificate No. CDN/2078/B(U)-96. The additional information is for Docket No. 71-3076, MDS Nordion F-458 family of transport packages, Canadian Package Design Certificate No. CDN/2078/B(U)-96.

MDS Nordion verifies the integrity of the closure system for the F-242, F-248, F-250, F-256 and F-320 through pre-shipment assembly verification which ensures that the containment system is adequately sealed and that the O-ring is properly installed, secure, and free of defects. This method for verifying that the containment system is adequately sealed is in accordance with the IAEA Transport Regulations paragraph 502 (e) and 10 CFR 71.87. MDS Nordion has shown through regulatory testing, design, manufacturing, assembly verification, operational experience and robust seal performance that pre-shipment verification provides assurance in maintaining containment of the liquid contents.

Three proprietary copies of this response have been provided with two non-proprietary copies for the Public Document Room. In addition, I have attached a copy of an affidavit to support the MDS Nordion request to withhold parts of this response from public disclosure. Parts of the report have been deleted, as they are is specific to the design and fabrication of the F-458 and would enable a third party to manufacture a similar transport package.

Yours sincerely,

Marc-André Charette
International Transport & Nuclear Initiatives
Manager, Regulatory Affairs

Attachments: Report titled, "Additional Safety Information for the F-458 Family of Transport Packages"

Engineering drawings:

F124501-029 rev M	F124501-030 rev N
F124501-004 rev S	F124701-026 rev H
F124701-009 rev K	F124701-028 rev F
F125101-022 rev L	F125101-025 rev H
F125101-024 rev D	F125101-031 rev A
F125601-001 rev H	F125601-003 rev J
F125601-004 rev J	F132001-001 rev G
F132001-002 rev D	F132001-003 rev D

Copy to: Rick Boyle, USDOT
Shawn A. Williams, Robert Nelson, USNRC
Blair Menna, Luc Desgagne, MDS Nordion

Additional Safety Information for the F-458 Family of Transport Packages

INTRODUCTION

This report provides additional safety information regarding the F-458 family of transport packages for consideration by the USNRC and USDOT. The draft Safety Evaluation Report sent to the USDOT and MDS Nordion on January 16, 2006 added two additional conditions to the revalidation of the Canadian Package Design Certificate No. CDN/2078/B(U)-96:

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.

MDSN requests that these two additional conditions be removed. In support of this request, additional information has been provided which demonstrates an equivalent level of safety for transporting liquid isotopes in the F-458 family of transport packages.

Use of Medical Isotopes in the United States

The F-458 packages will be used to transport of liquid isotopes, primarily I-131 and Mo-99, used in medical research and treatments. Molybdenum-99 (Mo-99), which decays into Technetium-99m (Tc-99m), is the most widely used diagnostic imaging isotope in nuclear medicine. Of the 40,000 nuclear medicine procedures performed each day in North America, 80% use Tc-99m. It is a versatile isotope that emits an ideal energy for high-resolution diagnostic images such as cardiac and tumour imaging, and bone scans. Tc-99m accounts for about 75% of the diagnostic imaging procedures used in nuclear medicine.

In the USA, oral administration of I-131 has been a commonly accepted procedure for treatment of benign and malignant conditions of the thyroid since the 1940s. Over 20,700 new cases of Thyroid cancer are reported per year, however the mortality rate is very low (< 6.3%), due to ready availability of I-131 therapies. Over 92,800 patients in the USA were treated in 2002 with I-131, approximately 29% for thyroid cancer, and most of the remainder for hyperthyroidism. Usage of I-131 in the US is growing by about 3-5% per year.

Unlike Tc-99 which is used typically for imaging, Yttrium-90 (Y-90) holds promise in the treatment of cancer. It emits relatively high-energy beta particles, whose range is short inside the human body. This makes Y-90 ideal for cancer therapy as the tumour can be treated with targeted radiation that does not have the side effects or invasiveness of chemotherapy or surgery. Current applications include the treatment of non-Hodgkin's lymphoma and liver cancer.

Package Contents and Shipping

The F-458 family of transport packages are Type B packages, Category II (Normal Form, between $30A_2$ and $3000A_2$ and all <1.11 PBq). The maximum allowable activity for these packages per Canadian Certificate CDN/2078/B(U)-96, is 55.5 TBq of Mo-99 (equivalent to$75A_2$, where A_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use per 10 CFR 71 Appendix A Table A-1).

Consideration should be provided to the limited radiological hazard present due to the short lived liquid contents authorized in the F-458 package. The Category II Type B, liquid contents authorized for the F-458 are short-lived isotopes with a half life of less than 8 days, with the exception of Sr-90. The half lives for the various liquid isotopes and their maximum allowable quantities are listed in Table 1. The Category II Type B quantities of the liquid isotopes are close to the upper limit for Category III Type B packages and, given the very short half-lives, the leakproof inserts should be evaluated similarly to a Category III Type B package.

Table 1. Liquid Isotopes In Leakproof Inserts

Isotope	Half Life	Max. Liq. Qty	Max. Qty / A_2 *	Type B Pkg. Category
I-125	60 days	7.4 TBq	2.5 A_2	III
I-131	8.0 days	13 TBq	18.6 A_2	III
Mo-99/Tc-99m	2.7 days	55.5 TBq	75 A_2	II
Y-90	2.7 days	16 TBq	53.3 A_2	II
Sr-90/Y-90	28 years	16 TBq	53.3 A_2	II

* A2 values taken from 10 CFR 71 Appendix A, Table A-1.

Regulatory Framework

The IAEA Safety Standards Series TS-R-1, paragraph 502 requires that "Before each shipment of any package, the following requirements shall be fulfilled: (e) For each Type B(U), Type B(M) and Type C package, it shall be ensured **by inspection and/or appropriate tests** that all closures, valve and other openings of the containment system through which the radioactive contents might escape are properly closed and, where appropriate, sealed in the manner for which the demonstrations of compliance with the requirements of paras 656 and 669 were made."

Similarly, IAEA Safety Standards Series No. TS-G-1.1, paragraph 502.6 advises that "Every Type B(U), Type B(M) and Type C package should be tested, after closure and before transport, to ensure compliance with the required leaktightness standard. Some national authorities may permit an assembly verification procedure followed by a less stringent leakage test as offering equivalent confidence in meeting the design conditions. As example of an assembly verification procedure would be: **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 opened during loading need be inspected and/or tested as part of the assembly verification procedure."**

USNRC 10 CFR Part 71.87 indicates that, "Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this part and of the license. The licensee shall determine that –

(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid."

Assembly verification of the containment system has been an accepted method over many years by the international community. The IAEA regulations and 10 CFR Part 71.87 allow inspection as an appropriate test to ensure proper closure of the containment system. TS-G-1.1 specifically describes a method of assembly verification of the containment system that is currently in use by MDS Nordion.

Assessment - Demonstrating Containment

The containment of the F-458 family of transport packages is demonstrated in three ways:

1. Regulatory Testing
2. Assurance Through Design, Manufacture, and Verification
3. Challenging Seal Performance

Regulatory testing has been performed on the F-458 family of transport packages, including drop and fire testing, followed by leak testing. Between 2000 and 2001, regulatory testing of several leakproof inserts was completed with the F-458 family of transport packages. Four F-320 leakproof inserts, inside F-458 packages, were subjected to a total of ten 1 m pin drop tests and five 9 m drop tests. One F-256 leakproof insert was subjected to an 800°C fire test. None of the final leak tests showed any evidence of leakage.

Containment is assured through a robust design for the leakproof inserts. Five different leakproof insert designs are used in the F-458: F-242, F-248, F-250, F-256 and F-320. The inserts are different sizes, but the seal geometry is the same for each. Figure 1 shows the five leakproof inserts with the caps tilted to show the O-rings, and Figure 2 shows the inserts disassembled. These inserts all incorporate a thick-walled stainless steel vessel, a screw-on cap, and are sealed with a neoprene O-ring.

[redacted] Testing has shown that the O-ring provides an effective seal even before the cap is fully installed.

The O-ring interface is shown in Figure 3. It is not possible to partially-install an O-ring – that would prevent the cap from being installed. If no O-ring were present, the operator would immediately be able to see the missing O-ring (high visual contrast of black on stainless steel). A new, greased O-ring is installed prior to loading the insert, and O-rings are never re-used. This ensures that the O-rings are in pristine condition for every shipment.

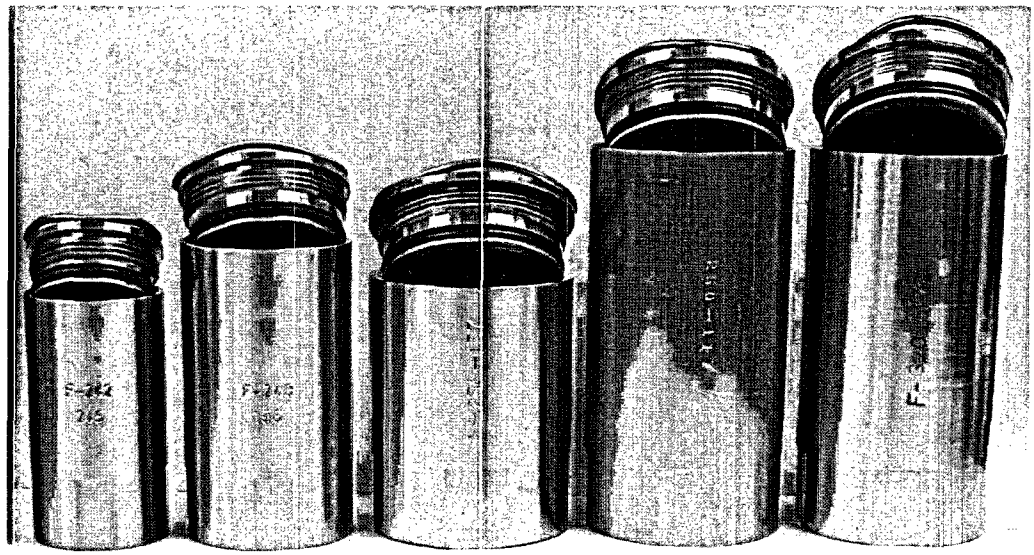


Figure 1: F-458 Leakproof Inserts (L to R): F-242, F-248, F-256, F-250, F-320

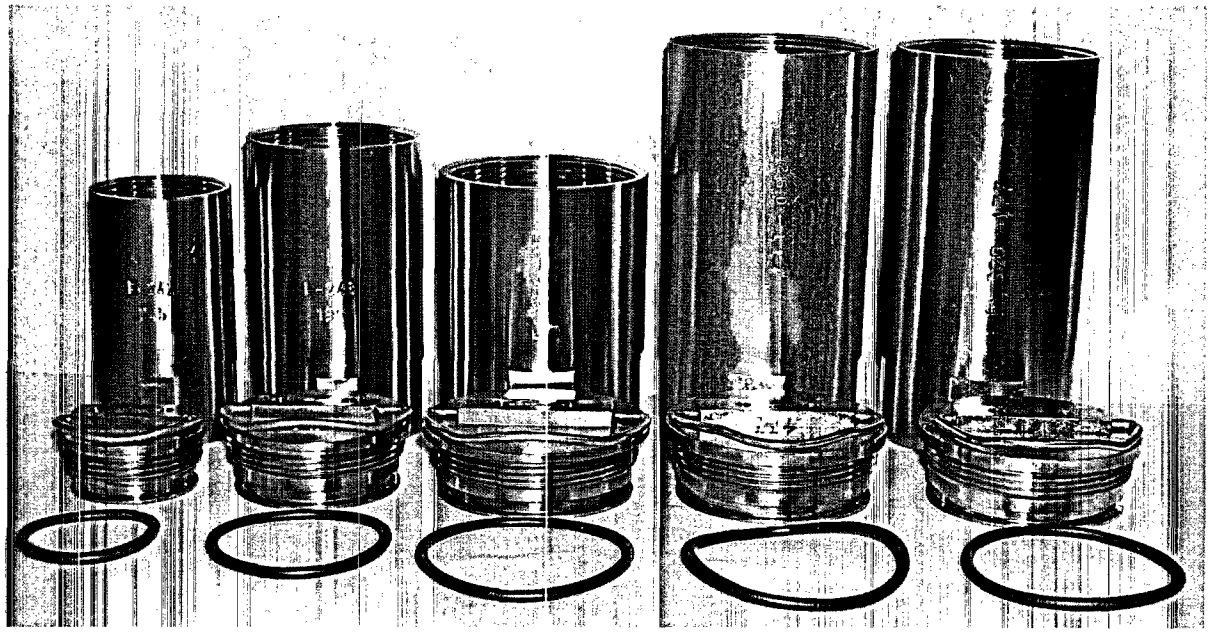


Figure 2: Inserts Disassembled (L to R): F-242, F-248, F-256, F-250, F-320

Figure 3: Leakproof Insert O-ring Interface

It is not possible to cross-thread the caps, due to the coarse thread pitch (all inserts have [redacted] threads) and long lead-in length of the cap. [redacted] With a gap of [redacted] between cap and body, the O-ring functions fully (this is the same for all inserts). This gap would be immediately obvious to the operator, and the normal installation procedure states that the cap shall bottom-out on the body (no gap). The assembled leakproof inserts are visually inspected to ensure that the cap is fully seated. A gap larger than 0.02 inch would be identified. Therefore it is assured that all leakproof inserts are assembled properly prior to shipment.

Engineering drawings of each insert are attached. Table 2 summarizes the dimensions of the leakproof inserts. As shown in Table 2, all the inserts (F-242, F-248, F-250, F-256 and F-320) have similar dimensions. The geometry of all the O-ring interfaces is similar. Tests validating the leak-tightness of the F-256 and F-320 inserts can reasonably be extrapolated to the other leakproof inserts listed in Table 2.

Table 2. Leakproof Insert Dimensions

LPI Model:	F-242	F-248	F-250	F-256	F-320
Outside Height	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Outside Diameter	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Thread	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
O-ring spec	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
O-ring width	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Min. O-ring compression	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Max. O-Ring compression	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
O-ring material	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Insert body material	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Insert cap material	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Manufacturing quality of these leakproof inserts is assured via the engineering drawings (attached) and quality assurance. [redacted] Every component is given a detailed inspection (including hydrostatic leak testing and helium leak testing) before entering service. It is thereby assured that the manufacturing is compliant.

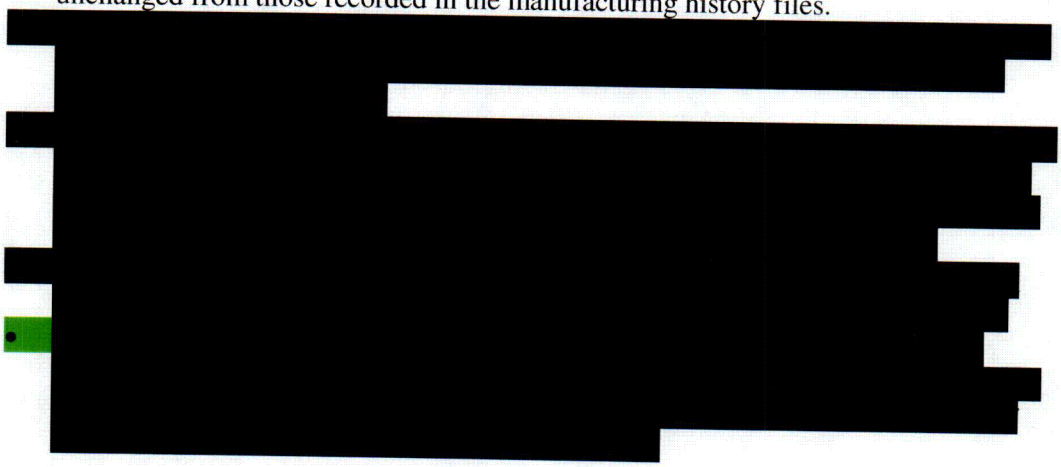
Additionally, assurance of containment is achieved through verification. Prior to every shipment, new O-rings are greased and installed by hand by trained operators. A test assembly is done before the inserts are introduced into the cell. After dispensing within the cell, the insert cap is tightened using an electrical motor, which is stopped once the cap is fully engaged. The loaded insert is visually inspected to ensure that it was assembled properly, before leaving the cell. Leakproof inserts are given a thorough cleaning and visual examination after returning from every shipment. If any defect is suspected, the unit is sent for detailed inspection.

On a yearly basis or if defects are suspected, detailed inspections are performed on the leakproof inserts. Tests include hydrostatic leak testing and helium leak testing (as of 2003, helium leak

testing replaced vacuum bubble leak testing as the primary leak-tightness validation method). Any test failures would result in the unit being removed from service.

Finally, the robustness of the O-ring seal has been assured by challenging the seal performance. In 2001, eight F-256 inserts were taken at random from the available inventory. The sample group represented two lots of inserts manufactured by two different suppliers, with three in service since 1992, and five since 1999. Shipping data showed them to have been used 164 times in the previous five years, approximately 6 times per year. Each had been inspected after each shipment, and had gone through annual leak testing. No defects were identified during any of the following tests:

- A dimensional inspection of the eight F-256 inserts showed all seal dimensions were in conformance with the current engineering drawings. Variation in seal compression was found to be about 0.001 inch (0.025 mm) between the eight inserts, with a nominal compression of 0.014 inch (0.36 mm). The dimensions were unchanged from those recorded in the manufacturing history files.



Through challenging the performance of the O-ring seal and finding no increase in leak rate, the results support the conclusion that the leakproof insert design is robust. This ensures containment, even in less-than-optimal circumstances.

Assessment - Operational experience

Almost 10,000 shipments have been made using the F-242, F-248, F-250, F-256 and F-320 in the past 5 years without a single complaint regarding loss of containment. During that same period, over 1300 vacuum bubble tests and more than 400 helium leak tests have been successfully completed.

In 2003, MDSN implemented an updated helium leak testing procedure for all leakproof inserts as the primary method to validate leak-tightness. Inspection of all units in service has shown them to remain leaktight, after up to 10 years of service, to a sensitivity of 1×10^{-8} std cc/s. This confirms the robustness of the design under long-term operating conditions.

Testing cannot practically be completed on a loaded leakproof insert due to high radiation levels. Testing within hot cells is not practical, due to the volatility of some of the products, the potential for increased contamination, and deterioration of test equipment due to radiation.

If pre-shipment testing were performed on the vessels outside the hot cell, this would result in an estimated operational dose of 500 mrem. Furthermore, introduction of this additional test would bottleneck operations and complicate logistics. The additional time required for testing would jeopardize the delivery of time-sensitive products. (Currently most shipments are delivered within one day.)

Conclusion

Regulatory testing and validation tests have repeatedly demonstrated the integrity of the leakproof insert seal. Multiple drop tests and a fire test completed on the same units have shown no deterioration of seal performance. Inspection of all units in service has shown them to remain leaktight, after as much as 10 years of service.

The combination of design and manufacturing controls, demonstrated seal performance, operational experience and pre-shipment inspection shows that the leakproof inserts reliably retain their contents.

This system of pre-shipment verification for the F-242, F-248, F-250, F-256 and F-320 ensures that the containment system for the liquid contents is adequately sealed, the O-ring is properly installed, secure, and free of defects.