SAFETY EVALUATION REPORT
Docket No. 71-9378
Model No. OP-RMSC
Certificate of Compliance No. 9378
Revision No. 0

Office of Nuclear Material Safety and Safeguards
United States Nuclear Regulatory Commission

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SUMMARY

By letter dated December 18, 2020, as supplemented August 3, 2021, August 31, 2021, September 27, 2021, and November 1, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML20363A167, ML21216A176, ML21216A179, ML21291A176, and ML21334A355, respectively), Industrial Nuclear Company, Inc. (INC or the applicant) submitted a request to the U.S. Nuclear Regulatory Commission (NRC) for a new certificate of compliance (CoC) for the Outer Package-Raw Material Shipping Container (OP-RMSC) package, Model No. OP-RMSC, CoC No. 9378, as a Type B(U)-96 package. The package was evaluated against the regulatory standards in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, including the general standards for all packages and the performance standards under normal conditions of transport (NCT) and hypothetical accident conditions (HAC). The analyses performed by the applicant demonstrate that the package provides adequate structural, materials, and thermal protection to meet the containment and shielding requirements after being subjected to the tests for NCT and HAC. NRC staff (staff) reviewed the safety analysis report (SAR) submitted with the application using the guidance in NUREG-2216, "Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material." Based on the statements and representations in the application, as supplemented, staff finds that the package meets the requirements of 10 CFR Part 71. The November 1, 2021 submittal, Revision 4 of the SAR, contained a consolidated SAR.

1.0 GENERAL INFORMATION

1.1 Packaging

The OP-RMSC is a Type B(U)-96 package designed for transportation of only special form radioactive materials, which are contained in the Raw Material Shipping Container (RMSC) payload. The OP-RMSC is designed to transport the RMSC payload which carries up to four raw material special form capsules. The maximum gross weight of the package is 650 pounds. The OP-RMSC package is comprised of three major components: 1) the outer packaging, also referred to as the OP-RMSC, 2) the RMSC, and 3) the RMSC special form capsule holder. Both the OP-RMSC and the RMSC payload consist of a welded cylindrical shell with bolted closure lids. The OP-RMSC's outer packaging consists of four major fabricated components: 1) a welded, outer stainless-steel pipe assembly that is welded to an inner stainless-steel pipe which forms a cavity for the RMSC payload, 2) a bolted vented, outer closure lid that is secured to the outer pipe, 3) a bolted inner closure lid that covers the RMSC payload cavity, and 4) polyurethane foam that fills the cavity formed by the inner and outer pipes and their stainless steel end plates. The RMSC payload consists of four major fabricated components: 1) a welded stainless-steel pipe assembly welded to a stainless steel baseplate and to a smaller pipe assembly, which extends a short distance into the cavity of the larger, outer pipe, 2) a top piece of tungsten shielding that sits in the inner pipe and covers and shields the top of the cavity for the special form radioactive material contents, 3) a solid bolted closure lid that covers and secures the tungsten shield, and 4) a fixed tungsten shield that fills the lower portion of the RMSC and forms the wall and base of the cavity for the special form contents and that also extends into the cavity between the outer pipe and inner pipe assemblies in the upper portion of the RMSC. All welding procedures and welding personnel are qualified in accordance with Section IX of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code.

The OP-RMSC package is secured to a pallet for transport by straps, cargo net, or other standard tie-down equipment that does not attach to the package. The package does not have a pressure boundary. The OP-RMSC package outer closure lid is fitted with a 3/8-16 UNC threaded hole to attach a standard lifting device to facilitate handling.

The applicant provided licensing drawings with tolerances, dimensions, welding symbols and definitions, material designations, and associated standards. The applicant described and detailed the component description and arrangement of components relative to each other. The applicant described the weight of the package with its contents as well as the overall physical dimensions of the package. The applicant presented the package dimensions in Drawing No. OP-RMSC-SAR-TA, Sheets 1-4, Rev. 1 and Drawing No. RMSC-SAR-TA Sheets 1-3, Rev. 2. The applicant also presented information, including relevant dimensions, about the capsule holder used with (as part of) the package in Drawing No. RMSC-SPFH-SAR, Sheet 1, Rev. 0.

1.2 Contents

The contents of the OP-RMSC packaging consists of up to four raw material special form capsules, each containing a maximum of 4,000 Ci (148 TBq) of Ir-192, or 4,000 Ci (148 TBq) of Se-75. For the total four raw material special form capsules, the maximum radioactive content for the OP-RMSC package is 16,000 Ci (592 TBq).

1.3 Drawings

The package is constructed and assembled in accordance with the following drawings:

OP-RMSC-SAR-TA, sheets 1-4, Rev. 1

RMSC-SAR-TA, sheets 1-3, Rev. 2

RMSC-SPFH-SAR, sheet 1, Rev. 0

1.4 Evaluation Findings

The staff reviewed the information presented in the application and, based upon that review together with the reviews described in the other chapters of this SER, finds that the following criteria have been met:

F1-1 The application describes the package in sufficient detail to provide an adequate basis for its evaluation.

F1-2 The drawings contain information that provide an adequate basis for evaluation against 10 CFR Part 71 requirements. Each drawing is identified, consistent with the text of the application, and contains keys or annotations to explain and clarify information on the drawing.

F1-3 The application for package approval includes a reference to the applicant’s approved quality assurance program.

F1-4 The application for package approval identifies applicable codes and standards for the package design, fabrication, assembly, testing, maintenance, and use.

F1-5 The drawings submitted with the application provide a detailed packaging description that can be evaluated for compliance with 10 CFR Part 71 for each of the technical disciplines.

F1-6 The application specifies any restrictions on the use of the package.

Based on a review of the statements and representations in the application, staff concludes that the package description meets the requirements of 10 CFR Part 71.

2.0 STRUCTURAL EVALUATION

The objective of the structural evaluation is to verify that the applicant has adequately evaluated the structural performance of the package (packaging together with contents) and demonstrated that it meets the regulations in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".

2.1 Special Form Radioactive Material

The applicant designed the OP-RMSC package to transport only special form radioactive material as discussed in SAR Section 2.10. The staff's review and potential issuance of a Certificate of Compliance for the OP-RMSC package does not address the qualification of the special form radioactive material contents. While the special form radioactive material contents are qualified separately from this review, the qualification of special form radioactive material is important to understanding the staff's review of the OP-RMSC package and the design criteria of the OP-RMSC package, which is primarily to provide shielding for the special form radioactive material contents. This Section presents the qualifications of special form radioactive material required by 10 CFR Part 71 for reference in other sections of this report.

10 CFR 71.75 describes the requirements and qualifications for special form radioactive material. The regulations require special form radioactive material be subjected to an impact test consisting of a 30-foot drop onto a bounding rigid surface. The regulations require special form radioactive material be subjected to a percussion test consisting of a strike with a flat steel billet to produce an impact equivalent to a free drop of 40 inches. The regulations also require special form radioactive material be subjected to a bending test, a heat test at temperatures of 1,475 °F, and a leaching test by submerging the special form material in water for 7 days.

2.2 General Requirements

2.2.1 Minimum Package Size

Given that the minimum package dimension is greater than 10 cm, the staff finds that the package satisfies the requirements of 10 CFR 71.43(a) for minimum size.

2.2.2 Tamper-Indicating Feature

The closure of the package is facilitated by a tamper indicating seal (i.e., wire/lead security seal) attached to a pair of the closure lid bolts on the outer lid of the OP-RMSC package. The seal provides visual evidence that the closure lid was not tampered with. As a result, the staff reviewed the package closure description and finds that the package satisfies the requirements of 10 CFR 71.43(b) for a tamper-indicating feature.

2.2.3 Positive Closure

Positive closure of the package is facilitated by the bolted closure lid with a required bolt preload. Hence, the OP-RMSC package cannot be opened inadvertently. The staff reviewed the package closure description and finds that the package satisfies the requirements of 10 CFR 71.43(c) for positive closure.

2.2.4 Package Valve

The OP-RMSC package is a confinement system and designed to transport only special form radioactive materials. There are no valves or other pressure retaining device on the package. The staff reviewed the package closure description of the package and finds that it satisfies 10 CFR 71.43(e).

2.3 Lifting and Tie-Down Standards

2.3.1 Lifting Devices

The applicant describes lifting and handling in the SAR Section 2.5.1. The OP-RMSC package is lifted by attaching a standard lift ring or other standard lifting component to the 3/8-16 UNC-2B threaded hole in the center of the 0.75-inch-thick closure lid. The package gross weight is 650 lbs. The applicant used 700 lbs at 400 °F conservatively to calculate factor of safety for lifting. The calculated factor of safety was 5.51, which is greater than the factor of three against yielding required by 10 CFR Part 71. Based on the applicant's calculations reviewed by staff, the staff concludes that the requirements of 10 CFR 71.45(a) for lifting have been satisfied.

2.3.2 Tie-Down Devices

The package is secured to a pallet for transport by straps, cargo net, or another standard tie-down equipment that does not attach to the package. The 3/8-16 UNC threaded hole in the closure lid that is utilized for lifting is disabled during transport. The staff finds that the package design does not have any structural tie-down devices, and therefore, the OP-RMSC package satisfies the requirements of 10 CFR 71.45(b).

2.4 General Considerations for Structural Evaluation of Packaging

The applicant evaluated the package with full-scale drop testing to determine the structural integrity of the package after being subjected to both NCT and HAC conditions. As described in the SAR Section 2.12, "Appendix", prior to free drop and puncture testing, the applicant loaded the two RMSC certified test units (CTUs) with dummy raw material source capsules and a holder to simulate the special form capsules. The OP-RMSC is qualified primarily by full-scale testing, with acceptance criteria being the ability to demonstrate shield integrity. The applicant considered two main potential failure modes for the package: 1) failure of both the inner and outer lids of the OP-RMSC allowing the RMSC payload to evacuate the OP-RMSC and sustain damage which could affect the shielding components contained within the RMSC payload; or 2) failure of the closure lid of the RMSC payload allowing the shielding components to separate from the special form radioactive material source.

The staff reviewed the application and finds that the package was evaluated by subjecting a specimen in a manner acceptable to the Commission, and therefore satisfies the requirements of 10 CFR 71.41(a).

2.4.1 Drop Testing Campaign

The applicant performed a series of physical tests on the OP-RMSC package to evaluate the package for the 10 CFR Part 71 NCT and HAC. The testing campaign subjected two OP-RMSC packages to a series of tests covering the NCT free drop, the HAC free drop, and the HAC puncture tests in various orientations. Following each test, the applicant evaluated the OP-RMSC test specimens against the two potential failure modes developed based on the safety function of the components of the OP-RMSC package, which is primarily relied upon to provide shielding to the special form radioactive material source.

For the NCT and HAC drop tests, the applicant used a target of a horizontal concrete slab approximately 9 to 12 inches thick, 10 feet wide, and 15 feet long with a 2 in by 48 in^2 steel plate grouted and secured to the pad by four 0.625-inch anchor bolts and 5-inch thick steel plate welded to the 2-inch thick plate. For the HAC puncture tests, the applicant constructed a target consisting of a 6-inch diameter, 25-inch long bar welded to a 0.75-inch thick steel plate. The top of the bar was rounded to a maximum radius of 0.25 inches. Following the free drop tests, the 0.75-inch thick plate with the bar was placed on top of the drop test target (i.e., the 5-inch thick steel plate, 2-inch thick plate, and concrete pad) and welded in place.

The 10 CFR Part 71 free drop and puncture tests require the package to be tested in orientations that are expected to cause maximum damage to the package. The applicant identified three orientations for the free drop testing of the package to ensure bounding results with maximum damage were achieved: 1) a top-down drop orientation with the package's outer closure lid striking the target; 2) a side drop; and 3) a top corner drop orientation with the package's center of gravity positioned directly above the top corner of the package when striking the target. The applicant performed the HAC puncture testing for the three orientations to demonstrate the cumulative effect of the puncture drop with the free drop tests in those orientations. The staff reviewed the applicant's description of the orientations chosen for the drop test campaign and concludes that the drop orientations considered in the evaluation are the most damaging for the OP-RMSC package. The staff finds that the top-down, side, and top corner drop orientations produce the greatest accelerations for impact analysis and target the vulnerable components of the package considering the structural failure modes. Thus, the staff finds that the applicant evaluated the critical free-drop orientations for the OP-RMSC package consistent with guidance in Section 2.4.4.2 of NUREG-2216.

The applicant conducted two sequences of testing on two separate OP-RMSC packages, denoted Certified Test Unit 1 (CTU-1) and Certified Test Unit 2 (CTU-2). The applicant subjected CTU-1 to the 4 ft NCT free drop in the top-down orientation, followed by the 30 ft HAC free drop in the top-down orientation, and then the 40-inch HAC puncture drop in the top-down orientation. The applicant subjected CTU-2 to the 30 ft HAC free drop in the side drop orientation, followed by the 30 ft HAC free drop in the top corner drop orientation, followed by the 40-inch HAC puncture drop in the side drop orientation, and then the 40-inch HAC puncture drop in the top corner orientation. Following each drop, the applicant assessed and recorded the damage to the package. Following the full sequence of tests for the specimen, the applicant conducted radiation surveys and then dissembled the package and conducted a detailed assessment of the cumulative damage. The staff's review of the results of these tests are discussed in the applicable NCT and HAC sections of Chapter 2 of this SER.

The staff reviewed the applicant's description of the drop test campaign and finds that the evaluation of the package by testing is consistent with the guidance in Section 2.4.4.2 of NUREG-2216 and meets the requirements of 10 CFR 71.41(a).

2.5 Normal Conditions of Transport

2.5.1 Heat

The applicant discussed the NCT heat analyses in SAR Section 2.6.1 and further evaluated it in SAR Section 3.3.1. The applicant determined that the maximum temperature of the stainless-steel structural components for the NCT heat test is 407 °F. The OP-RMSC package was exposed to temperatures over 200 °F for several days in an environmental chamber for the certification drop testing with no detrimental effects to the package. The applicant noted that there is only a slight reduction in the minimum ultimate strength of the stainless-steel structural components up to 500 °F. The applicant concluded that the NCT heat test would not affect the operational capability of the package or result in structural damage.

The applicant evaluated the effects of differential thermal expansion for the HAC thermal test in SAR Section 2.7.4. The staff's review of the differential thermal expansion analysis is discussed in Section 2.6.4 of this report. The applicant's assessment and analysis of differential thermal expansion at the higher HAC thermal test temperatures concluded that the package would not experience increased stresses in structural components of the package from differential thermal expansion. The staff finds that the conclusions of the differential thermal expansion evaluation for the HAC thermal test are sufficient to demonstrate that differential thermal expansion will not increase stresses in structural components of the package at the lower NCT heat test temperatures.

Based on the applicant's assessment of the NCT heat test temperatures on the materials of construction and structural performance of the package, evaluation of differential thermal expansion, further thermal analysis in SAR Section 3.3.1 and staff analysis in SER section 3.3.1, the staff concludes that, in aggregate, the OP-RMSC package meets the requirements of 10 CFR 71.71(c)(1).

2.5.2 Cold

The applicant discussed the NCT cold analyses in SAR Section 2.6.2 and further evaluated it in SAR Section 3.3.1. The applicant stated that the OP-RMSC package was subjected to subzero temperatures for several days in an environmental chamber. Following this test, the applicant observed no detrimental effects to the package.

Based on the applicant's demonstration of the NCT cold analysis, materials of construction, structural performance of the package, further thermal analysis in SAR Section 3.3.1, and NRC staff evaluation in SER Section 3.3.1, the staff concludes that, in aggregate, the OP-RMSC package meets the requirements of 10 CFR 71.71(c)(2).

2.5.3 Reduced External Pressure

The applicant noted that the package is designed to maintain confinement and shielding of special form radioactive material content and does not have a pressure boundary. The applicant concluded through engineering judgment that the reduced external pressure test would not meaningfully challenge the structure.

The staff notes that the design of the OP-RMSC package does not provide any seal or pressure boundary and incorporates open features like the wire screens which encompass much of the area of the outer lid of the OP-RMSC. The staff finds that these design features are sufficient to prevent the pressure differential of the reduced external pressure test from inducing meaningful stresses in the structural components of the OP-RMSC package. The staff notes that the primary safety function of the package is to provide shielding to the special form radioactive material. The staff also considered the special form radioactive material qualifications, discussed in Section 2.1 of this report. While the qualifications for the special form content do not require the content be exposed to an external pressure test, the required impact and percussion tests do provide some meaningful assurance of the special form radioactive material's structural ability to withstand stresses.

The staff finds that the applicant's assessment of the reduced external pressure, the design features of the package, and consideration of the special form radioactive material qualifications are adequate to demonstrate that the OP-RMSC package passes the reduced external pressure test through reasoned argument and meets the requirements of 10 CFR 71.71(c)(3).

2.5.4 Increased External Pressure

As with the reduced external pressure test, the applicant noted that the package is designed to maintain confinement and shielding of special form radioactive material content and does not have a pressure boundary. The applicant concluded through engineering judgment that the increased external pressure test would not meaningfully challenge the structure of the package.

The staff notes that the design of the OP-RMSC package does not provide any seal or pressure boundary and incorporates open features like the wire screens which encompass much of the area of the outer lid of the OP-RMSC. The staff finds that these design features are sufficient to prevent the pressure differential of the increased external pressure test from inducing meaningful stresses in the structural components of the OP-RMSC package. The staff notes that the primary safety function of the package is to provide shielding to the special form radioactive material. The staff also considered the special form radioactive material qualifications, discussed in Section 2.1 of this report. While the qualifications for the special form content do not require the content be exposed to an external pressure test, the required impact and percussion tests do provide some meaningful assurance of the special form radioactive material's structural ability to withstand stresses.

The staff finds that the applicant's assessment of the increased external pressure, the design features of the package, and consideration of the special form radioactive material qualifications are adequate to demonstrate that the OP-RMSC package passes the increased external pressure test through reasoned argument and meets the requirements of 10 CFR 71.71(c)(4).

2.5.5 Vibration

The inner and outer lids of the OP-RMSC package are secured with eight 1/2-inch diameter hex head bolts tightened to a minimum torque of 75 lb-ft. The closure lid for the RMSC payload is secured with six 3/8-inch bolts tightened to a minimum torque of 35 lb-ft. The applicant considered that these bolt preloads and the rigidity of the package, demonstrated by the physical drop testing, would prevent the package from experiencing any detrimental effects caused by vibrations incident to normal conditions of transport.

The staff notes that components of the package are not highly stressed under the NCT and finds that the package is not significantly susceptible to failure due to any increased stresses of fatigue caused by vibrations. The staff finds the preload specified for the bolts sufficient to prevent loosening as a result of vibrations. The staff finds that the structural design of the package and the bolt preload adequately address the effects of vibrations normally incident to transport for the OP-RMSC package and are consistent with guidance in Section 2.4.5.5 of NUREG-2216.

The staff also considered the special form radioactive material qualifications, discussed in Section 2.1 of this SER. While the qualifications for the special form payload do not require the payload be exposed to a vibration test, the required impact and percussion tests do provide some meaningful assurance of the payload's structural ability to withstand stresses.

The staff finds that the applicant's assessment of vibrations, the design features of the package, and consideration of the special form radioactive material qualifications are adequate to demonstrate that the OP-RMSC package passes the vibration test through reasoned argument and meets the requirements of 10 CFR 71.71(c)(5).

2.5.6 Water Spray

The applicant noted that the exterior of the OP-RMSC package is constructed of stainless-steel, and as such the water spray test will have a negligible effect on the package. The staff finds this consideration an acceptable evaluation of the requirements of 10 CFR 71.71(c)(6) and the package has been shown to pass the water spray test through sufficient reasoned argument.

2.5.7 Free Drop

The applicant described the evaluation of the NCT free drop in SAR Section 2.6.7 with further detail in SAR Appendix 2.12. Since the OP-RMSC package is less than 11,000 pounds, the free drop test requires the package be subjected to a 4-foot drop onto a flat, essentially unyielding surface in an orientation causing maximum damage. The staff's review of the details and methodology of the drop testing regimen are discussed in Section 2.4.1 of this report. The applicant observed no significant deformation to the package following the NCT free drop test.

Following the entire certification regimen, the applicant performed a radiation survey which demonstrated that the OP-RMSC packaging was able to maintain its shielding function. The applicant concluded that the package maintained its confinement integrity given the results of the radiation survey and the survey of damage following the NCT drop test. Following the NCT free drop, the applicant subjected the test specimen to the HAC free drop discussed in Section 2.6.1 of this report.

The staff reviewed the test procedures and results of the NCT free drop test performed on the OP-RMSC package. Based on the results of the physical NCT drop test, the staff finds that the package meets the requirements of 10 CFR 71.71(c)(7).

2.5.8 Corner Drop

The corner drop test does not apply to the OP-RMSC package since the package does not incorporate fiberboard or wood in its design and will not contain fissile material in accordance with 10 CFR 71.71(c)(8).

2.5.9 Compression

As discussed in SAR Section 2.6.9, the applicant subjected the package to a 3,390-pound force, which is greater than five times the gross package weight for a 24-hour period. The applicant observed no structural deformation following the compression test. The staff finds that this physical compression test and the qualitative, observed results are sufficient to satisfy the requirements of 10 CFR 71.71(c)(9) for the OP-RMSC package.

2.5.10 Penetration

The applicant considered the NCT penetration test described in 10 CFR 71.71(c)(10) which evaluates the impact of a 1.25-inch diameter, 13-pound steel cylinder dropped from a height of 40 inches onto the most vulnerable, exposed surface of the package. For the OP-RMSC package, the applicant judged the most vulnerable, exposed surface to be a section of the outer lid. The applicant stated in the September 20, 2021 response to the NRC's RAI (ADAMS Accession No. ML21216A178), response to RAI 2.1, that "the penetration bar could potentially strike the wire screen on the OP-RMSC outer lid and strike the 3/8-inch thick inner lid. However, the remaining impact energy from the steel rod would not cause any damage to the inner lid or any other component of the OP-RMSC package." From this assessment, the applicant concluded the effects of the NCT puncture test would be negligible for the OP-RMSC package.

The staff considered this assessment as well as the multiple layers of packaging which provide defense in depth against the effects of a dropped cylinder. These layers of packaging consist of an outer closure lid with wire screen and inner closure lid on the OP-RMSC package and a closure lid on the RMSC payload, which contains the shielding and special form radioactive material content. The staff notes that the primary safety function of the OP-RMSC package is to provide shielding to the special form radioactive material.

The staff finds that the applicant's assessment of the penetration test and the design features of the package are adequate to demonstrate that the OP-RMSC package passes the penetration test through reasoned argument and meets the requirements of 10 CFR 71.71(c)(10).

2.5.11 NCT Conclusion

The staff reviewed the structural performance of the packaging under the normal conditions of transport prescribed in 10 CFR 71.71 and concludes that there is no substantial reduction in the structural effectiveness of the packaging that would prevent it from satisfying the requirements of 10 CFR 71.51(a)(1) for a Type B package.

2.6 Hypothetical Accident Conditions

2.6.1 Free Drop

The applicant described the evaluation of the HAC free drop in SAR Section 2.7.1 with further detail in SAR Appendix 2.12. The applicant subjected the OP-RMSC package to physical free drop testing through a distance of 30 ft onto a flat, essentially unyielding surface in an orientation causing maximum damage. The staff's review of the details and methodology of the drop testing regimen are discussed in Section 2.4.1 of this report.

Following the HAC free drop test in the top-down orientation, the applicant observed no significant damage to the exterior of the package. The bolts of the inner OP-RMSC lid failed allowing the inner lid to contact the outer lid. However, the RMSC payload remained inside its cavity in the OP-RMSC package, and the applicant observed no damage to the RMSC payload. Following the HAC free drop in the side drop orientation, the applicant noted flattening of the exterior of the package, roughly 4 inches in width, and the failure of one closure bolt on the outer lid. Following the side drop, the applicant subjected the same package specimen to the

HAC free drop in the top corner drop orientation. From the top corner free drop, the applicant noted a deformation of the corner extending 0.5 inch down the length of the outer shell of the package. The top corner drop resulted in failure of five bolts in the outer closure lid. The failure of these five bolts was in addition to the failure of the single outer lid bolt from the side drop; leaving only two bolts intact securing the outer closure lid. However, the outer lid did not separate from the package.

Following the entire certification regimen, the applicant performed a radiation survey which demonstrated that the OP-RMSC packaging was able to maintain its shielding function. The applicant concluded that the package maintained its confinement integrity given the results of the radiation survey and the survey of damage following the HAC drop tests. Following the HAC free drop, the applicant subjected the test specimen to the HAC puncture drop tests discussed in Section 2.6.3 of this report.

The staff reviewed the test procedures and results of the HAC free drop tests performed on the OP-RMSC package. Based on the results of the physical HAC drop tests, the staff finds that the package meets the requirements of 10 CFR 71.73(c)(1).

2.6.2 Crush

The HAC crush test is not required for the package, since the OP-RMSC package has a weight less than 1,100 lb, a density greater than 62.4 lbm/ft^3, and the package contents are special form. The staff finds this consistent with the requirements of 10 CFR 71.73(c)(2).

2.6.3 Puncture

The applicant described the evaluation of the HAC puncture drop in SAR Section 2.7.2 with further detail in SAR Appendix 2.12. The applicant subjected the OP-RMSC package to physical puncture drop testing through a distance of 40 inches onto an appropriate HAC puncture test target in an orientation causing maximum damage. The staff's review of the details and methodology of the drop testing regimen are discussed in Section 2.4.1 of this report.

Following the HAC puncture drop test in the top-down orientation, the applicant observed no additional damage to the package, beyond the damage suffered in the top-down free drop test. Following the HAC puncture drop in the side drop orientation, the applicant noted only small deformation to the outer shell of the OP-RMSC package, beyond the damage suffered in the previous side drop and top corner drop HAC free drop tests. Following the HAC puncture drop in the side drop orientation, the applicant subjected the same package specimen to the HAC puncture drop in the top corner drop orientation. From the top corner puncture drop, the applicant noted a small deformation of the corner in addition to the damage resulting from previous side orientation free drop, top corner orientation free drop, and side orientation puncture drop.

Following the entire certification regimen, the applicant performed a radiation survey which demonstrated that the OP-RMSC packaging was able to maintain its shielding function. The applicant concluded that the package maintained its confinement integrity given the results of the radiation survey and the survey of damage following the HAC drop tests.

The staff reviewed the test procedures and results of the HAC puncture drop tests performed on the OP-RMSC package. Based on the results of the physical HAC puncture tests, the staff finds that the package meets the requirements of 10 CFR 71.73(c)(3).

2.6.4 Thermal

The HAC thermal test of 10 CFR 71.73(c)(4) requires the package to be exposed to a 1,475 ºF fire for 30 minutes. The applicant described the assessment of the HAC thermal test in SAR Section 2.7.4. The applicant noted that all the materials that comprise the structural and shielding components of the OP-RMSC package and the RMSC payload have melting temperatures that are significantly higher than the specified 1,475 ºF temperature of the HAC thermal test. The applicant also calculated the effects of differential thermal expansion experienced during the HAC thermal test in SAR Section 2.7.4. Particularly, the applicant focused on the differential thermal expansion between the bolts and the lids of the OP-RMSC package. The analysis demonstrated that no tensile stresses developed in any bolts due to the differential thermal expansion from the HAC thermal test temperatures. The applicant concluded that these assessments demonstrate that the HAC thermal test would not affect the safety function of the structural components of the package to maintain confinement or the shielding components of the package to provide gamma shielding.

Based on the results of the differential thermal expansion analysis and the applicant's assessment of the effects of the HAC thermal test temperatures on the structural and shielding materials of the package components, the staff finds that the OP-RMSC package meets requirements of 10 CFR 71.73 (c)(4) for the thermal test.

2.6.5 Immersion - Fissile Material

The fissile material immersion test does not apply to the OP-RMSC package since the package will not contain fissile material in accordance with 10 CFR 71.73(c)(5).

2.6.6 Immersion - All Packages

The applicant noted that the package is designed to maintain confinement and shielding of special form radioactive material content and does not have a pressure boundary. The applicant concluded through engineering judgment that the HAC immersion test for all packages would not meaningfully challenge the structure of the package.

The staff notes that the design of the OP-RMSC package does not provide any seal or pressure boundary and incorporates open features like the wire screens which encompass much of the area of the outer lid of the OP-RMSC. The staff finds that these design features are sufficient to prevent the pressure differential of the immersion test from inducing meaningful stresses in the structural components of the OP-RMSC package. The staff notes that the primary safety function of the package is to provide shielding to the special form radioactive material. The staff also considered the special form radioactive material qualifications, discussed in Section 2.1 of this report. The special form radioactive material qualifications require an impact and percussion tests that provide some meaningful assurance of the special form radioactive material's structural ability to withstand stresses.

The staff finds that the applicant's assessment of the immersion test, the design features of the package, and consideration of the special form radioactive material qualifications are adequate to demonstrate that the OP-RMSC package passes the immersion test for all packages through reasoned argument and meets the requirements of 10 CFR 71.73(c)(6).

2.6.7 Hypothetical Accident Conditions Conclusion

The staff has reviewed the structural performance of the packaging under the HAC prescribed in 10 CFR 71.73 and concludes that there is no substantial reduction in the structural effectiveness of the packaging that would prevent it from satisfying the requirements of 10 CFR 71.51(a)(2) for a Type B package.

2.7 Special Requirement for Type B Packages Containing More Than 10^5 A_2

The immersion test for Type B packages containing more than 10^5 A_2 does not apply to the OP-RMSC package, because the total activity of the package is not more than 10^5 A_2 in accordance with 10 CFR 71.61.

2.8 Evaluation Findings

F2-1 The staff has reviewed the package structural design description and concludes that the contents of the application satisfy the requirements of 10 CFR 71.31(a)(1) and (a)(2) as well as 10 CFR 71.33(a) and (b).

F2-2 The staff has reviewed the structural codes and standards used in package design and finds that they are acceptable and therefore satisfy the requirements of 10 CFR 71.31(c).

F2-3 The staff has reviewed the lifting and tie-down systems for the package and concludes that they satisfy the standards of 10 CFR 71.45(a) for lifting and 10 CFR 71.45(b) for tie-down.

F2-4 The staff has reviewed the package description and finds that the package satisfies the requirements of 10 CFR 71.43(a) for minimum size.

F2-5 The staff reviewed the package closure description and finds that the package satisfies the requirements of 10 CFR 71.43(b) for a tamper-indicating feature.

F2-6 The staff reviewed the package description and finds that the package does not contain a valve and therefore satisfies the requirements of 10 CFR 71.43(e).

F2-7 The staff reviewed the application and finds that the package was evaluated by subjecting a specimen to the specific tests and by other methods of demonstration acceptable to the Commission, and therefore satisfies the requirements of 10 CFR 71.41(a).

F2-8 The staff reviewed the structural performance of the packaging under the normal conditions of transport required by 10 CFR 71.71 and concludes that there will be no substantial reduction in the effectiveness of the packaging that would prevent it from satisfying the requirements of 10 CFR 71.51(a)(1) for a Type B package.

F2-9 The staff reviewed the structural performance of the packaging under the hypothetical accident conditions required by 10 CFR 71.73 and concludes that the packaging has adequate structural integrity to satisfy the shielding requirements of 10 CFR 71.51(a)(2) for a Type B package.

Based on a review of the statements and representations in the application, the NRC staff concludes that the structural design of the OP-RMSC package has been adequately described and evaluated and that the package has adequate structural integrity to meet the requirements of 10 CFR Part 71.

3.0 THERMAL EVALUATION

The purpose of this evaluation is to verify that the OP-RMSC package, as a byproduct material transportation package:

1) provides adequate protection against the thermal tests specified in 10 CFR Part 71, and

2) meets the thermal performance requirements of 10 CFR Part 71.

The thermal review is to ensure that the package component temperatures are below the allowable limits and the temperature gradients within the package components are minimized to reduce the thermal stresses under NCT and HAC.

3.1 Description of Thermal Design

The applicant stated, in SAR Section 3.1, "Description of Thermal Design," that the OP-RMSC package does not contain any specific thermal design features and the thermal performance of the package is demonstrated by test. The applicant stated that the OP-RMSC may contain up to 16,000 Ci (592 TBq) of Ir-192 or Se-75 in special form. The radiolytic decay heat of Ir-192 is 6.14×10^{-3} W/Ci and the radiolytic decay heat of Se-75 is 2.41×10^{-3} W/Ci. Therefore, the maximum decay heat load for the OP-RMSC package is 100 watts, from the Ir-192 payload.

After reviewing the OP-RMSC package thermal design, described in SAR Section 3.1, and examining the decay heat watts per Curie conversion provided in SAR, the staff determined that the description of thermal design and heat load of the package is appropriate for thermal evaluation.

3.2 Material Properties and Component Specifications

The applicant stated, in SAR Section 3.2, "Material Properties and Component Specifications," that the OP-RMSC package is constructed primarily of a stainless-steel pipe and plate welded assembly that surrounds a tungsten heavy metal shield. Since the structural integrity of the package is established by testing, the only pertinent temperature limits on the components are established by their melting temperatures for the HAC fire. The applicant reported that the melting temperatures for tungsten heavy metal and Type 304 stainless steel are 2,732 °F (1,500 °C), and 2,800 °F (1,538 °C), respectively, which staff confirmed and found acceptable.

The applicant stated, in SAR Section 3.2, that the OP-RMSC package does not contain any specific component or material that is important to the thermal performance of the package. The two primary structural materials are Type 304 stainless steel for structure and tungsten heavy metal shield. As noted in SAR Section 2.1.2.2.1, "Brittle Fracture," both materials have been tested to temperatures below -20 °F (-29 °C) with no loss of structural or shielding capability, in compliance with 10 CFR 71.71.

The staff reviewed the material properties and component specifications specified in SAR Section 3.2 and concluded that (A) they are sufficient to provide a basis for evaluation of the package against the thermal requirements of 10 CFR 71.71 and 71.73(c)(4) and (B) the payload was qualified per Qualification of special form radioactive material, in 10 CFR 71.75(b)(4).

3.3 Thermal Evaluation under Normal Conditions of Transport

3.3.1 Heat and Cold

Heat

The applicant stated, in SAR Section 3.3.1, “Heat and Cold,” that the thermal analysis was performed using the ANSYS code with the maximum decay heat load of 100 watts. The applicant calculated a maximum surface temperature of 168 °F (76 °C) of the stainless outer shell under the ambient temperature of 100 °F (38 °C) and insolation, and a maximum surface temperature of 152 °F (67 °C) in still air and in shade under an ambient temperature of 100 °F (38 °C).

The applicant stated, in SAR Section 3.3.1, that with the surface temperature of 152 °F (67 °C) in still air and in shade, which exceeds the temperature limit of 122 °F (50 °C) for non-exclusive use shipment, an expanded metal personnel barrier with a minimum open area of 75% is installed over the OP-RMSC package after it is secured to its shipping pallet. The applicant revised the thermal analysis to include the personnel barrier as shown in SAR Figure 3.3-1 and license drawings and predicted that the maximum temperature of the accessible surfaces of the personnel barrier is 100 °F (38 °C), which allows the package to be shipped as a non-exclusive use shipment, in compliance with of 10 CFR 71.43(g). The applicant summarized the maximum NCT component temperatures in SAR Table 3.3-2, including packaging component and payload temperatures in shade and under insolation, respectively.

The staff reviewed the configuration of the personnel barrier (an expanded, flattened metal sheet) provided on the license drawings which show the size of the openings and wire size of the barrier material. The staff confirmed that the personnel barrier, used for OP-RMSC package, meets the minimum open area of 75% required.

The staff reviewed SAR Section 3.3.1 and Table 3.3-2 and confirmed the following items:

- the presence of the barrier has a negligible effect on heat transfer between the package surface and the environment, because the distance between the barrier and the package and the minimum 75% open area of the expanded metal have no significant effect on the airflow that supports convection from the package surface and radiation through the barrier,

- the thermal analysis with the personnel barrier is acceptable and the package, if shipped as a non-exclusive use shipment, would comply with 10 CFR 71.43(g), and

- all packaging component and payload temperatures (in shade and under insolation) are below the allowable limits for NCT. The maximum temperature of the special form capsule is also below the allowable limit of 1,475 °F (800 °C), which is the test temperature for special qualification per 10 CFR 71.75(b)(4).

Cold

The applicant stated, in SAR Section 3.3.1, that for the cold condition with zero decay heat and a cold ambient of -40 °F (-40 °C), the package surface temperature will be equal to the low temperature ambient conditions of -40 °F (-40 °C).

The staff reviewed the service temperature ranges of the packaging components of OP-RMSC package and verified that the minimum allowable service limit of all components is less than or equal to -40 °F (-40 °C). The staff finds that the OP-RMSC package functions under NCT cold conditions even at an ambient temperature of -40 °F (-40 °C) and is thus in compliance with 10 CFR 71.71(c)(2).

3.3.2 Maximum Normal Operating Pressure

The applicant stated, in SAR Section 3.1, that the containment of the OP-RMSC package is provided by the special form sources and the gas can freely move from the internal cavity surrounding the sources to the environment during all phases of package operations; therefore, the package does not contain any pressure boundaries.

The staff reviewed the package design described in SAR Chapter 1, "General Information," and the design drawings of the package provided in Appendix 1.3.1, "General Arrangement Drawings," and agrees that there are no internal pressures that can diminish packaging structural and/or shielding effectiveness and there is no maximum normal operating pressure to be determined for the OP-RMSC package under NCT.

3.4 Thermal Evaluation under HAC

3.4.1 Initial Conditions

The applicant stated, in SAR Section 2.7.4, "Thermal," that the limiting temperatures for the OP-RMSC package are the melting temperatures of the structural and shielding materials, which are higher than the prescribed HAC fire temperature of 1,475 °F (800 °C). The applicant performed a transient thermal analysis, with initial conditions of NCT (with solar insolation), as described in SAR Section 3.4.1, to determine the fire effects during the HAC 30-minute transient and its post-fire cooldown.

The staff determined that the application of the initial conditions is consistent with the initial conditions described in Section 3.4.6.1, "Initial Conditions," of NUREG-2216, "Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material: Final Report." Based on the melting points of structural and shielding materials, the staff also confirmed that the combustion of the foam or the gasket materials, or an increased temperature of the RMSC payload, has no significant effect on the structural or shielding materials of either the OP-RMSC package or the RMSC payload.

3.4.2 Fire Test Conditions

The applicant noted, in SAR Section 3.4.2, "Fire Test Conditions," that there was no failure of the OP-RMSC packaging structure that exposed the RMSC that contains the tungsten heavy metal shield. Therefore, the peak package temperatures would not exceed the 1,475 °F (800 °C) fire temperature, which is well below the melting temperatures of either Type 304 stainless steel or the tungsten heavy metal. The special form qualification of the payload certifies that it could withstand the fire test without degradation or rupture.

The staff finds the fire test conditions setup by the applicant for evaluation of the thermal performance of the OP-RMSC package under HAC acceptable and in accordance with 10 CFR 71.73(c)(4). The staff recognized that both fire test and HAC thermal analysis provide reasonable assurance on package performance under the HAC fire conditions.

3.4.3 Maximum Temperatures and Pressures

The applicant provided the maximum peak temperatures for the OP-RMSC package components with the 100 W decay heat under HAC conditions in Table 3.4-1, which shows none of the components of OP-RMSC package or the RMSC payload exceeded their temperature limits as described in SAR Section 3.2.1, “Material Properties.” Additionally, the maximum HAC temperature of the special form capsule, shown in SAR Table 3.4-1, does not exceed the temperature limit of 1,475 °F (800 °C) for the special form certification per 10 CFR 71.75(b)(4). The applicant provided the HAC temperature responses of OP-RMSC package and RMSC payload, during the 30-minute fire and post-fire cooldown, in SAR Figures 3.4-3 and 3.4-4, respectively.

The staff finds that the package is designed to safely dissipate heat under passive conditions and the packaging component and payload temperatures will remain within their allowable limits or criteria for HAC as required in 10 CFR 71.73. The staff confirmed that the OP-RMSC package satisfies the HAC thermal requirements set forth in 10 CFR 71.73(c)(4) and the combustion of the polyurethane foam or the gasket material has no effect on structural or shielding materials of either the OP-RMSC package or the RMSC payload.

3.4.4 Thermal Stresses

The applicant stated, in SAR Section 3.4.4, “Maximum Thermal Stresses,” that the effects of HAC thermal stresses on the OP-RMSC package are minimal for the single event of the HAC fire, because the maximum fire temperature for the welded package would not exceed 1,475 °F (800 °C), which would not result in any metal fatigue or detrimental condition that affects the shielding or confinement safety functions of the package. In addition, the thermal expansion coefficient for stainless steel is over three times the thermal expansion coefficient for tungsten heavy metal. Since the tungsten heavy metal shields are not rigidly attached to the RMSC stainless steel, no significant thermal stresses will develop within the RMSC payload due to exposure to the 1,475 °F (800 °C) HAC fire environment. The combustion of the foam or the gasket material has no effect on the structural or shielding materials of either the OP-RMSC package or the RMSC payload.

The staff reviewed SAR Section 3.4.4 and Figure 2.1-2 for a sectional view of the OP-RMSC packaging, and finds that no significant thermal stresses will develop within the RMSC payload because (a) the melting temperatures of both stainless steel and tungsten heavy metal are higher than the specified fire temperature of 1,475 °F (800 °C), (b) the tungsten shields are not rigidly attached to the RMSC stainless steel, and (c) the coefficient of thermal expansion of the stainless steel is much higher that of the tungsten shield.

3.5 Evaluation Findings

F3-1 The staff has reviewed the package description and evaluation and concludes that they satisfy the thermal requirements of 10 CFR Part 71.

F3-2 The staff has reviewed the material properties and component specifications used in the thermal evaluation and concludes that they are sufficient to provide a basis for evaluation of the package against the thermal requirements of 10 CFR Part 71.

F3-3 The staff has reviewed the methods used in the thermal evaluation and concludes that they are described in sufficient detail to permit review of the package thermal design.

F3-4 The staff has reviewed the accessible surface temperatures of the package as it will be prepared for shipment and concludes that they satisfy 10 CFR 71.43(g) (for a non-exclusive-use shipment).

F3-5 The staff has reviewed the package design, construction, and preparations for shipment and concludes that the package material and component temperatures will not exceed the specified allowable limits during normal conditions of transport consistent with the tests specified in 10 CFR 71.71.

F3-6 The staff has reviewed the package design, construction, and preparations for shipment and concludes that the package material and component temperatures will not exceed the specified allowable limits during hypothetical accident conditions consistent with the tests specified in 10 CFR 71.73.

Based on a review of the statements and representations in the application, the staff concludes that the thermal design of the OP-RMSC package has been adequately described and evaluated, and that the package thermal performance meets the thermal requirements of 10 CFR Part 71.

4.0 CONTAINMENT EVALUATION

The containment of the radioactive material is provided by the sealed source capsule construction of the contents. The source capsule special form certifications can be found in SAR Section 4.0. INC also demonstrated by physical tests that the source remains within the sealed capsule under both NCT and HAC.

Based on a review of the statements and representations in the application, the staff concludes that the containment design has been adequately described and evaluated, and that the performance of the package meets the containment requirements of 10 CFR Part 71.

5.0 SHIELDING EVALUATION

The purpose of the shielding review is to confirm that the package (the packaging together with its contents) meets the external radiation requirements in 10 CFR Part 71. The applicant requested approval of a new package design, which the applicant has designated as the OP-RMSC. The applicant has designed the package for transport of special form sources of the following radionuclides: Ir-192 and Se-75. The staff used the guidance in NUREG-2216, “Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material,” to conduct this review.

5.1 Description of Shielding Design

5.1.1 Shielding and Design Features

The OP-RMSC package consists of two main parts, an outer packaging that the applicant designated the OP-RMSC and an inner packaging that the applicant designated the RMSC payload. The special form sources are loaded into the RMSC, which is then loaded into the OP-RMSC. The loaded OP-RMSC is secured to a transport skid with a personnel barrier placed around the package and attached to the skid.

The applicant relies only on the RMSC for the package’s shielding function, crediting only the RMSC in the evaluations to demonstrate compliance with the shielding requirements in

10 CFR Part 71 and to demonstrate that the package radiation levels will not exceed the regulatory limits in 10 CFR 71.47 and 10 CFR 71.51(a). In particular, the applicant has designed and evaluated the package so that package radiation levels do not exceed the non-exclusive use limits in 10 CFR 71.47(a).

The RMSC is comprised of components made from stainless steel and tungsten alloys. The RMSC shielding is provided primarily by the stainless steel body and cavity shields made of tungsten alloys. Each shield is made from a different tungsten alloy. The two alloys differ in density and amount (i.e., weight percent) of alloying metals, which are iron and nickel. The body shield's alloy has the higher density and lesser amount of alloying metals. The other components important to the package shielding include a steel plate forming the RMSC base, a steel pipe forming the RMSC side wall, a steel annular plate that tops the cavity in which the body shield sits, a steel pipe that forms the cavity into which the cavity shield is inserted, and a steel plate that forms the RMSC lid. There is a penetration in the RMSC lid into which a steel bolt is inserted that attaches a hoist ring to the lid for lifting the lid and the loaded RMSC. The body shield and cavity shield enclose a small cavity in which the special form sources are placed. The cavity shield also has a penetration for attaching a lifting device to move the cavity shield for loading and unloading operations. This penetration is empty in the package's transport configuration.

The package drawings include an American Society for Testing and Materials (ASTM) International material specification for each of the steel components that are important for shielding. The exception is the steel bolt that connects the hoist ring to the RMSC lid. These standards include requirements on dimensional tolerances. For dimensions for which the standards do not specify tolerances, the tolerances specified in the title block of the package drawings govern. For the tungsten alloy components, the package drawings also specify an ASTM materials standard, and the alloy class for each alloy from that standard. The standard does not specify dimensional tolerances; so, tolerances are specified in drawing RMSC-SAR-TA for diameters and lengths of the tungsten alloy components. With the material standard and alloy class specified in the drawing, the drawing provides the specifications of the tungsten alloy components' alloy composition, including the ranges of densities that these components may have.

The staff reviewed the description of the package in Chapter 1 of the application and the package drawings in the application. The staff also reviewed the shielding analysis in Chapter 5 of the application. In this review, the staff identified the package components that are important to and relied on for the package's shielding function. Based on this review, the staff found that the drawings provide an adequate description of the packaging components relied on for shielding, including dimensional and material specifications. The staff also reviewed the package drawings to identify those components which, while not relied on for shielding, could potentially impact the effectiveness of the components that are relied on for shielding. In this review, the staff conferred with the structural staff. Based on this review the staff finds that the drawings provide an adequate description of the remaining packaging components in terms of the package's shielding performance, including under NCT and HAC.

5.1.2 Codes and Standards

As described later in this SER chapter, the applicant performed a shielding evaluation using radiation measurements on prototype packages which underwent the conditions and tests specified in 10 CFR 71.71 and 71.73, as described in the application, for NCT and HAC, respectively. Thus, the applicant did not use any kind of shielding-related code or standard to develop or define the package's shielding design.

5.1.3 Summary Tables of Maximum External Radiation Levels

The applicant provided a summary of the maximum package radiation levels for each package surface (top, bottom, side) and at 1 meter from each package surface. These radiation levels are summarized in SAR Table 5.1-1. SAR Table 5.1-1 provides the package radiation levels for the Ir-192 contents. The applicant used the radiation levels for the Ir-192 contents to bound the radiation levels for the Se-75 contents. Based on a comparison of the energy spectra, gamma emission rates, and gamma constants for both nuclides as well as the proposed authorized quantities for both nuclides being equal, the staff finds that package radiation levels for the Ir-192 contents will bound those for the Se-75 contents. The staff performed a simple MicroShield® calculation that also supports this conclusion.

The radiation levels shown in SAR Table 5.1-1 indicate that the package radiation levels will not exceed the limits in 10 CFR 71.47(a) for the proposed authorized maximum contents' quantities and that the package can be used for non-exclusive use shipments. As indicated in the note for SAR Table 5.1-1, the radiation levels are from prototype packages that have undergone the conditions and tests for both normal conditions of transport and hypothetical accident conditions. Thus, the radiation levels at 1 meter from the package surface (i.e., the RMSC surface) are the same for both normal conditions of transport and hypothetical accident conditions.

While the applicant did not indicate the specific location of the maximum radiation level for each package surface, the applicant did describe the process, including the equipment that was used, by which the package radiation levels were measured. As described in the application, the applicant performed the radiation level measurements with the INC Model 4 survey meter. The specifications of this survey meter can be found on the applicant's website and in brochures available from the applicant. Based on a review of the detector specifications in the identified information sources, the staff finds the detector is appropriate for the measurements for the prototype and the sources used.

The application also indicates that this detector is calibrated to the face of the meter, which means the measured radiation level is at the RMSC's surfaces for the surface measurements. In other words, geometric correction factors are not needed to adjust the measured radiation level to determine the radiation level at the surface of the RMSC. The application includes the special form certificate for the package contents (see the table in Chapter 4 of the application). The specifications in the certificate include source dimensions. While the application does not specifically identify the specifications of the sources used in the prototype measurements, given the information in the application about the contents (such as the special form certificate, which is for INC-SFC-1 sources), it can be reasonably inferred that the sources used for the measurements meet these same specifications. This information, together with the information about the source holder in the application and used in the prototype measurements, provide an understanding of the source configuration. This includes the relative position of the sources versus the different features of the RMSC and its shielding components and the amount of potential movement of the sources within the RMSC cavity.

The application provides further important information about the prototype measurement process. This information includes that the properties (dimensions and densities) of the tungsten alloy shields were at the nominal values specified in the drawings. It also includes that the threaded hole in the top of the cavity shield was empty, consistent with the package drawings. The application also describes the radiation level measurement process involved scanning of each surface (top, side, bottom) and at 1 meter from each surface of each measured prototype to identify the maximum radiation levels. The staff finds this acceptable because such an approach does not presuppose the locations of highest radiation levels, instead using a methodical scan over the full surface, both at the surface and at distance, to identify the maximum radiation levels and their locations. Based on the descriptions of the prototype measurements, including the prototype configuration and the measurement process and equipment, given in the application, the staff finds reasonable assurance that the applicant identified the maximum radiation levels for each package surface and 1 meter from each package surface for the package condition and configuration at the time of the measurement.

Based on a review of the radiation levels in Table 5.1-1 of the application and the shielding evaluation from which those radiation levels were derived, as described in the following sections of this SER, the staff finds that the tables provide the maximum package radiation levels and demonstrate that the non-exclusive use limits in 10 CFR 71.47(a) will not be exceeded.

5.2 Radioactive Materials and Source Terms

The proposed package contents include special form sources of Ir-192 and Se-75. The proposed maximum authorized quantities are 16,000 Ci (592 TBq) of Ir-192 and 16,000 Ci (592 TBq) of Se-75. In addition to the maximum total activity, the applicant also stated that there is a limit of 4,000 Ci (148 TBq) per capsule for the Ir-192 and the Se-75 sources. Based on the shielding evaluation for these contents, which uses four capsules for the Ir-192 contents, the staff finds this per capsule limit is an important condition of the package's use. Therefore, the staff has included both the total and per capsule activity limits for the Ir-192 and the Se-75 sources in the package's certificate of compliance.

While specification of the Ir-192 source activity limit can be as output activity (see Note c of Table A-1 of Appendix A to 10 CFR Part 71), the applicant has proposed that the activity limit for the Ir-192 source as well as the Se-75 source be specified as a limit on the content activity. There is an important distinction between output activity and content activity. Output activity is for a source activity that is determined by measurement whereas content activity is the assigned activity value of the source. Output activity, since it is determined by measurement, includes the effects of shielding provided by the source material itself and the material of the capsule in which it is enclosed. The American National Standard N432, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," Section 8.1.2 describes the measurement procedure that would be used for determining the output activity and lists the gamma constants for a few common source radionuclides. Content activity does not credit any shielding afforded by the source material or the source's capsule. Since the applicant has proposed to define the maximum content activity as a content activity, the application does not need to address the considerations described above for output activity. The use of content activity is more limiting since it does not credit source self-shielding. Thus, the staff finds the content specification to be acceptable and will include that specification in the package's certificate of compliance.

5.2.1 Source-term Calculation Methods

For the Ir-192 and Se-75 source contents, the applicant used measurements of radiation levels on prototype packages to demonstrate the package radiation levels for those contents do not exceed regulatory limits. Thus, there is no calculation of the source terms for these nuclides. The applicant did refer to an article in the March 2012 issue of the Health Physics Society Journal in which exposure rate constants for numerous nuclides were provided. The applicant included the gamma ray constants for Ir-192 and Se-75 from this article in the application (see SAR Table 5.2-1). The staff compared the applicant's gamma ray constants to those given for these nuclides in the *Radiological Health Handbook* (January 1970 Edition). The applicant's selected values are quite similar to those in the staff' reference.

5.2.2 Gamma Sources

The applicant did not provide a calculated source term or spectrum for either the Ir-192 or the Se-75 contents. This is not necessary since the shielding evaluation method for these contents is measurement of radiation levels on a prototype package. The applicant used the average of the photon energies from each of these two nuclides and their respective gamma ray constants only for the purpose of demonstrating that the Ir-192 source at a total activity of 16,000 Ci (592 TBq) will be bounding for the Se-75 source at the same total activity. The staff used data available to it as well as very simple calculations with the MicroShield® code and confirmed that the Ir-192 source is indeed bounding for the Se-75 source for this package.

5.2.3 Neutron Sources

The proposed package contents are all radionuclides which have no neutron emissions. Therefore, there are no neutron sources for this package.

5.3 Shielding Model and Model Specifications

5.3.1 Configuration of Source and Shielding

The staff interacted with the structural review staff to confirm the impacts of the tests specified in 10 CFR 71.71 and 10 CFR 71.73 on the package. The applicant's shielding evaluation for all package contents relied only on the RMSC portion of the packaging. Thus, for shielding purposes, the staff's interest in the test results is confined to damage to the RMSC. Based on the structural review (see Chapter 2 of this SER), the staff determined that the package tests for both normal conditions of transport (i.e., the 10 CFR 71.71 conditions and tests) and hypothetical accident conditions (i.e., 10 CFR 71.73 tests) included package orientations that would maximize damage to the RMSC. Those tests did not result in any damage that affected the dimensional properties of the RMSC (e.g., no noticeable crushing or indentation of the RMSC). The tungsten components also showed no damage due to any of the tests. In addition, the RMSC lid remained firmly attached to the RMSC body. The applicant's evaluation is based on the RMSC with the dimensions and other properties as described in the package drawings. Based on the structural review of the package tests, the staff finds that this approach to the shielding evaluation is acceptable.

The applicant used measurements of radiation levels on prototype packages to demonstrate regulatory limits will not be exceeded for the Ir-192 and Se-75 source contents. The measurements were done at the surfaces (side, top, and bottom) and 1 meter from the surfaces of the RMSC to demonstrate that the maximum package radiation levels will not exceed the non-exclusive use limits in 10 CFR 71.47(a). For the measurements, the applicant loaded the RMSC with four capsules of Ir-192 with a total source strength of 4,297 Ci (159 TBq). The capsules were placed in a source holder assembly which is placed inside the RMSC cavity. The application includes a drawing for that source holder as well. The prototype packages experienced both the 10 CFR 71.71 and 10 CFR 71.73 tests prior to the radiation levels being measured. Thus, the applicant's measurements at 1 meter from the RMSC surfaces apply to both the limits in 10 CFR 71.47(a) and 10 CFR 71.51(a) and the results are the same for both normal conditions of transport and hypothetical accident conditions.

In its review of the measurement descriptions, the staff noted a few items of interest. The first is that the RMSC cavity space does allow for some movement of the source capsules. This movement can have an impact on the measured radiation levels for each surface. The applicant described the dimensions of the sources versus the RMSC cavity dimensions. Based on those dimensions, the sources could move axially about 1 inch within the cavity. However, as the applicant stated, the staff finds that this will have a minor impact on top and bottom radiation levels. The staff also expects that the axial shift would not result in the side radiation levels at points of differences in shielding configuration to change to such a degree as to affect the maximum radiation levels for the RMSC side. With the axial and radial variations in the RMSC shielding, the staff identified that the radiation measurements should be done to evaluate the impact of those variations and ensure the locations of maximum radiation levels are correctly identified. Based on the applicant's descriptions of the measurements as well as some simple staff evaluations of the shielding for different locations around the RMSC, the staff finds the applicant has appropriately accounted for the axial and radial shielding variations of the RMSC and has identified the maximum radiation levels for each surface for the package conditions and configurations used in the measurements.

The staff also noted that the package design allows for dimensional variations in the RMSC components. In particular, variations of the tungsten alloy shield components can have a significant impact on measured radiation levels. For the most significant gamma emissions from Ir-192, the staff identified that the half value thickness of the tungsten alloys is on the order of 3 to 4 millimeters. Therefore, a dimensional tolerance of this magnitude would be expected to result in radiation levels that are double those determined for the nominal dimension case. Accounting for the allowed minimum tungsten alloys' densities further increases the radiation levels versus those for the nominal case.

The dimensional properties of the RMSC components used in the prototype packages and the radiation measurements are at the nominal values specified in the package drawings. The staff identified that the RMSC side surface and 1-meter radiation levels and the RMSC base 1-meter radiation levels were of the most concern in terms of impacts from the tungsten alloy shields' dimension tolerances and density variations. The staff performed simple hand calculations to determine the minimum dimensions (i.e., the tolerance sizes) for which the surface and 1-meter radiation levels would not exceed their respective limits for the RMSC side and base. These calculations indicated that tolerances of approximately 0.05 inches for the body shield's diameters and 0.06 inches for the body shield's overall length would ensure the radiation levels would not exceed the non-exclusive use limits in 10 CFR 71.47(a), with the minimum alloy densities specified in the package drawings.

The staff used the result of these calculations to evaluate the package design as described in the package drawings, including the specified dimensional tolerances. The package drawings specify dimensional tolerances on the tungsten alloy body shield diameters and overall length that are less than the staff's calculated tolerances. Since the specified tolerances are smaller than the staff's calculated tolerances, the staff finds they will ensure the design will not exceed the regulatory radiation level limits and are therefore acceptable. The staff also identified that the radiation levels for the RMSC top surface and 1-meter locations and the RMSC bottom surface location have enough margin to compensate for the impacts of dimensional tolerances and density variations in the tungsten alloy shields. Thus, the staff finds that the radiation levels for those locations will also remain below the regulatory limits for non-exclusive use at the minimum design specifications and so those minimum design specifications are also acceptable. The applicant also provided a dimensional tolerance of the cavity shield's diameter that is the same as for the body shield's diameters. Having this same tolerance also helps to ensure the impacts on package radiation levels won't result in radiation levels that exceed the non-exclusive use limits.

The staff notes that the impacts of accounting for dimensional and material tolerances on radiation levels for a package containing the Se-75 source contents will be even greater than the impacts are for the Ir-192 contents. However, significant margins exist for the Se-75 source contents, versus the Ir-192 source contents. Thus, the staff finds that accounting for the impacts of these items in ensuring the regulatory limits are met for the Ir-192 source contents is sufficient to ensure the regulatory limits will be met for the Se-75 source contents when accounting for the same effects.

The top tungsten alloy shield includes a penetration in its center to be able to attach a tool to remove and insert that component in the package loading and unloading operations. This penetration remains void in the package's transportation configuration. Thus, this central area of this component has reduced shielding capability. However, the staff considered the source holder, based on the drawing for that component in the application. With the holder centered, and the applicant's description of the source capsules' geometry, in the nominal configuration, no source capsule can be located directly below the shield area with that penetration. For the tolerances on the RMSC's cavity diameter, a small part of a source capsule may be able to locate directly below the penetration. However, it would be a very small part of the capsule. Based on that, together with the radial size of the penetration and the use of an appropriate detector size, the staff finds that it is likely that the impact on surface radiation levels on the RMSC top would be relatively small and not impact the ability to comply with the regulatory limits at that location.

5.3.2 Material Properties

The staff reviewed the package material properties specified in the package drawings and those properties used in the shielding evaluation. As described above, the package drawings specify a material standard and the materials classes from that standard, which provide the relevant materials properties of the packaging's tungsten alloy components. This standard is ASTM B777, "Standard Specification for Tungsten Base, High-Density Metal."

Based on the information provided by the applicant regarding the tungsten alloy shield components in the prototype packages, the staff determined that those alloys are at their nominal materials properties. Accounting for the effects of components fabricated at the allowable minimum properties, including maximizing the amount of iron in the alloying metals in the alloy, will result in relatively significant increases in measured radiation levels. As noted above in Section 5.3.1 of this SER, the staff evaluated the impacts of accounting for the minimum material properties together with the other items described above (dimensional tolerances). Based on those evaluations and the specifications provided in the current revisions of the package drawings, the staff finds reasonable assurance that the package radiation levels will not exceed the non-exclusive use limits for the Ir-192 (and Se-75) contents for a package at the minimum design specifications.

The other material relevant to the shielding analysis is the stainless steel of the steel components of the RMSC. The ASTM standards specified for these components in the package drawings control their composition.

5.4 Shielding Evaluation

5.4.1 Methods

The applicant's evaluation method was to perform radiation level measurements on the RMSC components of two prototype packages. For the measurements, the applicant used Ir-192 sources at individual and total activities that are less than those proposed as the maximum authorized activities. Thus, the applicant scaled the measured radiation levels by a factor equivalent to the ratio of the proposed authorized total activity versus the total activity used in the measurement. This technique is an acceptable method provided that the ratio of the authorized activity versus the activity used in the measurements is not excessively large. Ratios that are significantly large enough can result in a ratio that provides an inaccurate estimate of the radiation levels for the proposed authorized activity for the package contents. The applicant used a total Ir-192 source that was a little more than one fourth of the total authorized Ir-192 activity for the package, as proposed in the application. In its review, the staff identified that this ratio is consistent with the guidance in industry standards with which the staff is familiar and that address shielding efficiency tests for items such as radiography devices and the directions in those standards related to the source strengths used in those tests versus the activity that represents the device's capacity. These standards include American National Standards Institute/Health Physics Society N43.9-2015, "For Gamma Radiography – Specifications for the Design, Testing, and Performance Requirements for Industrial Gamma Radiography System Equipment Using Radiation Emitted by a Sealed Radioactive Source." Therefore, the staff finds the source activity used in the measurements and the scaling factor for determining the package radiation levels at the authorized activity level to be acceptable. As noted above, the staff finds that measurements for Ir-192 will result in package radiation levels that are bounding for a package containing the Se-75 source contents.

The applicant conducted measurements on the RMSC component, neglecting the outer packaging components of the OP-RMSC. The staff finds this is acceptable and conservative since it neglects the presence of the OP-RMSC components which would be present in the package's transport configuration. It also is bounding for all the different impacts of the normal conditions of transport and hypothetical accident conditions tests and conditions. Based on the descriptions of the tests and their impacts on the package, other than the hoist ring shearing off in one of the tests, the RMSC did not experience any observable damage or deformation. The RMSC components were at their nominal dimensions, and the tungsten alloy shielding components were at their nominal densities and compositions. As noted in SER Section 5.3.1 above, simple calculations indicated that adjusting these properties to their minima as allowed in the current revisions of the design drawings will result in package radiation levels that, though increased versus the measured nominal configuration, will not exceed the non-exclusive use limits in 10 CFR 71.47(a). While the contents can move a little within the RMSC cavity, based on the sources' axial length and the use of the source holder, the amount of movement is limited and does not have a significant impact on package radiation levels.

Qualified personnel used a calibrated survey meter (INC's Model 4, specifications for which can be found at the applicant's website and brochures available from the applicant). The meter is calibrated to the meter's window surface. Therefore, measurements with this survey meter reflect the radiation levels at the package surface and not some distance from the surface that is inside the meter. The personnel performed a scan of each surface of the RMSC and a scan at one meter from each surface to identify the maximum radiation levels for each. The staff reviewed the information about the method, including the specifications for the radiation survey meter and its calibration and finds reasonable assurance that they ensure that the applicant identified the maximum radiation levels for each package surface and at one meter from each surface for the configuration of the package for which the measurements were performed.

5.4.2 Code Input and Output Data

Since the applicant used radiation measurements to evaluate package radiation levels, this section, which is for computer code analyses, is not applicable.

5.4.3 Fluence-Rate-to-Radiation-Level Conversion Factors

Since the applicant's evaluation method is radiation measurements, this section, which is for computer code analyses, is not applicable.

5.4.4 External Radiation Levels

SAR Table 5.1-1 shows the maximum radiation levels for each RMSC surface and at 1 meter from each of those surfaces. The most limiting radiation levels are on the surface of the side of the RMSC. At 123 mrem/hr (1.2 mSv/hr), the measured maximum on the RMSC side is 61.5% of the limit of 200 mrem/hr (2 mSv/hr) for non-exclusive use. All other measured maxima have greater margin to their respective regulatory limits for non-exclusive use. As noted above, these measured maxima are for an RMSC with nominal properties (dimensions and tungsten alloys' densities). Accounting for the minimum specifications allowed in the drawings results in increases in radiation levels. Section 5.3.1 above describes the staff's evaluation of the radiation level impacts due to dimensional tolerances and density variations for the tungsten alloy shields. As stated there, the staff finds reasonable assurance that, while radiation levels will increase when tolerances and density variations are accounted for, the radiation levels will not exceed their respective regulatory limits for non-exclusive use.

The staff also did some simple calculations to evaluate potential areas of increased radiation levels. The staff used hand calculations involving use of half value thicknesses. Based on these calculations, the staff expects that the maximum point on the RMSC base will be directly below the source, wherever the source is position in the RMSC cavity. The shielding properties in the RMSC base do not vary radially. For the package side, the staff looked at different angles that affected how much tungsten alloy was between the source and the detector. These results indicated that a location perpendicular to the RMSC side surface and axially level with the source location would have the maximum radiation levels for the RMSC's side surface. For the top, the staff also placed the source directly under the penetration of the tungsten cavity shield. The staff's analysis indicated that the radiation levels would peak in that location. However, as described in Section 5.3.1, for the currently proposed contents' configuration, the staff expects the impact of that penetration to be relatively small and not impact the package's ability to meet the regulatory limits. While staff used a gamma energy that is more consistent with the gammas from a cobalt-60 source, the staff expects that the results will be similar for the proposed Ir-192 and Se-75 contents.

5.4.5 Confirmatory Analyses

As described in this chapter of the SER, the staff performed some simple confirmatory calculations. The staff used these calculations to evaluate aspects of the package such as relative trends in reported radiation levels and to identify potential candidate locations for maximum radiation levels. The staff also used these analyses to evaluate the impacts of material and dimension variations allowed by the package drawings. These methods included hand calculations using the half value thicknesses for appropriate gamma energies and simple models in the MicroShield® gamma shielding code.

5.5 Evaluation Findings

As described in this chapter of the SER:

F5-1 The staff has reviewed the application and finds that it adequately describes the package contents and the package design features that affect shielding in compliance with 10 CFR 71.31(a)(1), 71.33(a), and 71.33(b), and provides an evaluation of the package's shielding performance in compliance with 10 CFR 71.31(a)(2), 71.31(b), 71.35(a), and 71.41(a). The descriptions of the packaging and the contents are adequate to allow for evaluation of the package's shielding performance. The evaluation is appropriate and bounding for the packaging and the package contents as described in the application.

F5-2 The staff has reviewed the application and finds that it demonstrates the package has been designed so that under the evaluations specified in 10 CFR 71.71 (NCT), and in compliance with 10 CFR 71.43(f) and 10 CFR 71.51(a)(1), the external radiation levels do not significantly increase.

F5-3 The staff has reviewed the application and finds that it demonstrates that under the evaluations specified in 10 CFR 71.71 (NCT), external radiation levels do not exceed the limits in 10 CFR 71.47(a) for non-exclusive-use shipments.

F5-4 The staff has reviewed the application and finds that it demonstrates that under the tests specified in 10 CFR 71.73 (HAC), external radiation levels do not exceed the limits in 10 CFR 71.51(a)(2).

F5-5 The staff has reviewed the application and finds that it includes operations descriptions, acceptance tests, and maintenance programs that will ensure that the package is fabricated, operated, and maintained in a manner consistent with the applicable shielding requirements of 10 CFR Part 71. This finding is based on the staff review and findings described in Chapters 8 and 9 of this SER.

Based on a review of the information and representations provided in the application and the staff's confirmatory calculations, the staff has reasonable assurance that the OP-RMSC package, the packaging together with its contents, satisfies the shielding requirements and limits in 10 CFR Part 71.

6.0 CRITICALITY EVALUATION

Since the OP-RMSC does not transport fissile material, no criticality analysis is required.

7.0 MATERIALS EVALUATION

The materials review of the OP-RMSC application was conducted using the guidance in NUREG-2216, "Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material," issued August 2020. In addition, the staff used additional NRC guidance documents as identified in the following sections to guide the materials review.

7.1 Drawings

The applicant provided drawings for the package including details of the outer package and the inner package for the raw material source container. The applicant's drawings included component safety classification, a bill of materials with material specifications for each component, and dimensions of the components with tolerances.

The staff reviewed the drawings using the guidance in NUREG/CR-5502, "Engineering Drawings for 10 CFR Part 71 Package Approvals," issued May 1999, and Regulatory Guide 7.9, "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material," for the recommended content of engineering drawings. In addition, the staff used NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," issued February 1996, and NRC Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," Appendix A, "A Graded Approach to Developing Quality Assurance Programs for Packaging Radioactive Material," for guidance on safety classification of transportation packaging components. The staff verified that the drawings included design features considered in the package evaluation, including:

- the closure device,
- internal supporting or positioning structures,
- gamma shielding,
- outer packaging,
- energy-absorbing features,
- lifting and tie-down devices, and
- personnel barriers.

The staff verified that the drawings include the information described in NUREG-2216 on the (1) materials of construction, (2) dimensions and tolerances, (3) codes, standards, specifications for materials, fabrication, examination, and testing (4) welding specifications, including location and nondestructive examination (NDE). The staff determined that the provided drawings for the package by the applicant are consistent with the design and description of the package, in accordance with 10 CFR 71.33, "Package Description." Therefore, the staff determined that the drawings provided by the applicant were acceptable.

7.2 Codes and Standards

The applicant stated that since the package contains limited quantities of radioactive material, and does not contain a pressure boundary, the OP-RMSC package is only designed to industrial metal fabrication standards. The bill of materials included drawings that include material specifications. The majority of the structural components are fabricated using ASTM material specifications. The applicant also specified ASTM materials for the closure hardware. The applicant stated that the tungsten heavy alloys, which include Densimet® 176 and Densimet® 185 for the shielding components, are manufactured in accordance with ASTM B777.

The staff reviewed the applicable codes and standards and material specifications for the packaging components. The staff determined that the applicant has accurately identified the codes and standards used for the design and construction of the OP-RMSC package. The staff determined that the Plansee Densimet® tungsten heavy metal shield materials and the stainless steel packaging components, including for the closure hardware, are manufactured in accordance with ASTM specifications that include controls on composition, processing, and material properties. Therefore, the staff determined that the description of the codes and standards applicable to the OP-RMSC package provided by the applicant was acceptable.

7.3 Weld Design and Inspection

The applicant stated that all welding procedures and personnel shall be qualified in accordance with the ASME B&PV Code, Section IX. In addition, the applicant stated that all welds shall be visually examined in accordance with the American Welding Society (AWS) D1.6. The staff reviewed the applicant welding procedures and personnel requirements and determined that they follow the requirements in ASME B&PV Code, Section IX. The staff determined that the weld inspection requirements of AWS D1.6, Table 8.1, are acceptable as the acceptance criteria for welds of important to safety components that are not part of the containment boundary or items relied on for criticality safety or shielding. Therefore, the staff determined that the description of the weld design and inspection specifications for the OP-RMSC package provided by the applicant were acceptable.

7.4 Normal Conditions of Transport

The applicant described the testing for NCT in SAR Section 2.6. The applicant's testing included heat, cold, free drop, and compression. For elevated temperatures, the applicant stated that the maximum steady state temperature for any component would be 1,005 °F (541 °C) for the stainless steel special form capsules. The applicant provided a summary of the package component temperatures in SAR Table 3.1-1. The applicant stated that the higher temperatures expected with a higher decay heat load would not cause a loss of operational capability or damage to the package. The staff reviewed the material properties as a function of temperature and verified that the design stress intensity did not decrease over the range of temperatures expected during NCT. The staff verified that the maximum steady state temperature of 1,005 °F (541 °C) for the stainless steel special form capsules is acceptable because stainless steels are regularly used and retain oxidation resistance at and above this temperature. In addition, the stainless steel special form capsules are tested at a temperature of not less than 1,475 °F (800 °C). Based on the information provided by the applicant and the staff's review of the material properties as a function of temperature, the staff determined that the testing conducted by the applicant was acceptable.

For the cold temperature exposure test, the applicant stated that the OP-RMSC package was exposed to temperatures less than −22 °F (−30 °C) for several hours in an environmental chamber without negative effects. The staff note that for the 10 CFR 71.71(b) states that the demonstration of compliance with the requirements of this part must be based on the ambient temperature preceding and following the tests remaining constant at that value between −29 °C (−20 °F) and 38 °C (100 °F) which is most unfavorable for the feature under consideration. The staff determined that the testing performed by the applicant was acceptable and that the lower temperatures would not result in adverse performance because the materials used in the construction of the OP-RMSC package are compatible with temperatures of −40 °F (−40 °C).

The applicant stated that the free drop test was conducted per the requirements of 10 CFR 71.71(c)(7). The applicant provided test results and confirmed that there was no significant visible deformation to the OP-RMSC test unit. In addition, the applicant stated that the radiation survey following all certification testing demonstrated the ability of the OP-RMSC packaging to maintain the shielding and confinement integrity of the RMSC payload. The staff reviewed the applicant's test results and determined that the testing was performed to the regulatory requirements of 10 CFR 71.71(c)(7).

The applicant stated that the compression test was conducted by applying a 3,390-pound (1,538-kg) force to the OP-RMSC package while sitting in its normal upright position for a period of 24 hours and no observable deformation and damage was detected. The staff reviewed the applicants test results and determined that the testing was performed to the regulatory requirements of 10 CFR 71.71(c)(9).

The applicant did not conduct testing at reduced external pressures or increased external pressures, stating that the OP-RMSC package is a confinement boundary for a special form payload and does not have a pressure boundary. The applicant did not conduct vibration testing stating that the package is essentially rigid with a very high natural frequency and that the OP-RMSC package will not experience any damage or detrimental effects due to vibration normally incident to normal conditions of transport. The applicant did not conduct water spray testing stating that the stainless steel materials of construction utilized for the OP-RMSC package would not be affected by the water spray test. The applicant did not conduct the penetration test called out in 10 CFR 71.71(c)(10) and stated that the OP-RMSC package was puncture tested more severely in accordance with the HAC per 10 CFR 71.73(c)(3), which requires the heavier package to be dropped 40 inches (1 meter) onto a 6-inch (15-cm) diameter bar in the most vulnerable orientation. The staff reviewed the applicant's justifications for not conducting the decreased external pressure test, the increased external pressure test and the water spray test and determined that the applicant's justifications were acceptable because the package is not a pressure boundary and because the special form payload is qualified per the regulatory requirements of 10 CFR 71.75. The staff reviewed the justification provided by the applicant for not conducting the NCT penetration test and determined that the applicant's justification was acceptable because the NCT penetration test is of negligible consequence for this package and the package was robust enough to withstand the HAC tests as demonstrated by the applicant.

7.5 Hypothetical Accident Conditions

The applicant described the testing for the HAC in SAR Section 2.7 with additional details provided in SAR Appendix 2.12. The applicant's testing included free drop tests and puncture tests. The applicant conducted multiple free drop tests and multiple puncture tests to ensure that the most vulnerable package features were subjected to worst-case impact forces and deformations. The applicant provided a summary of the tests and results in SAR Table 2.7-1. The applicant provided details of the testing conditions test results including post-test radiation surveys in the SAR Appendix 2.12. The applicant stated that the most important result of the testing program was the demonstrated ability of the OP-RMSC to contain its RMSC payload for shielding integrity. The staff reviewed the applicants HAC testing and post-test radiation measurements and determined that the free drop tests and puncture tests were conducted in accordance with the requirements of 10 CFR 71.73(c)(1) and 71.73(c)(3) respectively because the applicant conducted multiple tests to evaluate the maximum damage to the package as required.

The applicant did not conduct crush testing or immersion testing. The applicant stated that because the density of the OP-RMSC is greater than 62.4 lb/ft^3 (1,000 kg/m^3), and the radioactive payload is special form, the dynamic crush test is not applicable to the OP-RMSC package. The applicant stated that the OP-RMSC is a confinement boundary for special form payload and does not have a pressure boundary and therefore, the effect of pressure per 10 CPR 71.73(c)(6) is not applicable. The staff reviewed the applicant's justification and determined that the crush test was not applicable to the applicant's package design because the OP-RMSC is greater than 62.4 lb/ft^3 (1,000 kg/m^3), and the radioactive payload is special form.

The staff reviewed the applicant's justification for not conducting an immersion test and determined that because (1) the OP-RMSC does not have a pressure boundary and (2) the special form payload is qualified per the regulatory requirements of 10 CFR 71.75, the immersion test described in 10 CPR 71.73(c)(6) is not necessary to demonstrate package performance under HAC.

The applicant did not conduct thermal testing in accordance with 10 CFR 71.73(c)(4). The applicant stated that in the free drop and puncture tests, there was no separation of the RMSC payload from the OP-RMSC. In addition, the applicant stated that the structural and shielding materials for the OP-RMSC and the RMSC payload, which are Type 304 stainless steel with a melting temperature of at least 2,550 °F (1,400 °C) and sintered tungsten which has a melting temperature of 2,732 °F (1,500 °C) are significantly higher than the specified fire temperature of 1,475 °F (800 °C). The applicant stated that the only combustible materials in the OP-RMSC are the non-structural polyurethane foam, which fills the annulus between the payload cavity and the outer pipe body, and the gasket between the inner closure lid and the payload cavity. The applicant stated that combustion of the foam or the gasket material would have no effect on the structural or shielding materials of either the OP-RMSC or the RMSC payload. The applicant provided an evaluation for the HAC thermal event that showed that special form and other components do not exceed the HAC material limits and there is no loss of shielding material, or any oxidation damage of materials effecting shielding. Because the HAC material limits are significantly higher, the staff finds the applicant's evaluation demonstrated that the OP-RMSC meets the requirements of 10 CFR 71.51(a)(2) for the HAC thermal test. Therefore, the staff determined that the applicant's demonstration that the OP-RMSC meets requirements of 10 CFR 71.51(a)(3) for HAC was acceptable.

7.6 Mechanical Properties

The applicant provided yield strength, tensile strength, design stress intensity and modulus of elasticity for the Type 304 stainless steel materials as a function of temperature from -40 °F (−40 °C) to 400 °F (204 °C). The applicant used the material property values from the 2017 ASME B&PV Code Section II Part D. The staff reviewed the mechanical properties for the Type 304 stainless steel material. The staff reviewed the mechanical properties provided in the application and determined that (1) the listed properties are consistent with those published in the 2017 ASME B&PV Code Section II Part D and (2) austenitic stainless steels such as Type 304 are resistant to brittle fracture at low temperatures. Therefore, the staff determined that the mechanical properties of the stainless steel materials provided by the applicant were acceptable.

The applicant stated that the only safety function tungsten heavy alloys serve is shielding and that the mechanical properties for the tungsten heavy alloys were provided for information only. The applicant referenced the material supplier for the source of the mechanical properties. The applicant stated in SAR Section 2.1.2.2.1 that the tungsten shield material is not susceptible to brittle fracture at temperatures as low as −20 °F (−29 °C) and that based on the low temperature testing of the OP-RMSC package, brittle fracture of the tungsten gamma shields in the RMSC payload is not a concern due to robustness of the package during NCT and HAC drop testing, which had no damage to the inner stainless steel vessel or tungsten shielding material and no effect on radiation performance. The staff reviewed the material properties for the tungsten heavy alloys specified in the RMSC and determined that the mechanical properties were acceptable because the information provided by the applicant was consistent with the properties from the material manufacturer. Therefore, the staff determined that the mechanical properties of the tungsten heavy alloys provided by the applicant were acceptable.

The applicant stated that the annular space between the inner and outer pipes is filled with approximately 32 pounds of rigid polyurethane foam. The applicant stated that the rigid polyurethane foam is not needed to meet the requirements of 10 CFR Part 71 because the foam does not have a safety function and it is not relied upon during NCT and HAC. The applicant did not include material properties for the foam in the OP-RMSC SAR. In response to the staff's request for additional information (RAI) [ADAMS Accession No. ML21216A178] the applicant clarified that the only specification for the polyurethane foam is the minimum density, which is included in the OP-RMSC drawing. The staff reviewed the information provided by the applicant and verified that the rigid polyurethane foam is also an item not needed to meet the requirements of 10 CFR Part 71 in the OP-RMSC SAR drawing and that the drawing specifies the minimum foam density. Therefore, the staff determined that the specifications for the rigid polyurethane foam provided by the applicant were acceptable.

7.7 Thermal Properties of Materials

The applicant provided thermal expansion coefficients for the Type 304 stainless steel materials as a function of temperature from −40 °F (−40 °C) to 400 °F (204 °C) and the thermal expansion coefficients for the tungsten heavy alloys. The staff reviewed the information provided by the applicant on the Type 304 stainless steels and determined that it is consistent with the values published in the 2017 ASME B&PV Code, Section II, Part D. The staff reviewed the thermal expansion coefficients for the tungsten heavy alloys specified in the RMSC and determined that the values provided by the applicant were consistent with the properties from the material manufacturer. Therefore, the staff determined that the thermal properties of the materials provided by the applicant were acceptable.

7.8 Radiation Shielding

The applicant stated that two tungsten heavy alloys are used for the gamma-shielding materials in the RMSC package. The applicant provided the alloy specification and the manufacturer information. The staff reviewed the package design, materials specifications, and the information on the alloys available from the manufacturer. These alloys are produced by powder metallurgy methods using liquid phase sintering. The Densimet® 176 alloy has a density of 0.636 lb/in^3 (17.6 g/cm^3) and the Densimet® 185 alloy has a density of 0.668 lb/in^3 (18.5 g/cm^3). The high density of these alloys makes them effective gamma radiation shielding materials. Therefore, the staff determined that the information provided by the applicant including the package design and material selection for the shielding materials were acceptable.

7.9 Corrosion Resistance

The applicant stated that the OP-RMSC is constructed from Type 304 stainless steel with a rigid polyurethane foam for impact protection of the RMSC. The applicant stated that the stainless steel of the OP-RMSC does not have significant reactions with the interfacing components, air, or water. The applicant specified alloy steel materials for the outer and inner lid bolts. For the shielding materials, the applicant specified tungsten heavy alloys. In addition, the applicant stated that tungsten and Type 304 stainless steel materials are very near each other on the galvanic corrosion chart. There will not be a significant galvanic reaction between these two materials because there is no electrolyte present due to dry loading and the elevated temperature of the special form capsule, which will evaporate any electrolytic liquid. The applicant states that a composition galvanic corrosion cell will not form between the stainless steel and the tungsten heavy metal in the RMSC payload. Since the package is never immersed in water during normal use, and the loading operation is completely dry, the staff concludes that it satisfies the requirements of 10 CFR 71.43(d). Therefore, the staff determined that the applicant's evaluation of the corrosion resistance of the materials were acceptable.

7.10 Content Reactions

The applicant stated that the RMSC payload is sealed special form source material. The staff reviewed the applicant's evaluation and determined that the because (1) the packaging materials are stainless steel and tungsten, (2) the contents are sealed special form materials that must meet the requirements of 10 CFR 71.75, and (3) the operation of the package does not require routine immersion in an aqueous environment or exposure to corrosive environments, the formation of a galvanic couple or electrochemical reactions that produce flammable reaction products such as hydrogen are unlikely. Therefore, the staff determined that the applicant's evaluation that concluded no expected content reactions was acceptable.

7.11 Radiation Effects

The gamma radiation associated with the radioactive material will have no effect on the austenitic stainless steel or the tungsten shields comprising the structural and shielding materials of the OP-RMSC package. The applicant stated that the polyurethane foam provides only limited impact protection of the RMSC payload and that the effect of the radiation on the polyurethane foam to provide this minimal protection is negligible.

The staff reviewed the information provided by the applicant. The staff also reviewed information available on tungsten heavy alloys which have been used in several applications including as gamma radiation shielding materials. The staff found little information on the effects of gamma radiation on tungsten heavy alloy; however, metals and alloys are not typically damaged by gamma radiation. Therefore, the staff determined that the applicant's evaluation that the packaging materials would not be degraded by radiation exposure was acceptable.

7.12 Package Contents

The applicant stated that the RMSC will carry up to four special form capsules that contain the radioactive material. The applicant stated that the package contents are raw material special form source capsules of Ir-192 or Se-75 isotopes with each capsule containing a maximum of 4,000 Ci (148 TBq) of Ir-192, or 4,000 Ci (148 TBq) of Se-75. For the total of four raw material special form capsules, the applicant stated that the maximum radioactive content for the OP-RMSC is 16,000 Ci (592 TBq) and the maximum decay heat for the OP-RMSC is 100 W (341 Btu/hr). The staff reviewed the information provided by the applicant and determined that the applicant has identified the contents of the package in accordance with 10 CFR 71.33(b). Therefore, the staff determined that the description of the package contents provided by the applicant was acceptable.

7.13 Bolting Material

The applicant stated that the OP-RMSC includes a bolted vented closure lid that is secured to the outer stainless steel pipe assembly that is welded to an inner stainless steel pipe, which forms the payload cavity and a bolted inner closure lid that covers the payload cavity. The applicant stated that the RMSC is a welded stainless steel pipe assembly that is welded to a smaller pipe assembly and has a bolted closure lid. The applicant provided specifications for the bolts in the bill of materials included in the drawings. The applicant provided mechanical properties for bolting material in SAR Table 2.2-3. The staff reviewed the information provided by the applicant including the design of the package, closure lids and the ASTM specifications for bolts to secure the package lids. The staff verified that the bolts specified for the package meet ASTM specifications and are produced from materials that are compatible with the package structural materials. Therefore, the staff determined that the specifications and properties of the bolting materials provided by the applicant were acceptable.

7.14 Seals

The RMSC does include a silicone gasket located between the RMSC lid and the RMSC body; however, the applicant stated that the RMSC is not a pressure boundary and does not include seals that require leakage testing. The staff reviewed the package design and materials and determined that the silicone material for the RMSC gasket was acceptable.

7.15 Evaluation Findings

F7.1 The staff has reviewed the package and concludes that the applicant has met the requirements of 10 CFR 71.33. The applicant described the materials used in the transportation package in sufficient detail to support the staff's evaluation.

F7.2 The staff has reviewed the package and concludes that the applicant has met the requirements of 10 CFR 71.31(c). The applicant identified the applicable codes and standards for the design, fabrication, testing, and maintenance of the package and, in the absence of codes and standards, has adequately described controls for material qualification and fabrication.

F7.3 The staff has reviewed the package and concludes that the applicant has met the requirements of 10 CFR 71.43(f) and 10 CFR 71.51(a). The applicant demonstrated effective materials performance of packaging components under normal conditions of transport and hypothetical accident conditions.

F7.4 The staff has reviewed the package and concludes that the applicant has met the requirements of 10 CFR 71.43(d) and established package operations to ensure the requirements of 10 CFR 71.87(b) will be met (see Chapter 8 of this SER). The applicant has demonstrated that there will be no significant corrosion, chemical reactions, or radiation effects that could impair the effectiveness of the packaging. In addition, the package will be inspected before each shipment to verify its condition.

Based on review of the statements and representations in the application, the NRC staff concludes that the materials used in the transportation package design have been adequately described and evaluated and that the package meets the requirements of 10 CFR Part 71.

8.0 PACKAGE OPERATIONS

The objective of this operating procedures evaluation is to verify that the operating controls and procedures for the package (packaging together with contents) meet the requirements in 10 CFR Part 71 and that the package will be operated in a manner consistent with its design and evaluation for approval.

The applicant provided written procedures for the OP-RMSC and RMSC package operation and shipment preparations. The applicant provided a high-level description of the essential elements needed to prepare the package for shipment to assure safe performance of the package under normal conditions of transport and hypothetical accident conditions. The steps are presented in sequential order, with allowed deviations, as applicable. The following operational activity sections and subsections (with step by step instructions) are provided in the package operations chapter of the application:

- Package Loading
- Preparation of the OP-RMSC for loading
- Loading the special form contents into the RMSC
- Preparation for transport
- Package unloading
- Receipt of OP-RMSC from carrier
- Removal of special form contents from the RMSC
- Preparation of empty OP-RMSC for transport.

The staff reviewed each of the sections in SAR Chapter 7, “Package Operations” and their subsections to ensure the package operations are consistent with and ensure the package will be operated as designed and evaluated in the application with respect to shielding. The staff checked that the package operations ensure the package is appropriately assembled for each type of operations, including placement of the tungsten cavity shield within the RMSC prior to closure of the RMSC and loading of the RMSC into the OP-RMSC. The staff also reviewed the operations descriptions to ensure they include appropriate checks of the conditions of the package (e.g., that it is in an unimpaired condition).

The staff also identified that several operations in each section of the operations chapter of the SAR include checks of radiation levels and contamination levels. The applicant confirmed that the operations descriptions include clear definitions of the criteria for determining the radiation levels and contamination levels are acceptable. The staff identified that the applicant uses the regulatory limits for radiation levels and contamination levels as the acceptance criteria in the package operations. In reviewing the package operations descriptions, the staff also considered the operations descriptions of other similar package types for which certificates of compliance have been issued. Based on the consistency with the operations descriptions of these other similar package types and that, for package operations, the requirements of 10 CFR 71.87(i) and (j) only require compliance with these limits to allow the shipment to be made, the staff finds these acceptance criteria acceptable in the package operations. The staff notes that, based on the shielding analysis, these criteria could still allow for something like a higher-than-authorized activity source to be loaded; however, the staff expects that operations to ensure compliance with the other requirements in 10 CFR 71.87 (e.g., 10 CFR 71.87(a)) will contribute to ensuring such does not occur.

The staff notes that the descriptions given in SAR Section 7.3 for preparation of an empty package for shipment are very limited. However, much of what the staff would expect for operations descriptions in SAR Section 7.3 is addressed by the package operations descriptions in SAR Section 7.2.2. Thus, the staff finds the package operations for an empty package to be adequate.

Based on this review, the staff finds that the package operations are appropriate and adequate to ensure the package will be operated consistent with the package design and the relevant regulatory limits for each type of package operations.

8.1 Evaluation Findings

As described in this chapter of the SER:

F8-1 The NRC staff has reviewed the description of the operating procedures and finds that the package will be prepared, loaded, transported, received, and unloaded in a manner consistent with its design and evaluation for approval.

Based on review of the statements and representations in the application, the NRC staff finds that the operating procedures have been adequately described and meet the requirements of 10 CFR Part 71.

9.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM REVIEW

The objective of this acceptance test and maintenance program evaluation is to verify that the acceptance tests for the packaging, as documented in the application, meet the requirements of 10 CFR Part 71. This review will also verify that the maintenance program, as documented in the application, is adequate to assure continued packaging performance while in service.

The applicant provided the acceptance tests each packaging must be subject to before first use to verify that it was fabricated in accordance with its approved design and that its performance will meet the regulatory requirements of 10 CFR Part 71 and be consistent with the package's evaluations.

The application specifically discussed the following package acceptance tests to be performed and the acceptance criteria to demonstrate structural and shielding performance:

- Visual inspections and measurements (requirements delineated on SAR drawings)
- Weld examinations (requirements delineated on SAR drawings)
- Shielding tests (49 CFR 173.441 criteria).

The applicant also provided in this chapter of the application the packaging maintenance program which includes inspections every quarter, and repair and replacement of components on an as-needed basis.

9.1 Acceptance Tests

For this package, there are two sections in the application of acceptance tests that are particularly relevant to the package's shielding design and performance. The first is SAR Section 8.1.1. This section includes visual inspections and measurements. For shielding, the necessary inspections and measurements include those that confirm the materials of construction and the dimensions of the package components meet the requirements of the package drawings, which are included as a condition of the certificate of compliance. For components that are made to a specified industry standard, these inspections and measurements are sufficient to ensure those components' shielding performance. The standards specified in the drawings for the steel components include dimension and tolerance requirements for those components to meet.

The drawings also specify a materials standard and alloy class for each of the tungsten alloy components. The standard includes specifications on alloy compositions and densities, including allowed variation in the densities. The drawings also specifically identify the tolerances on the dimensions of these components. Thus, dimensions of fabricated tungsten alloy components will, per SAR Section 8.1.1 of the application, need to be checked to verify they conform to those dimensions given in the drawings. Plus, these fabricated components will need to be checked to verify conformance with the specified material standard, consistent with any means for that verification that are identified in that standard. The SAR Section 8.1.1 tests also include checks to ensure there are no surface defects (e.g., cracks, pin holes). While SAR Section 8.1.1 states the checks are on the observable surfaces of the tungsten shields, the staff understands that the checks will be done at a stage of package fabrication when all the surfaces of the shields are observable. The staff also understands that the fabrication process for the tungsten alloy components, a powder metallurgy process that involves powder compaction and sintering, is a well-established process that involves controls (e.g., for powder size and distribution) that ensure high quality in fabricated components. The staff reviewed the acceptance tests described in Section 8.1.1 of the application and finds that, accounting for the staff's understanding of the pedigree of their fabrication process, the described tests include the needed inspections and measurements to ensure the tungsten alloy components meet the design specifications in the package drawings.

The staff notes that Drawing No. RMSC-SAR-TA includes a note that the tungsten alloy components will be examined per SAR Section 8.1.6. However, that does not substitute for the visual examinations and measurements in SAR Section 8.1.1 for confirming dimensional and material compliance of the tungsten alloy components. The test in SAR Section 8.1.6 is in addition to those examinations and measurements.

The other section of importance for shielding is SAR Section 8.1.6. The acceptance tests in this section typically are for those components for which the package drawings do not specify an industry standard, the industry standard does not address the needed specifications for shielding, or dimensional or other relevant specifications cannot be determined by visual exam or measurements because of the package design and component fabrication process. Lead shielding that is poured between two steel shells is an example of such a component. For this package, the applicant has proposed a shielding effectiveness test for the tungsten alloy shield components in the RMSC. Based on the staff's review of the SAR Section 8.1.1 tests described above along with the staff's understanding of the components' fabrication process, the staff finds the test in SAR Section 8.1.6 to be an extra backstop against a major fabrication error for the currently proposed package contents. The tests in SAR Section 8.1.1 are sufficient to ensure the fabricated tungsten alloy components meet the minimum design specifications in the package drawings (part of the certificate of compliance) and perform their shielding function as designed and evaluated in the application and so are the basis for the staff's approval of the acceptance tests in relation to shielding.

In its review of the SAR Section 8.1.6 test description, the staff determined that the acceptance test description should include additional information about the acceptance test process that provides assurance that the test is sufficient to identify any portions of the shield components that do not meet the minimum design specifications in the package drawings. The staff also has concerns with the acceptance criterion in terms of its connection to the minimum design specifications in the package drawings. While it may show that the regulatory limit for non-exclusive use is not exceeded for the maximum authorized Ir-192 content, that criterion allows for acceptance of fabricated components that have portions with properties that are significantly outside of the design specifications in the package drawings (based on the evaluation of a package with the drawings' specifications), which are part of the package's certificate of compliance and so must be met. Additionally, were other sources of higher gamma energies to be part of the package's authorized contents and their quantity limits based on analyses or measurements with the tungsten shields at the property specifications defined in the package drawings, the radiation levels for fabricated components that pass the acceptance criterion of the regulatory limit for the Ir-192 contents would significantly exceed the limit for these other, higher gamma energy- emitting contents. This would have been the case for the cobalt-60 content at the quantity initially proposed and evaluated by the applicant. Hence, the staff determined that the acceptance test in SAR Section 8.1.6 is not adequate to confirm the fabricated tungsten alloy shields meet the package design requirements specified in the CoC (i.e., the package drawings which are a condition of the CoC). Thus, the staff's evaluation and findings rely on the SAR Section 8.1.1 tests and the pedigree of the tungsten alloy components' fabrication process, as described above.

9.2 Maintenance Programs

The maintenance program section of the application does not include any maintenance programs or tests specific to shielding. The staff finds this acceptable because the main shielding components are tungsten alloys, which, based on their characteristics, are not expected to age or degrade over time in a way that other shield materials that would need such programs and tests would. Those kinds of shields include polymer-based neutron shields and poured lead shields, among others. Thus, the staff finds a shielding maintenance test and program is not necessary for the shielding components of the proposed package design.

9.3 Evaluation Findings

As described in this chapter of the SER:

F9-1 The staff has reviewed the description of the acceptance tests and finds that the tests are adequate to ensure the requirements of 10 CFR 71.85 will be met for fabricated packages.

F9-2 The staff has reviewed the description of the maintenance program and finds that it is adequate to ensure the package will be maintained consistent with the design to meet the requirements in 10 CFR Part 71 Subparts E and F.

Based on review of the statements and representations in the application, the NRC staff finds that the acceptance tests and maintenance program have been adequately described and meet the requirements of 10 CFR Part 71.

10.0 QUALITY ASSURANCE EVALUATION

The objective of this review is to verify that the application for a transportation package for radioactive material certificate includes a quality assurance program description (QAPD) or references a previously approved QA program. The QAPD must demonstrate that the applicant's QA program complies with the requirements of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," Subpart H, "Quality Assurance."

The applicant references previously NRC approved and current, at the writing of this SER, Industrial Nuclear Company, Inc. Quality Assurance Program Form 311 Approval 0062 Revision 12, under docket 71-0062 in the SAR. The staff reviewed the previously approved Industrial Nuclear Company, Inc. QAPD against the requirements of 10 CFR Part 71.

10.1 Evaluation Findings

The staff has reviewed the applicant's reference to a previously NRC approved description of its QA program and concludes that it is in compliance with applicable NRC regulations and industry standards, and the prior acceptance of the QA program description by NRC allows implementation of the referenced QA program for the design, procurement, fabrication, assembly, testing, modification, maintenance, repair, and use of transportation packagings.

The staff finds, by its prior NRC approval, that the referenced QA program for transportation packagings meets the requirements in 10 CFR Part 71 and addresses all 18 criteria as required in Subpart H to 10 CFR Part 71. The staff also finds that the referenced QA program encompasses design controls, materials, and services procurement controls, records and document controls, fabrication controls, nonconformance and corrective actions controls, an audit program, and operations or programs controls, as appropriate, adequate to ensure that the package will allow safe transport of the radioactive material authorized in this approval. The staff reached this finding based on a review that considered applicable NRC regulations and regulatory guides and the statements and representations contained in the referenced QAPD.

CONDITIONS

In addition to the package description, drawings and contents, the following conditions were included in the CoC:

> Condition No. 6 specifies that "The name plate on the overpack must be fabricated of materials capable of resisting a 1475°F fire environment for one-half hour and maintain its legibility."
>
> Condition No. 7 requires that the operating procedures and the maintenance and acceptance tests listed in Chapter Nos. 7 and 8 of the application, respectively, are followed.
>
> Condition No. 8 authorizes the certificate for use under the general license provisions of 10 CFR 71.17.
>
> Condition No. 9: Expiration date: January 18, 2027.

The references section lists the application provided as part of the review process.

CONCLUSIONS

Based on the statements and representations contained in the application, as supplemented, and the conditions listed above, the staff concludes that the design has been adequately described and evaluated, and the Model No. OP-RMSC package meets the requirements of 10 CFR Part 71.

Issued with Certificate of Compliance No. 9387, Revision No. 0.