UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SAFETY EVALUATION REPORT

Docket No. 71-9385
Model No. IR-100ST
Certificate of Compliance No. 9385
Revision No. 0

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SUMMARY

By letter dated August 12, 2024 (INC, 2024), as supplemented on January 24, 2025 (INC, 2025a), October 1, 2025 (INC, 2025b), and February 12, 2026 (INC, 2026), Industrial Nuclear Company, Inc. ((INC) or the applicant thereafter) requested the U.S. Nuclear Regulatory Commission (NRC) staff (the staff thereafter) to review the application for the Model No. IR-100ST package (also called exposure device or IR-100ST) and issue a certificate of compliance (CoC). The staff issued the CoC for a period of five years. This document includes the staff's safety evaluation and corresponding findings.

REGULATORY REQUIREMENTS

The NRC reviewed the information provided by the applicant for the Model No. IR-100ST package design and its supplements against the regulatory requirements in Title 10 of the *Code of Federal Regulations* (10 CFR), "Packaging and Transportation of Radioactive Material." The staff used NUREG-2216, "Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material," (NRC, 2020) to perform this review.

Enclosure 2

CONDITIONS

The CoC of the Model No. IR-100ST is a new certificate. Therefore, almost all the conditions in the certificate are new, with exception of the “PREAMBLE” and Condition No. 4 “Conditions.” The CoC No. 9385, Revision 0, for Model No. IR-100ST and its corresponding conditions can be found in ML26113A543.

1.0 GENERAL INFORMATION

1.1 Description of the Packaging

Section 1.2.1 of the application, Revision 2, includes the description of the packaging considered in this safety evaluation report. The IR-100ST package is a modified Model No. IR-100 package design, which is an NRC-approved transportation package (Docket No. 71-9157). The main modifications to the Model No. IR-100 package design were due to the addition of security features to track the package in case of loss or theft. Both packages will be procured under the quality assurance program Docket No. 71-0062.

The IR-100ST package is a Type B(U)-96 package designed for transportation of a special form capsule. The capsule is attached to a pigtail assembly that, along with the lock assembly and lock-ball, secures the capsule within the center of the depleted uranium (DU) gamma shield.

The IR-100ST consists of four major fabricated components:

a. a stainless steel housing and lock assembly that enclose and secure the contents,

b. a DU gamma shielding that provides shielding,

c. polyurethane foam that provides protection of the DU from moisture, and

d. a urethane sensor surround that provides remote tracking of the package.

The housing is a rectangular shell structure with overall dimensions of approximately 10.65-inch high × 6.25-inch wide × 10.5-inch long. The housing is constructed entirely of Type 304 stainless steel that completely encloses the foam and the DU gamma shield. The urethane sensor surround incorporates a handle for lifting and tie-down is provided to facilitate handling operations and remote tracking. Welded to opposite ends of the housing are the lock and outlet port assemblies. These assemblies provide the operational capability during use and secure the location of the special form capsule during transportation. The maximum gross weight of the package is 58 pounds (lbs.), according to section 2.12.1.4, which includes approximately 2 lb. of polyurethane foam that fills the space between the DU gamma shield (38 lbs.), per section 2.1.3, and stainless-steel housing. The housing encloses the DU shield and its surrounding polyurethane foam.

1.2 Description of the Content

Section 1.2.2 of the application includes a brief description of the contents of the packaging. Model No. IR-100ST is authorized to transport either a special form Ir-192 or Se-75 source capsule with a maximum of 120 Curies (Ci) (4.44 Terabecquerels (TBq)). The capsule is attached to a pigtail assembly that, along with the lock assembly and lockball, secures the capsule within the center of the DU gamma shield.

The A_2 values of 16 Ci (0.6 TBq) and 81 Ci (3.0 TBq), respectively. The maximum decay heat load for the IR-100ST package is 0.84 watts (W), which is negligible.

1.3 Drawings

Section 1.3.1 of the application, Revision 2, includes the drawings considered in this safety evaluation. Section 7.1 of this SER includes the safety evaluation of the licensing drawings.

1.4 Evaluation Findings

Based on the review of the statements and representations in the application, the staff conclude that the description of the package and drawings in the applications are acceptable and are adequately described and evaluated and they meet the applicable 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 and demonstrated that it meets the regulations in 10 CFR Part 71.

2.1 Structural Design

2.1.1 Description of Structural Design

For the structural design description, refer to Section 1.1, "Description of Packaging," of this SER.

Appendix 1.3.1 of the safety analysis report (SAR) (the application hereafter) includes details of the IR-100ST packaging design drawings. The applicant provided licensing drawings with tolerances, dimensions, material designation, and associated standards. Component descriptions and the arrangement of components relative to each other were detailed by the applicant. The applicant described the weight of the package with center-of-gravity location in section 2.1.3 of the application.

The NRC staff (the staff hereafter) reviewed the package structural design description presented in the "General Information" and "Structural Evaluation" sections of the application and found that the applicant adequately addressed the applicable regulatory requirements of 10 CFR 71.31(a) and 71.33. Therefore, the staff concludes that the contents of the application and package description satisfy the applicable requirements of 10 CFR 71.31(a)(1), 10 CFR 71.31(a)(2), and 10 CFR 71.33.

2.1.2 Design Criteria

The applicant discussed the design criteria for the package structural evaluation in application section 2.1.2. Since the IR-100ST is primarily demonstrated to satisfy the requirements of 10

CFR 71 via full-scale tests, meeting 10 CFR 71, Subpart E, “Package Approval Standards,” of the package upon completion of the tests are the basic design criteria.

The staff notes that the primary safety objectives of the free drop and puncture testing program are to demonstrate the IR-100ST package ability to retain the radiographic source in-place and to maintain integrity of the gamma shielding. Containment is provided primarily by the special form source itself.

Based on the review of the proposed design criteria and structural evaluations in the application, the staff finds that the tests used to evaluate the package under the normal conditions of transport (NCT) and the hypothetical accident conditions (HAC) incorporate the environmental and test conditions specified in 10 CFR 71.71 and 71.73, and tests results are evaluated to meet the structural performance requirements to achieve the primary safety objectives. Therefore, the staff finds that the design criteria are appropriate for the intended purpose and are properly applied, and concludes they satisfy the regulatory requirements of 10 CFR 71.41(a) by testing a full scale prototype of the package.

2.1.3 Codes and Standards for Package Design

The applicant demonstrated that design of the Model No. IR-100ST satisfied the requirements of 10 CFR Part 71 through full-scale tests. For the package fabrication, the applicant utilized conventional metal forming and joining techniques, identified applicable American Society for Testing and Materials (ASTM) standards for the material specifications on the drawings, and identified applicable American Society of Mechanical Engineers (ASME) and American Welding Society (AWS) standards for welding and non-destructive examinations.

The staff reviewed the drawings and found that the ASTM standards specified for the structural material and material grade are appropriate for the material performance of the packaging components. Standard welding symbols and examinations shown on the drawings are in accordance with the applicable ASME/AWS codes and standards.

Based on the review of the proposed codes and standards, the staff concludes that the applicant appropriately applied the standards and used them for their intended purpose.

2.2 General Requirements

2.2.1 Minimum Package Size

The minimum package dimension is 6.25 inches in width, which is greater than 4 inches. Therefore, the staff finds that the package satisfies the requirements of 10 CFR 71.43(a) for minimum size.

2.2.2 Tamper-Indicating Feature

A tamper-indicating seal (wire/lead security seal) is attached to the dust cap of the lock assembly, which provides visual evidence that the closure was not tampered during transport. The staff reviewed the package tamper-indicating feature description and its location and found that the package satisfies the requirements of 10 CFR 71.43(b) for a tamper-indicating feature.

2.2.3 Positive Closure

The staff reviewed the package drawings and the description for positive closure and notes that the lock assembly is designed to conform to 10 CFR 34.23 requirements to prevent unauthorized or accidental removal of the sealed source from its shielded position. The primary containment of the package is provided by the special form sealed source capsule. This capsule is secured to a flexible wire assembly that is captured by the locking assembly, which in turn is positively fastened to the package, preventing its movement. Therefore, the source pigtail assembly in the Model No. IR-I00ST cannot be exposed without opening a key operated lock, and this prevents any inadvertent or unintentional opening of the package during transport. Thus, the staff finds that the requirements of 10 CFR 71.43(c) are satisfied.

2.2.4 Package Valve

The primary containment of the package is provided by the special form sealed source capsule. There are no penetrations to the containment system, and no valves or pressure relief devices. Therefore, the staff finds that requirements of 10 CFR 71.43(e) do not apply to this package.

2.3 Lifting and Tie-Down

2.3.1 Lifting Devices

The staff reviewed the drawings and evaluation in application section 2.5.1 for a lifting device and finds that the package does not have a lifting attachment that is a structural part of the exposure device container body (i.e., housing). However, it is manually lifted by the sensor/handle jacket assembly that surrounds the housing and consists of a urethane elastomer that is molded around the 1/16-inch stainless steel wire rope for the handle structure. The applicant’s evaluation indicated that there was not any measurable distortion or damage to the handle when a force of 182 lbs. (i.e., greater than three times the maximum gross package weight of 58 lbs.) was applied to the handle. Therefore, the handle can support three times the package weight without compromising the safety of the package when lifted by the handle. The staff also finds that there is no other feature on the package other than the handle by which the package can be lifted. Therefore, the staff finds this evaluation by test to be acceptable and concludes that the requirements of 10 CFR 71.45(a) are met.

2.3.2 Tie-Down Devices

Based on review of the evaluation in application section 2.5.2 for a tie-down device, the staff finds that the package may be tied down to secure it during the transport by wrapping nylon straps or rope around the sensor surround handle as shown in figure 7.1-1 of the application. There are no features on the package that are a structural part of the package to which a tie-down device can be attached. Therefore, the applicant tested the package utilizing nylon straps to secure the package to a horizontal surface in a configuration similar to that shown in figure 7.1-1 of the application. Loads equivalent to 10g, 5g, and 2g accelerations were then applied in the horizontal direction of travel, lateral, and vertical directions, respectively, as shown in figure 2.5-1 of the application. The applicant’s evaluation indicated that no damage of the sensor surrounds or the package was observed. Based on review of the tie-down test method, configuration and test results including the response to the staff’s request for additional information (INC, 2025b), the staff finds that the requirements of 10 CFR 71.45(b) are met.

2.4 General Considerations for Structural Evaluation of the Package

The primary structural evaluation of the IR-100ST is performed with various full-scale tests. The applicant used two IR-100ST certification test units (CTUs) during the tests that are identical to the IR-100ST package design depicted in application section 1.3.1, "General Arrangement Drawings." The only difference with the CTUs from the package design is the use of dummy source capsule assemblies during the tests. The maximum gross weight of the IR-100ST exposure device is 58 lbs., while the actual weight of the CTU-1 and CTU-2 before the tests were 55.9 lbs. and 56.4 lbs., respectively. The applicant utilized a horizontal concrete slab with a 2-inch thick steel plate anchored to the slab on a firm ground for the regulatory NCT and HAC free drop and puncture tests. The staff reviewed the details of the unyielding target pad and noted that the mass of the drop pad (concrete and steel plate) is more than 36 times the mass of the IR-100ST CTU. Based on this characteristic and other details, the staff concludes that the drop pad satisfies the requirement of 10 CFR 71.71 and 71.73 for an essentially unyielding, horizontal surface. The puncture bar for the puncture tests is a 6-inch diameter by 12-inch long, solid steel bar with top edges rounded to 0.25-inch maximum radius and welded at the bottom to the steel plate of the drop pad. The staff reviewed the arrangement and details of the puncture bar setup and found it acceptable to potentially cause maximum damage to the CTU. Thus, the staff concludes that it meets the requirements of 10 CFR 71.73(c)(3).

<u>Technical Basis for Drop and Puncture Tests</u>

The objective of the drop and puncture tests is to demonstrate structural integrity of the confinement system and the DU gamma shield assembly during the NCT and HAC. For the confinement system to fail, the radioactive source from the central location within the DU gamma shield assembly either needs to move or separate from its stored position. This potential failure mode may only occur if the lock assembly of the IR-100ST is broken free of the stainless steel housing or damaged, and/or the DU gamma shield assembly translates away from the lock assembly/pigtail assembly such that the source is significantly moved from its desired stored position.

The structural integrity of the confinement system can be compromised by:

a. maximizing damage to the lock assembly or cause significant movement of the special form source within the DU gamma shield of the IR-100ST packaging.

b. maximize damage to the welded stainless steel body (housing) such that it results in a loss of shielding due to a self-sustaining oxidation of the DU during a subsequent HAC thermal test.

Therefore, to maximize the damage to the IR-100ST and potentially separating the radioactive source, the applicant has selected two orientations for the free drop tests:

(1) CG-Over-Lock Assembly (Hot and Cold) and

(2) CG-Over-Lock Assembly Lower or Upper Edge (Hot and Cold).

These same orientations were selected in the subsequent puncture drop tests to produce the worst-case cumulative damage to the package. Unlike free drop tests, the puncture drop tests were performed only at the ambient temperature condition.

The staff reviewed the technical bases provided in application section 2.12.1.5, including the response to the staff's request for additional information. The staff found that the test methods, selected drop orientations, and test sequences are appropriate and sufficient for maximizing the damage to the critical components of the package and are supported by a sound technical basis and rational, and consistent with the requirements of 10 CFR 71.71 and 71.73. The staff also found that the test methods used for the structural evaluation are consistent with the guidance provided in NUREG-2216 (NRC, 2020). Therefore, the staff finds the test methods acceptable to satisfy the requirements of 10 CFR 71.41(a).

The results of these tests and their safety evaluations are provided in the following sections.

2.5 Normal Conditions of Transport

2.5.1 Maximum Normal Operating Pressure

The containment of the package is provided by the special form sealed source capsules, which are independently certified as noted in application section 2.10. The IR-100ST is a confinement boundary for a special form payload and does not contain a pressure boundary. Therefore, the staff concludes that the maximum normal operating pressure requirement of 10 CFR 71.71(b) does not apply to the package.

2.5.2 Heat

The staff reviewed chapter 3.0, "Thermal Evaluation," of the application, and found that the package evaluation for the worst-case high temperature under the normal condition is based on the maximum heat from the lithium power cells at steady-state temperature of 60°C (140°F), an ambient temperature of 38°C (100°F), and maximum insolation. The results of this evaluation indicate that the maximum surface temperature on the upper stainless steel surface is 156°F, and the average surface temperature is 135°F. For the NCT and HAC hot conditions, the certification test unit CTU-1 was pre-heated to a temperature greater than 133°F. The staff considers this acceptable, since the assumed lithium power cells at steady-state temperature of 60°C (140°F) is significantly greater than the heat generated by the actual 2.5 W (8.54 Btu/hour) during charging as noted in application section 3.3.1. The staff concludes that the ambient heat requirements for the package satisfy the standards of 10 CFR 71.71(c)(1).

2.5.3 Cold

In application section 2.6.2, "Cold," the applicant states that the IR-100ST stainless steel body was exposed to a dry ice environment (-109ºF [-78ºC]) for an extended period of time in an ice chest without detrimental effects. The staff notes that -109ºF is lower than the regulatory temperature requirement of -20ºF. The applicant also confirmed in sections 2.12.1.7.2.1 and 2.12.1.7.2.2 of the application that the measured surface temperature of the CTU-2 package was less than -20ºF and -21ºF, respectively.

Based on review of the relevant sections of the application, the staff notes that the two primary structural materials are austenitic stainless steel and the DU gamma shield. As noted in application section 2.12.2.5.1, the cold temperatures below -20°F were utilized at the time of IR-100ST NCT and HAC free drop certification testing. The results of the certification tests demonstrated that extreme cold temperatures had no effect on the shielding integrity of the DU gamma shield in the IR-100ST.

In addition, the austenitic stainless steel and DU materials are not susceptible to brittle fracture, as delineated in application section 2.1.2.2.1, “Brittle Fracture.” The housing, lock assembly and outlet port assembly of the IR-100ST are fabricated from austenitic stainless steel, which does not undergo a ductile-to-brittle transition in the temperature range down to -40ºF (-40ºC), and does not require evaluation for brittle fracture.

The applicant has shown by test that the Model No. IR-l00ST design can withstand the cold NCT. Also, as per the NRC Regulatory Guide 7.11 (NRC, 1991), the stainless steel is not susceptible to brittle failure at temperatures encountered in transport, and their use is acceptable to the staff without having to demonstrate resistance to brittle failure. Therefore, the staff concludes that the requirements of 10 CFR 71.71(c)(2) are satisfied.

2.5.4 Reduced External Pressure

The containment of the package is provided by the special form sealed source capsules, which are independently certified as noted in section 2.10 of the application. The IR-100ST is a confinement boundary for a special form payload and does not contain a pressure boundary. Therefore, the staff concludes that the reduced external pressure requirement of 10 CFR 71.71(c)(3) does not apply to the package.

2.5.5 Increased External Pressure

The containment of the package is provided by the special form sealed source capsules, which are independently certified as noted in application section 2.10. The IR-100ST is a confinement boundary for a special form payload and does not contain a pressure boundary. Therefore, the staff concludes that the increased external pressure requirement of 10 CFR 71.71(c)(4) does not apply to the package.

2.5.6 Vibration and Fatigue

The applicant states that the effects of vibrations induced by NCT on the IR-100ST package are bounded by past experience of the similar IR-100 package that has been subjected to both NCT as well as rugged field use over an extended period of time. The packages have not experienced any damage or effects due to the vibrations induced by NCT, and this does not have any significant effects on packaging safety.

Based on the application review, the staff notes that the package is compact in size and is tied down as described in section 7.1.3 of the application which ensures a limited effect from transport vibration and acceleration to critical components. In addition, the applicant has shown by past experiences that similar packages did not experience any damage or adverse effects due to the vibrations during NCT. Therefore, the staff concludes that the package will withstand vibrations normally incident to the transport and satisfy the requirements of 10 CFR 71.71(c)(5).

2.5.7 Water Spray

The exterior surfaces of the packages are metal and are partially wrapped around by a urethane elastomer jacket assembly. Therefore, the water spray condition will have negligible effect on the packaging. As a result, the staff concludes that the water spray test will not impair the package and concludes that it satisfies the requirements of 10 CFR 71.71(c)(6).

2.5.8 Free Drop

The applicant provides the free drop evaluation of the IR-100ST in section 2.12.1 of the application. The applicant performed actual tests to meet the requirement of 10 CFR Part 71. Since the gross weight of the IR-100ST is less than 11,000 lbs., a 4-feet (ft.) free drop is required. The NCT, 4-ft. free drop, was performed by aligning the center-of-gravity (CG) over the lock assembly lower edge on the certification test unit (CTU) CTU-1 as an initial condition for subsequent HAC tests. The applicant performed a radiation survey following the HAC certification testing to demonstrate the ability of the IR-100ST packaging to maintain its shielding integrity.

The staff reviewed the test methods and test results and found that a 4-ft. free drop to meet NCT requirement was performed only in one orientation described above with a worst-case initial hot condition. This resulted in the cap for the keyed lock separating from the assembly, but no further damage was observed. Furthermore, the staff notes that a radiation survey was only done after all the HAC free drop and puncture tests were performed with the two CTUs in two different orientations with an initial hot and cold conditions.

Based on the review of the radiation survey results, the staff finds that the radiation dose levels were below the requirements of 10 CFR 71.47(a) for the NCT. Based on the review of the test methods and the test results, the staff concludes that the package satisfies the free drop requirements of 10 CFR 71.71(c)(7).

2.5.9 Corner Drop

The corner drop test does not apply to IR-100ST package, since the materials of construction do not include wood or fiberboard, as delineated in 10 CFR 71.71(c)(8).

2.5.10 Compression

As stated in application section 2.6.9, the applicant performed a compression test by applying a 299.7-lb. force to the IR-100ST handle while sitting in its normal upright position, which is greater than five times the gross package weight. No observable deformation or damage was detected at the end of the test.

The staff notes that this package is not stackable with the handle on the top, while sitting in its upright position. Regardless, the applicant has conservatively shown by test that this package is capable of withstanding a load of five times the package weight without any observable deformation or damage to the packaging. Therefore, the staff concludes that the requirements of 10 CFR 71.71(c)(9) are satisfied.

2.5.11 Penetration

The applicant has shown in application section 2.6.10 that the IR-100ST can safely withstand the penetration load based on the previous tests performed on a similar IR-100 package. The tests on the IR-100 were performed by dropping a 1.25-inch diameter, 13-lb. hemispherical end steel bar from a height of 40 inches in an effort to pierce the housing and possibly damage the lock assembly. The bar was dropped onto the outlet end, the side, and the lock body. These tests resulted in a 3/16-inch spherical dent in the impacted surface and a 3-degree angular shift of the lock assembly relative to the housing. The penetration tests demonstrated that the weld integrity was not compromised, there was no damage to the source pigtail assembly, and there was no loss in operational capability of the basic IR-100 package.

The staff reviewed the applicant's evaluation and drawings for both the packages and finds that the IR-100ST and IR-100 packages are similar, especially the housing (stainless steel body) is almost identical, while the lock assembly of the IR-100ST appears to be more robust than the IR-100 lock assembly. Thus, the previous penetration tests for the IR-100 package bound the response of the IR-100ST package to the penetration test. Therefore, the staff concludes that the requirements of 10 CFR 71.71(c)(10) are satisfied.

2.5.12 Conclusion for NCT

The staff reviewed the structural performance of the IR-100ST package under the NCT required by 10 CFR 71.71 and concluded that there will be no substantial reduction in the effectiveness of the package that would prevent it from satisfying the requirements of 10 CFR 71.51(a)(1).

2.6 Hypothetical Accident Conditions

As part of the structural evaluation, the primary proof of performance for the HAC tests is via the use of full-scale testing. In particular, the applicant performed free drop and puncture tests of IR-100ST CTUs to demonstrate that the package will retain its shielding integrity and position of the special form source material following the HAC tests sequence. The structural evaluation for HAC is based on sequential application of the HAC tests specified in 10 CFR 71.73(c) to determine the cumulative effect on the package, in accordance with 10 CFR 71.73(a). The package is evaluated for the most unfavorable initial conditions specified in 10 CFR 71.73(b). The following subsections provide the staff's evaluations, where each accident condition is addressed.

2.6.1 Free Drop

Subpart F of 10 CFR Part 71 requires that a 30-foot (ft.) (9-meter (m)) free drop be considered for the IR-100ST. The free drop is to occur onto a flat, essentially unyielding, horizontal surface, and the package is to strike the surface in an orientation for which the maximum damage is expected. The HAC free drop precedes both the puncture and thermal tests. To properly select a worst-case package orientation for the 30-ft. (9-m) free drop event, items that could potentially compromise shielding integrity and/or the special form source of the IR-100ST were clearly identified, as discussed in section 2.4 of the safety evaluation report (SER).

The applicant tested the Model No. IR-100ST test unit for two orientations of drop impact and for two extreme temperature conditions for a 30-ft. drop test. The applicant used two IR-100ST packages for the 30-ft. drop tests. The CTU-1 drop test sequence consisted of NCT 4-ft. drop test, HAC 30-ft. drop tests, and puncture test, for hot temperature condition, and the CTU-2 drop test sequence consisted of HAC 30-ft. drop tests and puncture test for cold temperature condition. These free drop impact tests are:

(1) CTU-1 CG-over-Lock Assembly at temperature > 133°F,

(2) CTU-1 CG-over-Lower or Upper Edge at temperature > 133°F,

(3) CTU-2 CG-over-Lock Assembly at temperature < -20°F, and

(4) CTU-2 CG-over-Lower Edge at temperature < -20°F.

These free drop tests resulted in:

(1) The CTU-1 lock assembly impacted as intended, minor deformation was observed, the lock cap was missing, and the keyed lock was unlocked but reset easily.

Under the second 30-ft. drop condition with a different orientation, the CTU-1 resulted in a slight deformation of the stainless steel upper edge and nameplate, but no cracks or breach of the DU gamma shielding.

(2) The CTU-2 had pre-existing cracks in the sensor surround due to cold conditioning.

The impact broke the cap for the keyed lock and a part of the sensor surround broke off. Under the second 30-ft. drop condition but with a different orientation, the CTU-2 resulted in the lower section of sensor surround separating from the package, but no damage to the housing.

The staff notes that the NCT free drop test (from a height of 4 ft.) was conducted on CTU-1 as an initial condition for subsequent 30-ft. drop tests, although undamaged packages can be used for 30-ft. drop tests as 10 CFR 71.73 does not specify otherwise. Furthermore, the staff notes that the damage to the CTUs under the drop tests described above only affected the non-important-to-safety components (e.g., sensor surround, cap, etc.) of the package. The most important result of these tests is the demonstrated ability of the IR-100ST package to maintain its shielding integrity. Significant results of the free drop tests are as follows:

(1) No evidence of distortion or damage of the lock assembly occurred that would have significantly displaced the special form source from its desired shielded position.

(2) There was no evidence of rupturing of the stainless steel housing that could have resulted in thermal degradation of the DU gamma shield by excessive oxidation in a subsequent thermal test.

The staff finds that the testing of the CTUs indicates that the various IR-100ST packaging design features are adequately designed to withstand the drop and puncture tests specified in 10 CFR 71.73. Based on the review of the test methods and the test results, the staff conclude that the package satisfies the free drop requirements of 10 CFR 71.73(c)(1).

2.6.2 Crush

The crush test is required only when the specimen has a mass not greater than 1,100 lbs. (500 kg), an overall density not greater than 1,000 kilograms per cubic meter (kg/m^3) (62.4 pounds per cubic feet (lb./ft^3)) based on external dimension, and radioactive contents greater than 1,000 A_2 not as special form radioactive material. Since the package overall density is greater than 1,000 kg/m^3 (62.4 lb./ft^3) and radioactive contents of the packages are qualified as special form radioactive material, the staff concludes that the dynamic crush test requirement of 10 CFR 71.73(c)(2) is not applicable.

2.6.3 Puncture

The puncture tests involve a 40 inch (1 m) free drop of the package onto the upper end of a solid, vertical, cylindrical, mild steel bar mounted on an essentially unyielding, horizontal surface. These tests are performed to demonstrate the ability of the IR-100ST to adequately withstand a puncture drop condition by testing two full-scale, IR-100ST CTUs. The applicant performed these tests to ensure that the most vulnerable package features were subject to the worst-case loads and deformations as discussed in section 2.4 of the SER. The CTUs orientation was selected to maximize damage to the locking assembly and maximize opening in the previously damaged housing area and provide more exposure of the DU gamma shield for the subsequent thermal test. The specific conditions selected for the IR-100ST certification test units (CTUs). Tables 2.7-1 and 2.12.1-1 of the application summarize the test results.

The staff reviewed the puncture test method, test sequence, packages orientations, and test results and found that the puncture test material, dimensions, orientation, test method and sequence were appropriate as per the applicable regulatory requirements. Furthermore, the drop orientations for puncture tests were adjusted to target and impart the most damage to the same critical parts of the package as the free 30-ft. drop tests. The staff notes that the puncture tests performed at an ambient temperature have insignificant impacts on the test results as the fracture toughness, strength and ductility of the structural materials in the packages do not change significantly at or between the extreme hot and cold temperature conditions. Also, the test results did not indicate any significant displacement of the special form source from its shielded position, or any evidence of rupture in the stainless steel housing that contains shielding and the source material. The results confirm that the package maintains structural integrity under the prescribed puncture conditions, with no compromise to the housing and only minor, localized deformation to the lock assembly. Therefore, the staff concludes that the package satisfies the puncture test requirements of 10 CFR 71.73(c)(3).

2.6.4 Thermal

Subpart F of 10 CFR 71 requires performing a thermal test in accordance with the requirements of 10 CFR §71.73(c)(4). The applicant's evaluation of the Model No. IR-100ST package thermal performance for HAC relied on the results of the HAC thermal tests of the NRC-approved Model No. IR-100 package design. As noted in section 2.12.1.5.4 of the IR-100 application, the CTU that experienced a failed weld seam on the bottom long edge was utilized for the HAC thermal test. The staff notes that the free drop and puncture certification testing of the IR-100ST package resulted in no failure of welds in the stainless steel housing from the free drop and puncture tests, as documented in application section 2.7.3.3, "Summary of Results" from the puncture drop tests.

The staff's detailed review and safety evaluation of the thermal performance of the package are provided in chapter 3.0 of this SER.

2.6.5 Immersion - Fissile Material

The IR-100ST package is not authorized to transport fissile material. Therefore, the requirements of 10 CFR 71.73(c)(5) do not apply.

2.6.6 Immersion - All Packages

The containment of the packages is provided by the special form sealed source capsule which has met the ANSI N542 and ISO 2919 classification of Class 3 for pressure. This classification is more limiting than an equivalent immersion pressure load of 21 psig. Therefore, the staff concludes that the requirements of 10 CFR 71.73(c)(6) are satisfied.

2.6.7 Conclusion for HAC

As discussed in the previous sections, the cumulative damaging effects of free drop and puncture drop were satisfactory during certification testing for the IR-100ST. The subsequent post-test radiation survey of the CTUs confirmed that shielding integrity was maintained throughout the HAC test series. Therefore, the staff concludes that the packages maintained their structural integrity and shielding effectiveness during and after the HAC tests and, therefore, satisfy the requirements of 10 CFR 71.73.

2.7 Special Form Radioactive Material

The contents of the IR-100ST are special form source capsules that are authorized for transport under certificate numbers USA/0297/S, USA/0393/S, and USA/0785/S-96 separately from this transport package. Therefore, the test requirements of 10 CFR 71.75 for qualification of special form radioactive material do not apply to this package.

2.8 Evaluation Findings

Based on the review of the statements and representations in the application, the staff conclude that the structural design has been adequately described and evaluated and that the structural design of the package meets the applicable requirements of 10 CFR Part 71.

3.0 THERMAL REVIEW

The objective of this review was to verify that the thermal performance of the IR-100ST package has been adequately evaluated for the tests specified under both NCT and HAC and that the package design satisfies the thermal requirements of 10 CFR Part 71.

3.1 Description of Thermal Design

Section 1.0 of this SER includes a description of the package. Figure 1.2-1 indicated the packaging consists of the welded stainless steel body, DU shield (approximately 38 lb.), lock assembly, outlet port assembly, molded urethane sensor surround (i.e., urethane jacket surrounding the stainless steel housing), polyurethane foam (filling the space between the uranium shield and stainless-steel housing), radioactive source capsule/pigtail assembly, housing vent, and Persistence Monitoring (PM) Tag with lithium power cells. Section 3.1.4 of the application and the response to RAI-Th-1 (INC, 2025b) noted that the housing is vented, which prevents the package from being pressurized. Section 2.1.1 indicated the polyurethane foam that is filled around the DU shield within the housing provides moisture protection of the DU during normal conditions.

Section 1.2.2 of the application described the containment system and content. The content includes a single, special form capsule of Ir-192 or Se-75 with a maximum activity of 120 Ci. Section 3.1.2 of the application indicated that the Ir-192 content provides the bounding decay heat of 0.84 W. As noted in sections 1.2.2, 1.2.4, 2.4.3, and 7.1.2, the special form capsule is secured within the center of the DU gamma shield by the pigtail assembly, lock assembly, and lockball during transport. Section 3.2.1 indicated the special form capsules are qualified per the requirements of 10 CFR 71.75, which includes being exposed to 800°C, and its corresponding higher internal pressure (e.g., ideal gas law), for 10 minutes followed by leakage rate testing.

3.2 Material Properties and Component Specifications

Section 2.2.1, table 2.2-1, and table 2.2-2 of the application includes a discussion of the structural and mechanical properties of the metal and non-structural materials within the package. The applicant provided safety classifications, dimensions, and material specifications of package components in the drawings (e.g., S-tube constructed from ASTM B-338 Grade 9 titanium). Section 2.3.1 and drawing No. IR100ST-B, "IR-100ST Body Assembly SAR," of the application indicated that welds are per ASME/AWS A2.4, "Standard Symbols for Welding, Brazing, and Nondestructive Examination," and welding procedures and personnel are to be qualified in accordance with ASME Boiler and Pressure Vessel Code (B&PVC), Section IX, "Welding, Brazing, and Fusing Qualification." In addition, section 3.2.1 described thermal properties (e.g., thermal conductivity, emissivity, absorptivity) of package materials, including 304 stainless steel, copper, polyurethane foam, and polyurethane elastomer that were applied to the thermal evaluation.

Sections 2.10 and 4.0 of the application listed the allowable content's three U.S. Department of Transportation (DOT) Special Form Certificate numbers (with the associated model number and manufacturer) as USA/0297/S, USA/0393/S, and USA/0785/S-96. Section 4.0 and the certificates indicated that the special form capsule materials can be metallic vanadium, Type 304, Type 316, or Type 316L stainless steel and are seal welded (e.g., heliarc seal welded, laser welded). The special form capsules that receive a DOT Special Form Certificate are certified to withstand the tests described in 10 CFR 71.75, including being exposed to an 800°C environment for 10 minutes and subsequently meeting leakage requirements, or the Class 6 temperature test specified in ISO 2919, "Radioactive protection – Sealed radioactive sources – General requirements and classification."

Section 3.2.1 of the application provided the melting point of the DU and stainless steel, which have the primary safety functions of the package. Table 1 includes a summary of the melting points and safety functions of these materials.

Table 1. Melting points of main materials of construction and safety functions of the Model No. IR-100ST.

Material of Construction	Safety Function	Melting Point Temperature
DU	Primary Shielding	1,133°C (2,071°F)
stainless steel	Primary Structural	1,538°C (2,800°F)

3.3 General Considerations

Section 2.2.2 of the application indicated that interfacing package material components do not result in significant reactions. For example, copper shims are placed between DU and stainless steel to prevent formation of eutectics and the "S" tube made of titanium does not react with DU or stainless steel. Section 2.1.1 of the application noted that the polyurethane foam is a closed cell material.

The thermal request for supplemental information (RSI) and observation responses (INC, 2025a) and information (e.g., battery details, references) provided in sections 1.2.1 and 2.7.4 of the application indicated the PM Tag assembly holds four $LiFePO_4$ batteries (battery type 18650).

The application (e.g., sections 2.7.4 and 3.4.2) and the RSI and Observation responses (INC, 2025a) stated that the batteries could potentially react during the postulated HAC fire, thereby resulting in higher-than-normal temperatures. Specifically, the application often referred to runaway reaction temperatures (and, therefore, its associated thermal energy) of more reactive-chemistry Li-ion power cells/batteries (e.g., $LiCoO_2$ chemistries) of approximately 1,000°C. The applicant indicated that they are using less reactive power cell/batteries, $LiFePO_4$ chemistry, for the IR-100ST package, which would have lower runaway reaction temperatures (i.e., 365°C). Therefore, the result would be a lower associated reaction thermal energy.

Based on the staff's review of the application and associated references an approximate cumulative heat release from four runaway reaction batteries can be estimated as 0.4 megajoules (MJ), which is a fraction of the thermal energy input to the exposed surface of the IR-100ST package from a 30 minute HAC fire at 800°C. The staff notes that this thermal input would tend to be conservative since the application's supporting documents indicated that the thermal input from a $LiFePO_4$ battery runaway reaction would be less than the thermal input from a similar sized $LiCoO_2$ battery. Further discussion of thermal effects due to potential reactions is presented in section 3.5.2 of this SER.

3.4 Thermal Evaluation under Normal Conditions of Transport

3.4.1 Model Description

Section 3.3.1 and the response to RAI-Th-1 (INC, 2025b) discussed package model thermal parameters (e.g., emissivity, absorptivity) as well as the heat condition and cold condition thermal evaluations during NCT. The "hot" thermal analysis conditions, based on maximum insolation of 10 CFR 71.71(c)(1) averaged over a 12-hour period and a 38°C ambient temperature, were applied to an ANSYS model that included a PM Tag enclosure temperature of 140°F (60°C) to account for its 2.5W battery power. The response to RAI Th-1 also indicated that the ½ symmetric ANSYS thermal model accounted for radiation heat transfer between the package surface and a 100°F ambient temperature as well as natural convection heat transfer from the package using convection coefficient correlations based on geometry and package surface temperatures. The response to RAI-Th-1 also provided heat flow convergence values and stated that thermal model results were converged.

Finally, the response to RAI Th-1 (INC, 2025b) indicated that the IR-100ST thermal analysis and model details provided in the application (e.g., figure 3.3-1) were based on ANSYS 2024 R1 software and were performed in accordance with an NRC-approved quality assurance program.

3.4.2 Temperature Results

Results provided in section 3.3.1 and figure 3.3-1 of the application indicated a maximum surface temperature of 156°F (69°C) with an average temperature of 135°F (57°C) at hot conditions with insolation. In addition, section 3.3.1 indicated that hot NCT conditions at 100°F (38°C) without insolation would result in a maximum surface temperature of 100°F (38°C) due to the package's small decay heat (e.g., less than 1W), thereby having a surface temperature less than the 122°F (50°C) allowable surface temperature for non-exclusive use shipments and satisfying 10 CFR 71.43(g).

The staff notes that the package's hot temperatures would increase slightly (i.e., a few degrees), if the effect of the 0.84W decay heat was modeled. For example, although the focus of the above-mentioned thermal analyses was the package's outer surface, it is possible that temperatures higher than the ambient temperature would be found in the interior of the package at, and adjacent to, the special form source capsule with a 0.84W decay heat. Below are additional discussions of results based on temperature variations.

(1) Impact to shield and structural materials. The locally high temperatures at these locations due to the adjacent decay heat source would decrease as conduction heat transfer diffused outward through the adjacent DU metal shield and foam to the package surface. Interior temperatures would not reach high values because the decay heat is relatively low, the thick DU shield has relatively high thermal conductivity, and the amount of foam surrounding the uranium shield is relatively thin for a large portion of the package interior, according to drawing No. IR100ST-B, "IR-100ST Body Assembly SAR," sheet 3 of 3, Revision 1. Therefore, temperatures within the package would be below the allowable temperatures of the structural and shielding materials (e.g., stainless steel, uranium) reported in section 3.2.1 of the application.

(2) Stainless steel housing and DU shield. Section 2.6.1 of the application notes that the IR-100ST stainless steel housing and DU shield were exposed to a maximum temperature of 250°F (121°C) during the approximate three-hour foam cure without damage. Section 2.12.1.5.1 of the application indicated that the IR-100ST CTU was pre-heated to 133°F prior to the certification testing, thus indicating operating temperatures are within allowable temperatures.

(3) "Cold" NCT condition for a package. Section 3.3.1 also indicated a "cold" NCT condition for a package with no decay heat and no insolation would have temperatures equal to the ambient conditions. Sections 2.1.2.2.1 and 3.2.2 stated that the stainless steel and DU materials retain their performance at -20°F. In addition, sections 2.12.1.5.1, 2.12.1.7.2, and the response to RAI-St-3 (INC, 2025b) noted that the CTU package, which included the lithium power cells within the PM Tag, was pre-conditioned to -20°F prior to the cold drop tests by placing the CTU within an ice chest experiencing temperatures near the dry ice environment temperature of -78.5°C. It also was noted that the stainless steel housing was exposed to -40°C for an extended period of time without detrimental effects and section 3.2.2 indicated that stainless steel does not undergo a ductile-to-brittle transition down to -40°C.

(4) DU cold certification testing. Similarly, the DU was preconditioned in dry ice (-78.5°C) for cold certification testing and was previously drop and puncture tested at temperatures less than -20°F, ranging from -49°F to -23°F. Section 2.6.2 of the application noted that the package's urethane sensor surround could crack at the cold dry ice temperature, but section 2.12.1.7.2.1 indicated that the urethane sensor surround is not required for the shielding safety function.

As noted above, application section 3.3.1 indicated a "cold" NCT condition for a package with no decay heat and no insolation would have a steady-state temperature equal to the ambient temperature. However, section 2.4.6 of the application indicated that the power cells have an average power of 0.122W while transmitting and that cell charging has a 2.5W maximum power (with a 4 to 5 hrs. charging period), which occurs when the package is transported within an enclosed secure transport box in an enclosed transport vehicle. Therefore, the batteries' internal power generation (e.g., 2.5W) within the enclosed areas would result in battery temperatures greater than the ambient cold temperature.

3.4.3 Maximum Normal Operating Pressure (MNOP)

Sections 3.1.4 and 3.3.2 of the application noted that the package is designed so that gases can freely move between the package internal cavity and the environment; therefore, the package is not pressurized. In addition, the maximum package temperature of 156°F reported in section 3.3.1 and the temperature's resulting NCT special form capsule internal pressure are bounded by the special form qualification test parameters of 10 CFR 71.75, which are successfully tested for leakage after being exposed to an 800°C temperature and its corresponding internal pressure (i.e., ideal gas law) for 10 minutes.

3.4.4 Maximum Thermal Stress

Section 3.4.4 of the application noted that, based on post-test examinations, there was no damage due to thermal stress after the HAC. The staff notes that NCT package temperatures, which do not result in large temperature gradients, and resulting stresses are bounded by those during the fire HAC.

3.5 Thermal Evaluation under Hypothetical Accident Conditions

3.5.1 Evaluation Methodology

Section 3.4 of the application discussed the thermal performance of the IR-100ST package during the fire HAC. The HAC thermal test evaluation was based on a similar IR-100 certification test unit (per SAR reference 31), although it did not include a urethane sensor surround or PM Tag. The test unit, which had previously undergone drop and puncture tests, was placed within an oven and exposed to a forced convective environment such that the package surface was at least 800°C (1475°F) for 30 minutes. A post-test examination showed that the polyurethane foam surrounding the DU was consumed by the fire, such that the package experienced the thermal input from the HAC fire and the additional polyurethane foam combustion. The response to RAI-Th-2 (INC, 2025b) indicated that the package's polyurethane fill holes, which also act as vents to release heated gases within the housing, would not be covered from melted plastic of the urethane sensor surround and, therefore, would remain operational during the fire HAC.

3.5.2 Maximum Temperatures

According to section 3.4 of the application, the DU shield showed no appreciable oxidation and the outer package housing was not compromised. The peak temperatures of the DU gamma shield and stainless steel housing were below their melting point temperatures (see table 1 of this SER). Specifically, section 3.4.3 of the application stated that the maximum recorded package temperatures were more than 500°F (260°C) below the melting point of steel and DU.

Section 2.12.1.7.2.5 provided HAC post-test radiation survey results that indicated the IR-100ST certified test units holding an Ir-192 special form source continued to achieve radiation dose levels below 10 CFR 71.41.51(a)(2) requirements after the HAC structural tests. Similarly, section 3.4.2 indicated that a post-fire radiation survey of the IR-100 certified test unit showed that it did not suffer shielding degradation after the HAC fire test. Section 3.4.2 and the RSI and observation response (INC, 2025a) indicated that the special form capsule integrity would be maintained after the fire test based on its certified qualification, which was supported by there being no rupture of the test capsule located within the IR-100 test unit exposed to the HAC thermal environment.

As noted in section 3.3 of this SER, the IR-100ST includes $LiFePO_4$ batteries and a urethane surround that could result in additional thermal input towards the package if runaway reactions or combustion occurred during the fire HAC. The applicant noted in section 3.4.2 of the application that the 800°C thermal test of the IR-100 test unit included the effects of the package's polyurethane foam combustion. It also noted the thermal input from runaway reactions would not affect the safety function of the DU shield and the special form capsule centrally located within the shield.

Likewise, as noted in section 3.3 of this SER, the application indicated that reacting battery temperatures would be less than 800°C and the thermal input from the four $LiFePO_4$ batteries would tend to be a fraction of the thermal input from an 800°C HAC fire. Section 2.7 of the application and the RSI and observation response (INC, 2025a) indicated that only a portion of the thermal energy would be directed towards the package (i.e., the top side of the PM Tag enclosure that is adjacent to the stainless steel housing). In addition, the staff found that a simplified thermal calculation that modeled the temperature within the center of a spherical DU mass[1] surrounded by a thin layer of polyurethane foam and an outer stainless-steel housing with an external ambient temperature of approximately 1,000°C [2] showed interior temperatures of the high thermal mass shield would reach sufficiently less than 800°C during a 30 minute period.

The above-mentioned calculation included a number of conservative assumptions. For example, the time period of the additional transitory thermal inputs would tend to be less than 30 minutes. In addition, the modeled layer of internal polyurethane foam had a reduced thickness compared to actual fabrication, and therefore, was conservatively less insulative. The staff notes that the less than 800°C DU shield temperature surrounding the special form capsule is lower than a special form capsule being directly exposed to the 800°C temperature condition of the 10 CFR 71.75 special form thermal test. Based on the above discussion, there is reasonable assurance that the effect of additional thermal input beyond that of the 30 minute 800°C fire HAC, such as reactions from the urethane jacket and batteries, would not result in appreciable impacts on the package's DU shield or the integrity of the special form source centrally located within the DU shield.

3.5.3 Maximum Pressure

Section 3.4.3 of the application and the response to RAI-Th-1 (INC, 2025b) noted that package design allows for free movement of gases from the internal cavity to the environment during package operations and conditions (e.g., fire HAC) such that there is no pressurization in the package.

In addition, sections 2.7, 2.12, and 3.4 of the application and the thermal RSI and observation response (INC, 2025a) indicated that test results showed there was no damage to the DU shield (i.e., no oxidation), which confines the special form capsule, and no damage to the special form test source capsules within the package after the structural HAC transport tests or thermal input

[1] Approximately the weight of the DU shield in section 2.1.3 of the application.
[2] A higher flame temperature due to additional thermal inputs, such as urethane jacket combustion.

from the 30-minute HAC fire at 800°C. Specifically, the special form capsule remained within the insulative confines (i.e., not exposed to ambient conditions, including the 800°C fire temperature) of the 38 lb. DU shield during the HAC tests. As indicated in section 3.2.1 of the application, the special form source capsules are thermally tested (at higher internal pressure due to the ideal gas law) to withstand (without leakage) direct exposure to an 800 °C environment for 10 minutes.

3.5.4 Maximum Thermal Stresses

Section 3.4.4 of the application stated that no damage to the IR-100 certified test unit was observed during the fire test's post-examination due to thermal stresses.

3.6 Evaluation Findings

The staff reviewed the package description, material properties, component specifications, and the methods used in the thermal evaluation and has reasonable assurance that they are sufficient to provide a basis for evaluation of the package against the thermal requirements of 10 CFR Part 71. The staff reviewed the accessible surface temperatures of the IR-100ST package as it will be prepared for shipment and has reasonable assurance that the temperatures satisfy 10 CFR 71.43(g). The staff reviewed the package design, construction, and package preparations for shipment and has reasonable assurance that the package material and component temperatures will not extend beyond the specified allowable limits during NCT, consistent with the tests specified in 10 CFR 71.71. The staff also has reasonable assurance that the package material and component temperatures will not exceed the specified allowable short-time limits during HAC, consistent with the tests specified in 10 CFR 71.73.

Based on review of the statements and representations in the application, the staff concludes that the thermal design has been adequately described and evaluated, and that the thermal performance of the IR-100ST package meets the thermal requirements of 10 CFR Part 71.

4.0 CONTAINMENT EVALUATION

The objective of this review was to verify that the containment associated with the IR-100ST package (designated as Type B package) for transporting a specified special form source would meet the regulations under NCT and HAC. The regulations applicable to the containment review include 10 CFR 71.31, 71.33, 71.35, 71.43, and 71.51.

4.1 Description of Containment Boundary and Content

As noted in drawing No. IR100ST-A, "IR-100ST Package Assembly SAR," figure 1.2-1, and section 1.2.1 of the application, the IR-100ST package is a hand-held exposure device (e.g., radiography) in which a small special form source capsule (which is the containment boundary) is centrically located within a thick DU shield that is surrounded by an outer polyurethane foam inside a welded stainless-steel housing. A steel lock assembly is welded to one end of the housing and surrounds the lower elevation end of the S-shaped titanium source tube whereas a steel outlet port assembly is welded to the opposite end of the housing and surrounds the upper elevation end of the titanium source tube; steel dust covers attach to the lock and outlet port assemblies and block both ends of the source tube. As noted in sections 1.2.2, 1.2.4, 2.4.3, and 7.1.2 of the application, the special form capsule is secured within the center of the DU gamma shield by the pigtail assembly, source changer and lock, lock assembly, guide tube, drive cable components, and lockball during transport. Section 2.4.3 of the application indicated that these features result in the positive closure of the package to meet 10 CFR 71.43(c).

Section 2.1.1 of the application noted that the package is designed to transport a maximum of 120 Ci of Ir-192 or Se-75 in a special form capsule. Table 5-2 of the application indicated that the Ir-192 source has the higher unit dose per curie and section 3.1.2 of the application stated that it results in the package's maximum decay heat of 0.84W.

Sections 2.10 and 4.0 of the application listed the manufacturer, model number, and DOT certification number for the special form source capsules that contain Ir-192 in solid metallic form or Se-75 in a solid metal alloy. It stated that the INC special form capsules are welded metallic stainless-steel constructions whereas the SPEC VSe special form source capsules are welded metallic vanadium constructions. The referenced DOT Special Form Certificates included the source and capsule construction descriptions (e.g., drawings), including capsule materials and weld details. For example, the allowable content's three DOT Special Form Certificate numbers (with the associated model number and manufacturer) were listed as USA/0297/S, USA/0393/S, and USA/0785/S-96 and indicated that the special form capsule materials can be metallic vanadium, Type 304, Type 316 or Type 316L stainless steel and are welded, including by heliarc seal welding and laser welding.

Section 2.1.4 of the application stated that the IR-100ST does not contain a pressure boundary. However, section 3.2.1 of the application noted that the special form capsules are qualified per 10 CFR 71.75 tests, which includes a check for leakage to confirm that the capsules retain their integrity after undergoing test conditions (e.g., structural-related tests, the thermal test, and its corresponding internal pressurization).

4.2 General Considerations

Section 2.2.2 of the application indicated that material selection and package design resulted in no significant reactions between package components. For example, copper shims are placed between steel and uranium interfaces to prevent a possible eutectic reaction.

Section 2.1.4 of the application mentioned that the package is designed to industrial metal fabrication standards. Specifically, drawing No. IR100ST-B indicated that package welds are per ASME/AWS A2.4 code. Similarly, the drawing and section 2.3.1 of the application stated that all welding procedures and personnel are to be qualified per ASME B&PVC, Section IX. The drawings provided in section 1.3.1 of the application also provided package material designations (e.g., Type 304 stainless steel). Mechanical properties of the package's stainless steel were based on Section II, Part D, of the ASME B&PVC.

4.3 Containment Evaluation under Normal Conditions of Transport

Section 2.6.2 and section 3.2.2 of the application noted that DU and the stainless-steel material (e.g., housing) were tested to temperatures below -20°F and can withstand temperatures as low as -40°C. Section 2.12.1.5.1 noted that CTU-1 was heated to 133°F for the NCT and HAC hot condition. Similarly, section 3.2.1 noted that the high temperature limit of the DU and stainless steel is associated with their melting temperatures of 1,133°C (2,071°F) and 1,538°C (2,800°F), respectively, which are above the package HAC fire temperatures reported in section 3.4 of the application. Section 2.6 described the various structural-related normal conditions of transport test results for the IR-100ST test units, which indicated damage was limited to slight dents (approximately 3/16-inch) of the housing's impact surface or slight shifts (e.g., 3-degree) of the lock assembly with the housing; there was no reported damage to the DU shield. Therefore, the special form source capsule would remain within the undamaged shielded arrangement and remain confined within the package, thus satisfying 10 CFR 71.43(f).

4.4 Containment Evaluation under Hypothetical Accident Conditions

Sections 2.7, 2.12, and 3.4 of the application and the thermal RSI and observation response (INC, 2025a) indicated that test results showed there was no damage to the DU shield (i.e., no oxidation), which confines the special form capsule, and no damage to the special form test source capsules within the package after the structural HAC transport tests or thermal input from the 30-minute HAC fire at 800°C. Staff notes that the special form capsule remained within the insulative (i.e., not exposed to ambient conditions) confines of the 38 lb. DU shield during the HAC tests. As indicated in section 3.2.1 of the application, the special form source capsules are thermally tested (and at a higher internal pressure due to the ideal gas law) to withstand (without leakage) exposure to an 800°C environment for 10 minutes. Therefore, the special form capsule maintaining its integrity during NCT and HAC would satisfy 10 CFR 71.51(a).

4.5 Conclusion

The staff reviewed the applicant's description and evaluation of the package's containment system and concludes that the application identifies applicable and established codes and standards for the IR-100ST package and the containment system is securely closed such that it cannot be opened unintentionally or by pressure that may arise within the package. The staff reviewed the applicant's evaluation of the special form source capsule (i.e., containment boundary) as well as the package that surrounds it under NCT and concludes that the package is designed, constructed, and prepared for shipment so that under the tests specified in 10 CFR 71.71 the package satisfies the containment requirements of 10 CFR 71.43(f) and 10 CFR 71.51(a)(1) for NCT with no dependence on filters or a mechanical cooling system. The staff has reviewed the applicant's evaluation of the containment system under HAC and concludes that the package satisfies the containment requirements of 10 CFR 71.51(a)(2) for HAC, with no dependence on filters or a mechanical cooling system.

4.6 Evaluation Findings

Based on review of the statements and representations in the application, the staff finds that the IR-100ST package has been adequately described and evaluated to demonstrate that it satisfies the containment requirements of 10 CFR Part 71.

5.0 SHIELDING EVALUATION

The objective of this shielding evaluation is to ensure that the Model No. IR-100ST package, as it pertains to shielding, protects immediate area workers and members of the public against radiation that is above the regulatory limits stated in 10 CFR Part 71 for NCT and HAC. The applicant is requesting a Type B(U)-96 certification for this container designed to transport Ir-192 and Se-75 special form capsules.

The staff reviewed the package's effectiveness in safely shielding the radioactive contents and evaluated the potential external shipping dose rates.

5.1 Shielding Design Features

The IR-100ST incorporates several shielding design features to ensure safe operation. The device is a welded assembly that houses a DU gamma shield surrounding a titanium S-tube. A stainless-steel special-form capsule containing either an Ir-192 or Se-75 radioactive source is inserted into the S-tube using a pigtail assembly. During use, the source is positioned at the geometric center of the DU shield, providing optimal gamma-ray attenuation. Section 1.0 of the SER includes information regarding the package design.

5.1.1 Summary Table of Maximum Radiation Levels

Table 5-1 of the application summarizes the maximum measured external radiation levels for the IR-100ST CTUs loaded with the bounding payload configuration of 120 Ci (4.44 TBq) of Ir-192 under non-exclusive use shipment conditions. The measurement results demonstrate that exposure to both elevated and reduced ambient temperatures did not adversely impact the shielding safety function of the IR-100ST package.

The staff confirmed that the applicant:

(1) identified the package contents and provided the content specifications that produce the maximum external radiation levels,

(2) supplied the content configurations associated with the limiting radiation conditions for all intended uses of the package, and

(3) described the purpose of the package design and the corresponding safety evaluations.

The staff also verified that the application clearly identified the type of use and shipment conditions for which the package is designed and evaluated. In addition, the staff confirmed that the applicant calculated the maximum external radiation levels for all relevant and appropriate package surfaces. The highest radiation levels occur at the top surface, with an 11.5% margin to the applicable regulatory limits.

5.1.2 Gamma Sources

The radioactive contents of the IR-100ST are limited to 120 Ci (4.44 TBq) of either Ir-192 or Se-75. Table 5-2 shows that, Ir-192 produces an average photon energy of 0.380 Megaelectron volt (MeV)) per curie (MeV/Ci) of activity while Se-75 produces 0.280 MeV/Ci. Accordingly, the Ir-192 payload bounds the Se-75 payload for the approved 120-Ci (4.44-TBq) content limit.

5.1.3 Neutron Source

There is no fissile material for this package.

5.2 Shielding Model

The applicant used prototypic testing using a special form Ir-192 capsule instead of computational models. The Ir-192 source was utilized to perform tests for the effectiveness of the gamma shield that yielded a package surface dose rate of 171 millirem per hour (mrem/hr.) and a 1-m dose rate of 2.1 mrem/hr. for NCT. The applicant compared the gamma constants for

Ir-192 and Se-75 to their test results. The staff reviewed the gamma constants provided by the applicant and found their values compared to the gamma constants conservative with Ir-192 bounding Se-75.

5.2.1 Material Properties

The IR-100ST is constructed of a 12-gauge (0.105-inch) thick stainless steel outer skin surrounding polyurethane foam and a DU gamma shield. The payload was qualified per the "Qualification of Special Form Radioactive Material," in 10 CFR 71.75(b)(4).

5.3 External Radiation Levels

Testing of the prototypic IR-100ST package containing a sealed-source payload of 120 Ci (4.44 TBq) of Ir-192 was conducted under NCT in accordance with the requirements of 10 CFR Part 71.

Measured external radiation levels were:

a. *Surface dose rate:* 171 mrem/hr. (1.71 millisievert's (mSv)/hr.)

b. *Dose rate at 1-m:* 2.1 mrem/hr. (0.02 mSv/hr.)

These results demonstrate a substantial margin of compliance relative to the applicable regulatory limits:

> 10 CFR 71.47(a) establishes maximum allowable external radiation levels during transport, including a surface limit of 200 mrem/hr. (2 mSv/hr.) and a 1-meter transport index limit of 10 mrem/hr. (0.1 mSv/hr.).

The regulation, specifically 10 CFR 71.51(a)(2), requires that the package provides adequate shielding such that external radiation levels remain within the limits specified in 10 CFR 71.47 under NCT. The measured radiation levels are well below the regulatory limits at both the surface of the package and at 1-meter location, confirming that the shielding design of the IR-100ST package performs as intended when loaded with the tested Ir-192 source strength.

5.4 Evaluation Findings

Based on these results, the IR-100ST package meets the external radiation control requirements for NCT as specified in 10 CFR 71.47(a) and 71.51(a)(2), thereby demonstrating acceptable shielding performance and compliance with applicable federal regulations.

6.0 MATERIALS EVALUATION

The objective of the staff's materials evaluation for the IR-100ST package is to determine whether the applicant adequately described and evaluated the properties and performance of materials used in the construction IR-100ST package for ensuring that the package meets the requirements of 10 CFR Part 71.

6.1 General Description of the IR-100ST Package and General Arrangement Drawings

The IR-100ST exposure device is a Type B(U)-96 package designed to transport a single special form Ir-192 or Se-75 capsule for use as a radiographic gamma source. The application identifies the IR-100ST package as a modified version on the NRC-approved IR-100 package. The design of the IR-100ST package includes a new sensor/handle jacket assembly covering the exterior of the stainless steel package body housing. The sensor/handle jacket assembly includes a Lithium ion (Li-ion) battery-powered persistence monitoring (PM) tag to provide remote tracking of the package.

6.1.1 Components Important to Safety and Functions

The important to safety (ITS) functions of the IR-100ST packaging include gamma shielding and retaining the special form radioactive source capsule in its required position inside the DU shield assembly. Since the sealed special form source capsule itself provides the containment of the radioactive contents (i.e., Ir-192 or Se-75 sources), the packaging body components are not relied on for leak-tight containment of radioactive contents. However, they must ensure adequate protection and retention of the special form source capsule inside the DU shield assembly for all NCT and HAC conditions and tests. The Ir-192 and Se-75 special form radioactive contents are gamma source materials that include no fissile material. Therefore, the package design does not include any criticality safety structures or materials.

The ITS packaging body components for the IR-100ST and the NRC-approved IR-100 package design include a stainless steel housing that encloses the DU gamma shield assembly, with polyurethane foam filling the interior space between the DU shield casting and the stainless steel housing. A titanium S-tube is fully embedded within the DU shield casting for both the IR-100ST and NRC-approved IR-100 package design. The radioactive source capsule and attached pigtail assembly must remain secured in the middle of the S-tube inside the DU casting for maximum shielding when the package is not being operated as radiographic exposure device. The IR-100ST and IR-100 designs include an ITS lock assembly and a safety plug assembly (identified as the outlet port assembly in the modified IR-100ST design), constructed of stainless steel parts, that are welded to the stainless steel housing on the front and back ends of the package. The lock assembly secures the source-pigtail assembly in its proper shielded position in the S-tube inside the DU shield assembly. The lock assembly and safety plug assembly prevent inadvertent displacement or removal of the radioactive source from its safely stored shielded position inside the DU shield assembly.

6.1.2 Comparison with the IR-100 Package Design

The staff reviewed the applicant's description of the package components and radioactive contents and confirmed that the IR-100ST package is a modified version of the NRC-approved IR-100 package. The staff compared the NRC-approved IR-100 package design information to the design information for the IR-100ST and found that the materials of construction for the ITS packaging body components are generally the same for both package designs. The staff identified that the only significant difference between the IR-100ST and the IR-100 packaging components was the addition of a sensor/handle jacket assembly around the exterior of the stainless steel package body housing. The sensor/handle jacket assembly includes an elastomer jacket surrounding the stainless steel handle and package body housing, a rigid polymer persistence monitoring (PM) tag with electronics to provide remote tracking of the IR-100ST package during transport, and lithium-ion (Li-ion) batteries that are contained within the sealed PM tag enclosure to power the PM tag electronics. The general arrangement drawings, as updated in RAI response (INC, 2025b), include material specifications for the elastomer jacket, the polymer PM tag, and vendor product specifications for the Li-ion batteries.

6.1.3 Drawing Classifications and Evaluation

The staff confirmed that the general arrangement drawings include visual renderings of the packaging assemblies and components, listings of components and constituent parts, their material specifications, and their safety classifications. The staff noted that the applicant's safety classifications for packaging components, sensor/handle jacket assembly components, and parts generally follows the NRC guidelines in NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety" (NRC, 1996). The applicant classified the new sensor/handle jacket assembly components as NITS in the drawings since the applicant determined that these items are not relied on for performing the ITS functions of the package, including gamma shielding and safe positioning of the radioactive source. The staff determined that the NITS safety classification is consistent and acceptable provided that a failure or malfunction of these components would not lead to a loss or deterioration in the safety function of an ITS package component, such that package is not in compliance with applicable performance requirements for Type B packages in 10 CFR Part 71, Subpart E. The staff's evaluation of potential failure modes for the sensor/handle jacket assembly components and materials, in particular the Li-ion batteries, and their potential impact on the performance of ITS component safety functions is discussed in further detail below in sections 6.2, 6.3, and 6.4 of this SER.

6.2 Codes and Standards for Materials and Fabrication

The staff reviewed the application to determine whether it includes acceptable codes and standards for the materials and fabrication of the IR-100ST package. For ITS metallic components that are relied on to ensure the required structural performance for NCT and HAC, the staff confirmed that the general arrangement drawings include acceptable ASTM standard material specifications and alloy grades to ensure the required material properties and performance characteristics. The staff confirmed that the mechanical properties specified in the application for the stainless steel housing are consistent with those in the ASME B&PV Code, Section II, Part D. Since the qualification of the IR-100ST package for NCT and HAC is generally based on real tests performed on actual test units, the staff determined that detailed mechanical and thermal property tables are not required for other component materials (provided that they demonstrate acceptable performance for all applicable conditions and tests required under 10 CFR 71.71 and 71.73 for NCT and HAC, respectively). For the polyurethane foam inside the package body and the passive elastomer jacket and rigid polymer parts of the PM tag, the staff confirmed that the drawings include acceptable specifications for commercial polymer products with publicly available vendor product data sheets.

6.2.1 Welding

With regard to fabrication of the stainless steel package body housing welds, the staff confirmed that the general arrangement drawings specify that welding procedures and personnel shall be qualified in accordance with the requirements of the ASME B&PV Code, Section IX" Welding, Brazing, and Fusing Qualifications." The staff also noted that the drawings specify that all welds shall be visually examined in accordance with the requirements of AWS D1.6, "Structural Welding Code-Stainless Steel." The staff determined that these standards are adequate to ensure that the welds in the stainless steel housing have the required strength and are free of unacceptable fabrication defects that could result in a loss of structural integrity that leads to a loss of shielding function during NCT and HAC.

6.2.2 Li-ion batteries

The staff noted that section 1.2.1 of the application includes a description of Li-ion battery materials and lists references for Li-ion battery product specifications and associated international consensus standards that are used to determine that there is no significant risk of thermal runaway reaction for off-normal battery operating conditions (such as common electrical faults, including overcharging and short circuits) and NCT. The staff identified that, for certain battery types other than those described and referenced in section 1.2.1 of the application, a thermal runaway reaction affecting the safety performance of the package could potentially be initiated for NCT and off-normal battery operating conditions. Susceptibility to thermal runaway for NCT and off-normal battery operations would not meet the requirements of 10 CFR 71.43(d), as addressed further in section 6.4 of this SER. Therefore, the staff determined that the Li-ion battery type described and referenced in section 1.2.1 of the application needed to be included in the general arrangement drawing for the sensor/handle jacket assembly. In its RAI response (INC, 2025b), the applicant updated Drawing No. IR100ST-D for the sensor/handle jacket assembly to include a specification for the Li-ion batteries. The staff reviewed the Li-ion battery specification in the updated drawing and confirmed that it is consistent with the description of the batteries in section 1.2.1 of the application. Therefore, the specification of the Li-ion batteries in the drawing ensures that the batteries conform to applicable standards for protecting against thermal runaway for NCT and off-normal battery operating conditions.

6.3 Mechanical, Thermal, and Shielding Performance of Package Materials for NCT and HAC Tests

The applicant's testing and evaluation of IR-100ST package performance for NCT and HAC was based on real tests performed on actual test units. Therefore, the staff reviewed the applicant's description of package component performance as a result of the NCT and HAC drop tests and confirmed that the tests adequately demonstrate that all packaging materials and special form radioactive contents have the mechanical and shielding performance characteristics needed to ensure compliance with applicable requirements in 10 CFR Part 71, Subpart E. Specifically, the staff confirmed that the full sequence of NCT and HAC drop tests did not cause any structural failure of any ITS component.[3] The only damage was superficial plastic deformation, and did not lead to an unacceptable decrease in shielding performance or displacement of the special form radioactive source. The staff also confirmed that the NCT and HAC drop tests adequately demonstrated that failure of the passive components of the sensor/handle jacket assembly would not lead to a loss of safety function for the ITS components due to HAC drop tests since the tests showed that the DU shielding performance was maintained, and the source was adequately retained in the required position inside the shield assembly as a result of the tests. Therefore, the staff determined that the mechanical properties and performance of the package materials for NCT and HAC are acceptable.

6.3.1 Brittle Fracture

With respect to brittle fracture resistance of ITS metallic structural components of the packaging, the staff noted that the application documents that the DU shield material has been sufficiently qualified for brittle fracture resistance at the lowest service temperature (LST) since the

[3] Section 2.0 of the SER includes the structural evaluation of the package.

IR-100ST package was pre-conditioned at temperatures well below the LST for the HAC drop tests. The staff confirmed that that HAC drop tests showed that the integrity of the DU shield material was adequately maintained at temperatures below the LST. Since the other ITS metallic structural components of the package are predominately austenitic stainless steel, the staff determined that there is no risk of brittle fracture for these other components during NCT and HAC because austenitic stainless steel generally exhibits sufficient ductility at temperatures below the LST of the package. Therefore, the staff determined that the metallic structural materials of the IR-100ST packaging are acceptable with regard to their resistance to brittle fracture at the LST.

6.3.2 Combustion or Decomposition of Material

Based on review of allowable service temperature from vendor product specifications, the staff confirmed that the polyurethane foam inside the package body housing and the elastomer and rigid polymer materials used for the passive subcomponents of the sensor/handle jacket assembly will not melt or deteriorate at the highest calculated package surface temperature for the NCT heat test in 10 CFR 71.71(c)(1). Based on review of vendor product literature and associated technical studies of battery safety for high temperature conditions, the staff also confirmed that the Li-ion batteries described in the application and specified in the drawings will not undergo a thermal runaway reaction at the highest calculated package surface temperature for the NCT heat test in10 CFR 71.71(c)(1). Therefore, the staff determined that the thermal properties of the new sensor/handle jacket assembly components are acceptable for NCT.

The IR-100ST test sequence did not include an HAC thermal test, and the applicant’s evaluation of IR-100ST performance for HAC thermal conditions relied on data obtained from HAC thermal testing of the IR-100 test unit for certification of the NRC-approved IR-100 package design. The IR-100 test unit that was subjected to the HAC thermal test did not include the sensor/handle jacket assembly and Li-ion batteries. The applicant’s evaluation of the IR-100ST package determined that the HAC thermal test could initiate combustion of organic materials and thermal runaway in the Li-ion batteries, but these reactions would not prevent the package from meeting applicable HAC performance requirements in 10 CFR 71.51(a)(2). The staff’s thermal evaluation in section 3.0 of this SER evaluates the impact of the fire scenario and Li-ion battery thermal runaway reactions on the safety performance of package for the HAC thermal test.

With respect to packaging material integrity during the HAC thermal test, the staff identified that the applicant needed to demonstrate that heat inputs into the package due to exposure to the thermal test conditions of 10 CFR 71.73(c)(4), plus additional heat inputs due to combustion of new organic materials in the sensor/handle jacket assembly, and thermal runaway of Li-ion batteries, will not lead to over pressurization that could rupture the stainless steel housing. The staff identified that such a failure could cause an ingress of high temperature air into the package and lead to an unacceptable decrease in shielding performance due to rapid high-temperature oxidation of DU shielding material and dispersion of radioactive contents. In its RAI response (INC, 2025b) addressing this issue, the applicant identified that the stainless steel housing of the IR-100ST package is not a pressure boundary, and any gas generated by combustion of the interior polyurethane foam will exit the housing through foam fill holes in the top of the housing. The applicant indicated that the lack of pressure buildup inside the housing was previously demonstrated by the full-scale HAC thermal test of the IR-100 package.

The staff reviewed the RAI response and confirmed that the package body drawings show a foam fill hole located at the top of the stainless steel housing. The staff determined that such a hole would adequately protect against any significant pressurization of the housing during the

HAC thermal event. Further, the applicant's thermal evaluation shows that the stainless steel housing, DU shield, and sealed source will not be susceptible to melting, rapid oxidation, or other unacceptable phase transformation during the event. Therefore, considering the results of the staff's thermal evaluation in section 3.0 of this SER, the staff determined that the application adequately demonstrates that the additional heat inputs due to combustion of organic materials in the sensor/handle jacket assembly and thermal runaway of Li-ion batteries will not result in the release of radioactive material and external radiation dose exceeding the threshold values specified in 10 CFR 71.51(a)(2).

6.4 Corrosion, Chemical, Galvanic, and Other Reactions

The regulation 10 CFR 71.43(d) requires that a package must be made of materials that assure that there will be no significant chemical, galvanic, or other reaction among the packaging components, among package contents, or between the packaging components and the package contents, including possible reaction resulting from inleakage of water, to the maximum credible extent. This regulation also requires that account must be taken of the behavior of materials under irradiation. The staff identified that the gamma radiation emitted by special form radiography sources, including Ir-192 or Se-75, does not have any impact on the structural and shielding performance of any package materials. Compliance with 10 CFR 71.43(d) for protecting against significant reactions must be assured for NCT, whereas for HAC, in particular for the HAC thermal test of 10 CFR 71.73(c)(4), the absence of any significant chemical, galvanic, or other reaction is not required since the performance requirements of 10 CFR 71.51(a)(2) are controlling.

With respect to potential corrosion, including potential galvanic reactions from dissimilar metal contacts, the staff confirmed that the application adequately demonstrates that the ITS metallic components are adequately protected against significant corrosion that could lead to a loss or significant deterioration in safety function. Specifically, the staff confirmed that the stainless steel construction of the package body components that are directly exposed to outdoor air and moisture is sufficient to protect against general corrosion, and there are no dissimilar metal contacts that could lead to galvanic corrosion. The staff also confirmed that the interior components of the package, including the DU shield casting and titanium S-tube, are not susceptible to significant corrosion since the polyurethane foam that fills the space between DU shield and the stainless steel package body housing protects these components against moisture intrusion that could lead to corrosion, and there are no direct contacts between dissimilar metals that could lead to galvanic corrosion. The staff noted that the application documents that the DU shield casting has an epoxy coating to protect against direct metal contact with stainless steel and titanium components that could potentially lead to galvanic corrosion of DU in the unlikely event that moisture intrusion into the interior of the package were to occur. Therefore, the staff determined that the application adequately demonstrates that the ITS components of the package are adequately protected against corrosion and galvanic reactions for NCT.

The staff evaluated the effects of the new sensor/handle jacket assembly, PM tag, and Li-ion battery materials on the potential for chemical, galvanic, and other reactions amongst the packaging components and between the packaging components and the package contents. The staff reviewed publicly-available vendor material data sheets for the polyurethane foam, NITS elastomer jacket, and the polymer PM tag and confirmed that the highest package temperature for NCT will not result in unacceptable deterioration or adverse reactions in these items.

The staff reviewed the design specifications for the Li-ion batteries to determine if they are adequate to protect against a potential thermal runaway reaction in the batteries that could adversely affect the integrity of DU gamma shielding, the special form source capsule, or retention of the radioactive source inside the packaging body. Such reactions are generally prohibited for NCT in accordance with 10 CFR 71.43(d), if they adversely affect package safety performance. Section 1.2.1 of the application includes a general description of the Li-ion battery design and safety features, battery cell materials and chemistry, and references for battery vendor product specifications and international consensus standards for ensuring battery safety under various off-normal operating conditions, including electrical faults, mechanical damage, and high temperatures. The staff reviewed the description of the battery design characteristics and associated references to determine whether electrical faults, such as short circuit, overcharge, over-discharge, mechanical damage, or high service temperatures could initiate thermal runaway in the batteries. Based on its review of the information in section 1.2.1, the staff determined that the Li-ion batteries are acceptable for NCT since the tests performed on the batteries, as described in the product specifications and consensus standards, demonstrate that no significant thermal runaway reaction will occur due to short circuit, overcharge, over-discharge, crush, nail puncture, and high temperatures that exceed the highest analyzed NCT temperature. The staff also determined that the applicant included an acceptable product specification for the Li-ion batteries in Drawing No. IR100ST-D, as updated in the October 1, 2025 RAI response (INC 2005b), to ensure that the safety features of the batteries are included in design of the package.

The staff determined that the application adequately demonstrates that there will be no significant chemical, galvanic, or other reactions among the packaging components, among package contents, or between the packaging components and the package contents for NCT. Therefore, the staff finds that the IR-100ST package meets the requirements of 10 CFR 71.43(d).

6.5 Evaluation Findings

a. 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.

b. 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.

c. 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 NCT and HAC.

d. The staff has reviewed the package and concludes that the applicant has met the requirements of 10 CFR 71.85(a). The applicant has determined that there are no significant cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging.

e. The staff has reviewed the package and concludes that the applicant has met the requirements of 10 CFR 71.43(d), 10 CFR 71.85(a), and 10 CFR 71.87(b) and (g). 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 staff finds 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.

The staff reviewed the application and found that the IR-100ST package meets the applicable requirements of 10 CFR Part 71. The applicant adequately described the materials used in the package in accordance with 10 CFR 71.33, identified the relevant design, fabrication, testing, and maintenance codes and standards as required by 10 CFR 71.31(c), and provided sufficient controls where standards are not available. The applicant demonstrated acceptable materials performance under NCT and HAC in compliance with 10 CFR 71.43(f) and 10 CFR 71.51(a). In accordance with 10 CFR 71.85(a), the applicant has verified that the package contains no defects that could reduce its effectiveness. The applicant has also shown, consistent with 10 CFR 71.43(d), 71.85(a), and 71.87(b) and (g), that corrosion, chemical reactions, radiation effects, and other degradation mechanisms will not impair package integrity, and that inspections prior to each shipment will ensure continued acceptability. Based on the statements and representations in the application, the staff finds that the materials used in the package design have been adequately described and evaluated, and that the package complies with the requirements of 10 CFR Part 71.

7.0 OPERATING PROCEDURES EVALUATION

The objective of the staff's review of the package operating procedures is to verify that the Model No. IR-100ST package operational controls and procedures present acceptable operating sequences, guidance, and generic procedures to ensure that the package is operated in a safe and reliable manner pursuant to the provisions of 10 CFR Part 71. Section 7 of the application includes:

1) the preparation for loading the packaging,

2) the loading of the contents,

3) the preparation for transport of the package,

4) the package unloading that includes the receipt of the package and removal of the contents, and

5) the preparation for shipment of an empty packaging for transport.

The following sections include the staff's evaluation.

7.1 Package Loading

The Model No. IR-100ST application provides general loading procedures and identifies guidelines and requirements that are applicable to the use of the package. The development of detailed loading procedures remains the responsibility of each user, as needed.

Based on the information in section 7.1, the staff concludes that the loading procedures provide the relevant information for creating site-specific procedures and meeting relevant regulatory requirements. The staff further concludes that the procedures are in the proper sequence and contain sufficient detail to support users in preparing their site-specific loading procedures.

7.2 Package Unloading

The applicant provided the Model No. IR-100ST package unloading procedures to show a general approach to operational activities, which included a brief description of opening the package and removing the content. Section 7.2 of the application includes the inspections and special preparation for package unloading as well as conducting radiation and contamination surveys and the inspection of the tamper-indicating device.

7.3 Preparation of Empty Package for Transport

Section 7.3 of the application describes the operational steps for the user to follow in preparation of the empty package for transportation to ensure the package labeling meets the requirements of the DOT as specified in 49 CFR 172.428, "Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans."

7.4 Evaluation Findings

Based on the review of the description of the operating procedures in section 7 of the application, the staff finds that the package will be prepared, loaded, transported, received, and unloaded in a manner consistent with its design and evaluation for approval. The staff finds that the operating procedures have been adequately described and meet the requirements of 10 CFR Part 71, which consist of the review of statements and representations in the application.

8.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM EVALUATION

Section 8 of the application outlines the acceptance tests and maintenance program for the Model No. IR-100ST package. The application identifies the required acceptance tests and maintenance activities for this package type and summarizes the pre-use and periodic testing requirements, inspections, and criteria for component repair or replacement that applicable to the Model No. IR-100ST.

The acceptance tests from section 8.1 of the application include the following:

1) visual inspections and measurements,

2) weld examination,

3) structural and pressure tests,

4) leakage tests,

5) component and materials tests,

6) shielding tests,

7) thermal tests, and

8) miscellaneous tests.

The applicant summarized the Model No. IR-100ST acceptance tests to describe the general approach for each applicable test. The application includes a description of the test and the acceptance criteria, as appropriate. The staff review of the applicable acceptance tests verified that the applicant described the appropriate fabrication and periodic verification tests to demonstrate effectiveness of the shielding tests. The review also verified that there was a maintenance program to monitor any wearing of the S-tube inspections.

Section 8.2 of the application provides the maintenance program for the Model No. IR-100ST package. The maintenance program includes:

1) structural and pressure tests,

2) leak tests,

3) components and materials tests,

4) thermal tests, and

5) miscellaneous tests for shielding.

The staff based the maintenance program review in part on the descriptions and evaluations described in the application for the containment and shielding maintenance activities related to the packaging to verify that the packaging would maintain its effectiveness throughout its time in service.

8.1 Evaluation Findings

The staff has reviewed the identification of the codes, standards, and provisions of the quality assurance (QA) program applicable to the package design and finds that they meet the requirements specified in 10 CFR 71.31(c) and 10 CFR 71.37(b).

The staff has reviewed the description of the preliminary determinations for the package before first use and finds that it meets the requirements of 10 CFR 71.85 and 10 CFR 71.87(g).

The staff has reviewed the description of the routine determinations for package use preceding transport and finds that they meet the requirements of 10 CFR 71.87(b) and 10 CFR 71.87(g).

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

9.0 REFERENCES

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CONCLUSION

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. IR-100ST package meets the requirements of 10 CFR Part 71.

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