AFFIDAVIT

I, Kevin J. Schehr state as follows:

1) I am President of ISOFLEX Radioactive LLC and acting on behalf of ISO-RAD Canada Inc., a Canadian company, which controls the information described in the redacted Docket Number 71-3099 Request for Additional Information (RAI) submitted to the USDOT and subsequently being transferred to the USNRC for review. This information, which is sought to be withheld, and I am authorized to apply for its withholding.

2) The information sought to be withheld is the content of ISO-RAD Canada Inc. is specific information that has been redacted ([redacted]) in the redacted version of the RAIs and the supporting documents.

3) In making this application for withholding of security, proprietary, confidential or trade secret information of which it is the owner, ISO-RAD Canada Inc. relies upon the exemption from disclosure set forth in the Freedom of Information Act (FOIA) and the Trade Secrets Act, and NRC Regulations 10 CFR 9.17(a)(4), and 2.390(a)(4) for "Trade Secrets, Commercial, Proprietary/Privileged and Confidential Information."

4) Some examples of information which fit into the definition of proprietary/privileged and confidential information are:
   a. Information that discloses our security related information related to the ISORAD-TC1 Type B package.
   b. Information that would allow a competitor to learn about our unit volume, operational plans, variance over performance, vendors, or sales cycles.

   If the information identified in 4a and 4b above were used by competitor/competitors, it would lower their expenditure of resources or improve their competitive position in the design, manufacture, sales, shipment and licensing of similar product/products. The information sought to be withheld is considered to be proprietary for these reasons.

5) To address 10 CFR 2.390(b)(4), the information sought to be withheld is being submitted to NRC in confidence. The information is customarily held in confidence by ISO-RAD Canada Inc., is not available to the public or disclosed to third parties.

I declare that the foregoing affidavit and the information stated therein are true and correct to the best of my knowledge, information and believe.

DATED this the 28th day of October 2021

Kevin J Schehr
Signature of Affiant

KEVIN J. SCHEHR
Printed Name of Affiant

PRESIDENT
Title of Affiant

EVERETT RUSSELL
Notary Public - Louisiana
Jefferson Parish
Notary ID 137087

SWORN to and subscribed before me, this 28th day of October 2021

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October 31, 2021

Mr. Michael Conroy
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Department of Transportation,
East Building, 1200 New Jersey Avenue SE.,
Washington, DC 20590-0001

Mr. Nishka Devaser
Project Manager
Nuclear Regulatory Commission
Spent Fuel Licensing Branch Division of Spent Fuel Management,

Ref: Docket Number 71-3099 Response to RAIs from October 4, 2021 Type B Certificate CDN/2101/B(U)

Dear Mr. Conroy and Mr. Devaser,

The purpose of this letter is ISO-RAD Canada Inc.'s (ISO-RAD's) response to the Request for Additional Information (RAI)s issued on October 04, 2021 and October 5, 2021. The information is being submitted under 10 CFR Part 2.390 because the information in the responses contains proprietary confidential business information and security related information.

The following are ISO-RAD's responses to the RAIs:

General Information Review

RAI 1-1 Provide updated drawings for all inner container configurations that show the dimensions and materials of construction for the outer casing, top plate, bottom plate, lid, shield, brass bottom support, brass top support, and source cavity.

SAR Sections 71.31(a)(1), 71.35 (a)(1), 71.33(a)(5), and 71.35(a) of Part 71 of Title 10 of Code of Federal Regulations (10 CFR) require the application for a certificate of compliance of a transportation package to include drawings. The applicant states in the SAR Section 1.2.1.3.2 that the BPIC - Round top plate is 25.34 mm thick austenitic stainless steel; however, the drawing for that component does not contain the dimensional and material information for that component. This is true for other components such as the Bottom Plate and the inner cylinder. It is also applicable to all inner container configurations. In addition, the application identifies that both depleted uranium and tungsten can be utilized as shielding material for the ISO-RAD package; however, the SAR drawings only identify depleted uranium as the shielding material. The SAR drawings currently do not identify the shielding material thicknesses even though different SAR sections identify a minimum shield thickness (e.g., 1.2.1.3.4). This is especially true for the tungsten shielding material thicknesses since multiple SAR sections state that the amount of brass in the package is reduced, but do not quantify the reduction.

This information is necessary to satisfy the requirements in 10 CFR 71.31(a)(1), 71.33(a)(5) and 71.35(a).

ISO-RAD Response to RAI 1-1 is as follows:

1. The Tungsten versions of the ISORAD-TC1 are withdrawn from US Revalidation.

2. ISO-RAD has updated drawings specifically for the USNRC. The drawings are classified as RAI drawings and include additional dimensioning that contains proprietary trade secret information as well as security related information. The drawings will be submitted under 10 CFR Part 2.390. The following updated RAI Drawings are attached:
   A. RAI R180831-200 BPIC - Square
   B. RAI R180831-300 MPIC - Square
   C. RAI R180831-400 BPIC - Round
   D. RAI R180831-500 BPIC - 2835A
   E. RAI R180831-600 MPIC - Round
   F. RAI R180831-202 Plug Assembly
   G. RAI R180831-508 Plug Assembly
   H. RAI R180831-216 Top Plate and Cavity Assy
   I. RAI R180831-111B-9 ISORAD-TC1 2835A Spacer
   J. RAI R180831-TMD ISORAD-TC1 Thermal Model Drawing

RAI 1-2 Provide the shield plug assembly drawings for the BPIC – Square, BPIC – Round and the BPIC – 2835A package configurations.

SAR Sections 71.31(a)(1), 71.33(a)(5) and 71.35(a) of 10 CFR Part 71 require the application for a certificate of compliance of a transportation package to include drawings. The drawings for the BPIC – Square, BPIC – Round and the BPIC – 2835A package configurations, R180831-200, R180831-400, and R180831-500 respectively, identify a plug assembly as a package component. On each of the drawings, in the column marked "ASTM or Other," the information provided to describe the plug assembly is "SEE DRAWING." However, no drawings were provided that show the plug assembly dimensions, the materials used to fabricate the plug assembly, the fabrication methods, etc.

USNRC additional information added in supplemental email dated October 05, 2021, "Seeing the drawing was helpful, however, important dimensions are missing".

This information is necessary to satisfy the requirements in 10 CFR 71.31(a)(1), 71.33(a)(5) and 71.35(a).

ISO-RAD response to RAI 1-2 is as follows:

1. This information was provided on September 6, 2021, but an additional request for information to include more dimensional information was subsequently received. Please see the attached Drawing Number RAI R180831-202 (For the BPIC Square and Round) and Drawing Number RAI R180831-508 (For the BPIC 2835A). The drawings provide the additional requested information.

RAI 1-3 Clarify what materials are used to fabricate the BPIC – 2385A inner cylinder and shield. SAR Section 1.2.1.6 states that the BPIC – 2385A inner cylinder is fabricated from austenitic

stainless steel. SAR Section 1.2.1.6.4 states that the BPIC – 2385A inner cylinder is fabricated from either titanium or austenitic stainless steel. In addition, SAR Section 1.2.1.6, which provides a general description of the BPIC – 2385A inner container configuration, only identifies DU as the shielding material while SAR Section 1.2.1.6.4 states that the BPIC – 2385A shield is either DU or tungsten. Staff needs clarification on the package configuration to understand the package's shielding performance.

This information is necessary to satisfy the requirements in 10 CFR 71.33(a).

ISO-RAD response to RAI 1-3 is as follows:

1. SAR Section 1 has been updated to correct and clarify the error that the inner cylinder is titanium and that there is a Tungsten version. It appears that while assembling the SAR, the section for the BPIC – Square or Round was copied and only the reference dimensions were changed. The BPIC 2835A has only one version with DU shielding with an inner cylinder fabricated from austenitic stainless steel. ISO-RAD apologizes for this error in the SAR application. The original drawings submitted with the SAR R180831-500 and R180831-501 contain the correct information. The additional drawing RAI R180831-500 contains the additional requested dimensional information.

RAI 1-4 Provide the following information for the tungsten insert:

a. structural and shielding design (i.e., dimensions, material properties, etc.), and

b. the contents with which the tungsten insert must be used.

SAR Section 1.2.2 states that an optional tungsten insert may be used during shipments while SAR Section 5.1.1 states that the tungsten inserts are optional and used when necessary. However, staff cannot find information in the SAR which describes the tungsten insert. The applicant needs to provide a drawing to show the tungsten insert's configuration. A specification for the tungsten material properties is also needed as this information is necessary for shielding evaluation. In addition, the applicant should specify the contents which require use of the tungsten insert.

This information is necessary to satisfy the requirements in 10 CFR 71.33(a), 71.33(b), 71.47, and 71.51(a).

ISO-RAD response to RAI 1-4 is as follows:

1. The Tungsten versions of the ISORAD-TC1 are withdrawn from US Revalidation.

Chapter 2 – Structural Safety Evaluation

RAI 2-1. Provide evaluation on vibration of bolts. The applicant stated that bolts are used as part of the ISORAD-TC1 package. However, no evaluation is provided regarding the assurance that these bolts will not loosen during the transportation conditions. Provide analysis that demonstrates performance of bolts under these conditions.

This information is needed to comply with IAEA SSR-6 paragraph 613.

ISO-RAD response to RAI 2-1 is as follows:

1. ISO-RAD Canada could not find a vibration test requirement in 10 CFR Part 71 or vibration test requirement in IAEA SSR-6. See information from the regulatory documents:
   A. SSR-6(2018) Section 613 states, "The *package* shall be capable of withstanding the effects of any acceleration, vibration or vibration resonance that may arise under routine conditions of transport without any deterioration in the effectiveness of the closing devices on the various receptacles or in the integrity of the *package* as a whole. In particular, nuts, bolts and other securing devices shall be so designed as to prevent them from becoming loose or being released unintentionally, even after repeated use." (pg. 89).
   B. The SSR-6 guidance document IAEA SSG-26 Section 613.1 states, "Components of a packaging, including those associated with the containment system, lifting attachments and retention systems, may be subject to 'working loose' as a result of acceleration, vibration or vibration resonance. Attention should be paid in the package design to ensure that any nuts, bolts and other retention devices remain secure during routine conditions of transport." (pg. 137). Again, no test or acceptance criteria is provided.
   C. NUREG-1886 Section 2.6.5 states, "This section should describe the evaluation of the package for the effects of vibrations that are normally incident to transport, as specified in 10 CFR 71.71(c)(5) or Paragraph 612 of TS-R-1. The combined stresses attributable to vibration, temperature, and pressure loads should be considered, and a fatigue analysis should be included if applicable. If closure bolts are reused, the bolt preload should be considered in the fatigue evaluation. Packaging components, including internals, should be evaluated for resonant vibration conditions that can cause rapid fatigue damage." (pg. 23).

   SSR-6 section, SSG-26 section, nor the NUREG-1886 section suggest a test procedure to demonstrate a pass/fail criteria. The sections do not suggest parameters to perform the test such as frequency, amplitude, or duration.

2. The experience of the designer is one with 26 years in the industry and another engineer with nearly 50 years experience, we have not experienced a loose or missing bolt on any Type B packages handled during this time. The 26 year person shipped out over 1500 Type B packages per year and received about the same number of packages. In addition, an event report search was conducted, and two instances of loose bolts were found, but not in a similar package. The event report concluded that the loose bolts did not pose a safety hazard.

3. Other similar Type B package SARs provided the following information regarding vibration:
   A. According to [redacted], "**2.6.5 Vibration** In the 20 years that the [redacted] transport package has been in use, no transport packages have failed due to vibration. It is therefore concluded that the [redacted] will

withstand vibration normally incident to transport." (pg. 2-8).

B. According to [redacted], "The [redacted] package and its inner packages are similar in construction to many transport packages which have been in use in the radiography industry for many years. Specifically, it is very similar in design to the [redacted]. There have never been any reports of vibration induced failures of these packages. Therefore, we conclude that the [redacted] package, and the inner packages, will withstand the vibration normally incident to transport. (pg. 2-7).

4. ISO-RAD Canada designed the package with the intention of using split lock washers to secure the Outer Drum Lid. The M14 A4 Stainless Steel Lock Washers apply 700 n/mm^2 (157.37 pounds of force) on the bolt creating friction and tension to prevent the bolt from loosening during transportation. The recommended torque for an M14 x 2 A4/Grade 8.8 Hex Head Bolt is 87 to 118 Foot Pounds (References 6, 7, and 10). The torque required to make the split lock washer flatten (fully compress) is at least 157.37 foot pounds. Therefore, if the M14 A4 split lock washer is visually inspected as flat, the bolt is torqued above the recommended torque value. This should meet the vibration requirement of normal conditions of transport.

5. Two separate ISORAD-TC1 Packages were subjected to the Normal Conditions and Hypothetical Condition Tests and the M14 bolts remained tight. Both of the 9 meter (30 foot) drop tests were with the top of the package down (orientation 1 - 45 degree angle corner drop and Orientation 2 – Straight down) to provide the highest amount of stress to the M14 bolts. The interior M8 and M6 Cap Head screws also remained tight during the Normal Conditions and Hypothetical Conditions Tests. The temperature variation from -40° C to 40° C during the testing did not cause the bolts to loosen. The cork insulator also provides the additional benefits of shock absorbing and vibration dampening effects that will limit the vibration effects on the internal components of the Type B package namely the BPIC Inner Containers and the M8 and M6 Cap Head Screws.

RAI 2-2. Provide justification for the conclusion that the damage from the drop test would not impede the safety of the package nor render the package to not be fit for transport.
The applicant stated the following "When Prototype #2 was disassembled to load the radioactive material into the package, the only damage noted was minimal damage to the first spacer for the Inner Container 2835A configuration. The first spacer is butt up against the Inner Container lid. The lid has a raised point that impaled the first spacer causing a 3mm diameter break in the first spacer. <u>The damage would not impede the safety of the package nor render the package to not be fit for transport</u>."

It is not clear to the staff why the lack of functionality of the "impaled spacer" does not render the package unfit for transport. Provide additional justification for this statement and clarify safety classification of the spacer.

This is needed to comply with IAEA SSR-6 paragraph 716.

ISO-RAD response to RAI 2-2 is as follows:

1. The cork spacer serves to compensate for the height differential between the BPIC – Square or Round height 278.0 mm and the BPIC 2835A height 248.00 mm and adjustment for the protrusion to 240.85 mm. The spacer has two optional configurations:
   A. The spacer is one solid piece of cork, and
   B. The spacer consists of three layers of approximately 12.7 mm each.

2. The slight damage described in the SAR, was limited to the one of the three (the one closest to the BPIC 2835A lid). The damage did not render the spacer non-functional. The depth of the hole was 3 mm (0.118in) less than 1/8" and the diameter of the hole was 3 mm (0.118 in) less than 1/8". The movement of 1/8" did not cause an increase in significant movement and the post-test radiation reading demonstrated the pass criteria of no significant increase in radiation levels (>20%). Type A or Normal Conditions for Transport testing does not require the package to suffer no damage. Typically, Type B packages (transport container, source changers, and industrial radiography devices) suffer minor damage during normal transport conditions. ISO-RAD classifies minor damage as scratches, dents, small holes, etc. that do not impair the operation or cause a significant increase in the radiation dose levels. The ISORAD-TC1 2835 was tested and passed the Normal Conditions for Transport test criteria.

3. The BPIC 2835 spacer does not provide thermal protection as calculated in the thermal analysis. The thermal protection is calculated using only the Cork Assembly outside of the Drum Cavity and the Drum Cork Lid.

4. The safety classification of the cork spacer is Class B as noted on SAR Section 1 drawing R180831-101-5. An additional drawing is included RAI R180831-111B-9, detailing the spacer configurations. A lifting hole in the spacer serves to aid in insertion and removal the spacer and to fit over the protrusion eliminating the chance of impaling the spacer during transport.

RAI 2-3. Provide clarification on pressure calculations.

SAR Section 3.5.3.2 discusses pressure acting on the special form capsules and its associated bolts. Some of this discussion is unclear or hard to follow for the staff. In particular, the staff needs additional clarification on the following:

a. Page 3-14, states that "Therefore, the maximum stress on each bolt is 217.05 lbs/0.13272 in2 = 1,635.4766 psi." Clarify how the force of 217.05 lbs was calculated.

b. Page 3-15, the maximum stress calculation appears to be incorrect. The applicant seems to be dividing internal air pressure (lb/in2) by area (in2) and obtaining pressure (lb/in2). Please clarify this possible discrepancy.

c. Page 3-15, the area of the inside closure seems to be equating two distinct areas. Please clarify this possible discrepancy.

This information is needed to comply with SSR-6 paragraph 728.

ISO-RAD response to RAI 2-3 is as follows:

1. The results in SAR Section 3.5.3.2 are not correct. It appears ISO-RAD calculated the pounds of force (lbf) using the wrong A value of $4in^2$ number instead of the actual result of 1.2622232 in^2. The area (A) formula result used, then made the subsequent results invalid. The calculations have been corrected throughout the section. The result is a substantially less psi being applied to the bolts. Also keep in mind this package is open to the atmosphere and the result is based on a worst case scenario where the inner container reaches 800° C and is also sealed (neither condition occurred during testing or simulation). ISO-RAD has changed SAR Section 3.5.3.2 in its entirety to correct the calculations and to be more descriptive in the calculation variable labels.

2. The following formulas are used to derive the pressure, force, and stress results.
   A. $\sigma = F/A$ Where the stress result is derived by applying a force over an area
   B. $F = (A)(Pressure)$ Where the Force result is derived by applying the Area under pressure.
   C. $A = \pi \times (diameter)^2 / 4$ Where the area is calculated using the diameter of the source cavity to determine the area under pressure.

3. The units used are all in English units. ISO-RAD is using the following units in the calculations:
   A. lbf = pounds of force
   B. psi = pounds per square inch
   C. in^2 = square inch

4. The conclusion is that the original results presented overstated the psi experienced by the four (4) bolts securing the shield plug in place. Please see updated SAR Section 3 Rev 1 for results.

RAI 2-4. Provide clarification on applicability of collapsing pressure equation.
SAR Sections 2.6.4 and 2.7.6 discuss calculations related to collapsing pressure of some of the container components. The applicant cites Machinery's Handbook, 27 Edition, pages 292 – 298 to obtain the equation for the collapsing pressure of cylinders and tubes subjected to external pressures. Upon review of said reference, the staff noted the following excerpt "These formulas are substantially correct for all lengths of pipe greater than six diameters between transverse joints [underlined for emphasis] that tend to hold the pipe to a circular form." Based on the information provided in the SAR, it is not clear to the staff how the collapsing pressure equation used is applicable to the components under review. Please provide additional justification why this approach is acceptable and clarify its relationship with yield stresses of the steel.

This information is needed to comply with SSR-6 paragraphs 729 and 616.

ISO-RAD response to RAI 2-4 is as follows:

1. The construction of the inner container does not result in an unsupported hollow pipe. The only cavity that is supported on one end only is the source cavity. The outer casing is internally supported by the Depleted uranium shield, brass spacers, top shield support, and the bottom shield support. In addition, the outer casing is supported on one end by the stainless steel bottom plate and the stainless steel top plate. The source cavity is closed on one end and is surrounded by the depleted uranium shield. With contents installed the source cavity is filled with sources and the shield plug is installed, which contains a protrusion that helps support the source cavity. The calculations are based on collapsing pressure without internal support, which makes the calculations a worst case from the actual circumstance.

2. The formula used by ISO-RAD has been used in other SARs that have been approved by the USNRC. Please see Aspect 12K SAR, section 2.6.4, pages 2-6 and 2-7. There is not a perfect formula for a Type B package. The formula forms a worst case scenario as the design has less than six diameters before a supported end (i.e., the length of the casing is 278 mm and a diameter of 168.28 mm) translating into a higher collapsing pressure is necessary to collapse this configuration over a six times longer span (i.e., 168.28 mm x 1009.68 mm). The reference material dose not exclude using the formula for less than six diameters or more than six diameters between transverse joints, it states that it is substantially correct.
   A. Formula used in ISORAD-TC1 SAR:

$$P = 3.46 \times 10^8 \times \left(\frac{T}{d}\right)^3$$

   Where: P: Collapsing Pressure of Capsule
   d: Outside Diameter 1.3880787 inch
   T: Wall Thickness = 0.06003937 inch

   $P = 3.46 \times 10^8 \times (T/d)^3$
   $P = 346000000 \times (0.06003937/1.3880787)^3$
   $P = 346000000 \times (0.0432535777690415)^3$
   $P = 346000000 \times 0.00008092191$
   P = 27998.980862768 kPa or 28.0 MPa or 4060.90884 psi

   B. Alternately using Timoshenko's Collapsing Pressure Formula is expressed using the following:

$$Pcr = \left(\frac{2E}{1-u^2}\right)\left\{\frac{1}{\left[\frac{D}{t}-1\right]}\right\}^3$$

   Where: P_{cr} = External Pressure Circular Pipe
   E = Young's Modulus for Stainless Steel: (2.7×10^7)
   u = Poisson's Ratio for Stainless Steel (0.29)
   D_o = Outside diameter of casing: 1.3880787 inches
   t = Wall thickness: 0.06003937 inches

   $P_{cr} = (2E/1\text{-}u^2)\ (1/[D_0/t\text{-}1])^3$

P_{cr} = (2 x 27000000)/(1-0.29^2) x (1/[(1.3880787/0.06003937)-1])^3
P_{cr} = (54000000/1-0.0841) x (1/[23.1197477-1])^3
P_{cr} = (54000000/0.9159) x (1/22.1197477)^3
P_{cr} = (58958401.57) x (0.045208472)^3
P_{cr} = (58958401.57) x (0.00009239734)
P_{cr} = 5447.57943 psi or 5447.58 psi / 37.55974193 MPa or 37.56 MPa

C. Another alternative is using Glock's Collapsing Pressure Formula is expressed by using the following:

$$Pe = \left(\frac{2E}{1-v^2}\right)\left(\frac{t}{D}\right)^3$$

Where: E = Young's Modulus for Stainless Steel: (2.7×10^7)
v = Poisson's Ratio for Stainless Steel: 0.29
D = Outside diameter of casing: 1.3880787 inches
t = Wall thickness: 0.06003937 inches

Pe = (2E/1-v^2) (t/D)^3
Pe = (2 x 27000000)/(1-0.29^2) x (0.06003937/1.3880787)^3
Pe = (54000000/1-0.0841) x (0.043253577)^3
Pe = (54000000/0.9159) x (0.0000809219)
Pe = (58958401.57) x (0.0000809219)
Pe = 4,771.025876007383 psi or 4771.026 psi/32.89506631 MPa or 32.9 MPa

3. Conclusion: Both of the alternative formulas result in a higher collapsing pressure than the one used in the ISORAD-TC1 SAR. The safety margin is very high using these formulas versus the test requirement of sustaining 140 KPa (20.3053 psi). Taking the lowest result of 4060.91 psi / 10 = 406.091 psi is a 406.091/20.3053 = 19.999 times safety margin. Taking the lowest result of 4060.91 psi / 100 = 40.6091 psi is still at a two times safety margin.

Chapter 3 – Materials Safety Evaluation

RAI 7-1. Provide additional information on how the cork used in Safkeg-LS 3979A is "approximately the same cork specification as the ISORAD-TC1 package design" with respect to its performance in a fire.

The evaluation of the ISORAD-TC1 package in a fire accident relies on thermal performance data for cork (e.g., charring behavior, thermal conductivity variation with temperature) that was taken from the CROFT Safkeg package thermal analysis. The staff notes that cork products can be made of a variety of binders that may affect its fire performance. It is unclear to the staff how the cork used in the Safkeg package was determined to be representative of that used in the ISORAD design or how the ISORAD thermal analysis otherwise incorporates conservatisms to account for potential variations in the cork materials.

This information is needed to determine if the package meets the requirements of IAEA SSR-6 728 (a).

ISO-RAD response to RAI 7-1 from Chapter 3 is as follows:

1. The cork used by ISO-RAD is an agglomerated/amalgamated cork using a polyurethane resin binder. ISO-RAD is using cork produced by [redacted] (see [redacted] Reference 8). Polyurethane is a synthetic resin used to bind the cork together and exhibits high heat resistant properties. [redacted] states agglomerated/amalgamated cork with a resin binder the brand name stated in the [redacted] SAR is [redacted] agglomerated cork. According to the [redacted] website, the agglomerated cork also uses a polyurethane binder (see attached Amorim Reference 9). A Resin can be either natural or synthetic. As previously stated in the ISORAD-TC1 SAR, the cork products are essentially the same.

2. The conclusion is that the cork used by ISO-RAD is substantially the same as the cork used by [redacted].

Chapter 3 – Thermal Safety Evaluation

RAI 3-1. Provide temperature-dependent thermal properties or provide adequate justification for using single values for the thermal properties used to perform the thermal evaluation of the ISORAD-TC1 transportation package. Except for cork material, SAR Chapter 3 "Thermal Evaluation" provided only single values for thermal properties without adequate justification or explanation that single property values would be bounding. The staff needs this information to determine that adequate temperature dependent thermal properties are used in the analysis or to determine that single values bound the equivalent temperature-dependent property.

This information is needed to determine compliance with SSR-6 Paragraphs 654, 656, 657, and 728.

ISO-RAD response to RAI 3-1 is as follows:

Please see the attached Thermal Conductivity and Heat Transfer Analysis report in response to RAI 3-1.

RAI 3-2. Provide a detailed description of the thermal model used to perform the thermal evaluation of the ISORAD-TC1 transportation package during NCT and HAC. The staff reviewed SAR Chapter 3 "Thermal Evaluation" and did not find a description of the thermal model with sufficient details for the staff to make a safety determination of the adequacy of the thermal model. The staff needs this information to confirm that a proper thermal model that captures the principal details of the thermal design (that affect the thermal performance) was used to perform the thermal evaluation during NCR and HAC.

This information is needed to determine compliance with SSR-6 Paragraphs 654, 656, 657, and 728.

ISO-RAD response to RAI 3-2 is as follows:

1. The thermal model is the same as the actual SolidWorks designed model used to create the ISORAD-TC1 package drawings. The differences are that several components of like materials were combined to eliminate gaps providing continuous contact between like material components and was deemed a worst case because gaps would disrupt thermal transfer. For example, the Outer Casing, BPIC Lid, Top Plate, and Bottom Plate were combined as one piece to eliminate seams, gaps, screws, and threaded holes.

2. The Thermal model also eliminates threaded holes, bolts, screws, chamfers, and other small features throughout the Thermal Model.

3. ISO-RAD has created drawing number RAI R180831-TMD (see attached) to show the Thermal Model materials and dimensions.

RAI 3-3. Provide adequate description and results on the type of analysis used to validate the thermal code used to perform the thermal evaluation of the ISORAD-TC1 transportation package during NCT and HAC. SAR Chapter 3 states that the finite element analysis (FEA) and the thermal model of the package were validated against thermal analysis of other similar transport containers. However, the staff did not find any description or validation results that support this statement in the SAR. The staff needs this information to verify that the applicant used adequate analytical tools that would result in realistic or conservative estimate of thermal results.

This information is needed to determine compliance with SSR-6 Paragraphs 654, 656, 657, and 728

ISO-RAD response to RAI 3-3 is as follows:

1. Please see the attached SolidWorks Flow Simulation Validation Report created by ISO-RAD that includes validation data from Dassault Systemes SolidWorks.

Chapter 5 – Shielding Safety Evaluation

RAI 5-1. Demonstrate that the dose rate for a package containing Iridium-192 is bounding for all the other isotopes listed in the Canadian Competent Authority certificate.
The following isotopes listed in the Canadian Competent Authority Certificate emit, or have the potential to emit, either gamma particles with energies greater than the 612 keV gamma emitted by Iridium-192: Cesium-134, Cesium-137, Europium-152, Phosporus-32, Strontium-89, Yttrium-90, and Zinc-65. Although the quantities of material authorized for shipment in the Canadian Competent Authority Certificate for each of these isotopes is less than the amount authorized for Iridium-192, no information has been provided which demonstrates that a smaller quantity of material emitting higher energy particles results in package dose rates which meet the regulatory limits. Because some of the isotopes listed emit beta particles with energies greater than 1 MeV, the response should also address Bremsstrahlung radiation. In addition, the response should also provide additional information on the gamma radiations resulting from bremsstrahlung reaction of high energy beta particles with Tungsten-187.

USNRC additional information added in supplemental email dated October 05, 2021, "RAI has not been adequately addressed (RE: issues with approach of proving Ir-192 content bounds all gamma emitting contents)".

This information is necessary to satisfy the requirements in 10 CFR 71.33(a), 71.47, and 71.51(a).

ISO-RAD response to RAI 5-1 is as follows:

1. Please see the attached three (3) reports generated by Burnley Technology, Inc. using MCNP V6 software to conduct Monte Carlo studies in the ISORAD-TC1.
   A. Report 1: ISORAD-TC1 Bremsstrahlung Dose Rates
   B. Report 2: ISORAD-TC1 Gamma Dose Rates
   C. Report 3: ISORAD-TC1 ^{75}Selenium and ^{169}Ytterbium Dose Rates

2. Report 1: Bremsstrahlung Dose Rates report result is all Beta emitting isotopes listed on the certificate comply with the surface and one meter dose rate requirements.

3. Report 2: ISORAD-TC1 Gamma Dose Rates report result is four (4) isotopes exceed the surface and one meter dose rate requirements. The isotopes are [redacted], [redacted], [redacted], and [redacted]. The original calculations for these isotopes seem to be in error by a factor of 10. The error will be reported to the CNSC, and these isotopes will be eliminated from the ISORAD-TC1 certificate. Please withdraw these isotopes from the USA revalidation.

4. Report 3: ISORAD-TC1 ^{75}Selenium and ^{169}Ytterbium Dose Rates results demonstrate the relationship of Ir-192 to Se-75 and Yb-169. The transmission rates for Se-75 and Yb-169 are substantially lower and the surface and one meter dose rates are therefore substantially lower.
   A. Originally, ISO-RAD used the actual Ir-192 survey result as the baseline for the survey. The extrapolation formula used the gamma constant for Ir-192 (0.48 R/hr @ 1 meter) as the starting point and then used the Gamma Constant for Se-75 (0.203 R/hr @ 1 meter) and Yb-169 (0.125 R/hr @ 1 meter) to predict the dose rates.
   B. Originally, the calculation assumed the DU HVL for Ir-192 (2.794 mm [0.11 inch]) is the same for Se-75 and Yb-169 produces more conservative dose rate numbers. The analysis provided in the Shielding Efficiency Test report provides a worst case comparison even though the DU HVL for Se-75 and Yb-169 are substantially lower.
   C. The method used in Report 3 was the basis to recalculate the dose rates in the updated ISORAD-TC1 MPIC Shielding Efficiency Report (Updated).

RAI 5-2. Provide the method used to extrapolate the package dose rates when loaded with Selenium-75 and Ytterbium-169 from the package dose rates obtained from Iridium-192 and demonstrate the method is valid.

Information presented in SAR Section 5.5.2 asserted that the package will meet the dose rate regulatory limits when transporting Selenium-75 and Ytterbium-169 based on the extrapolated package dose rates for Iridium-192. However, a description of the extrapolation

method and a demonstration that the method is appropriate to obtain dose rates was not provided. In addition, the applicant needs to provide the valid range of this extrapolation because in most of the cases, an extrapolation method is valid only within given ranges of the parameters.

This information is necessary to satisfy the requirements in 10 CFR 71.33(b), 71.47, and 71.51(a).

ISO-RAD response to RAI 5-2 is as follows:

1. See the response to RAI 5-2 report ISORAD-TC1 ^{75}Selenium and ^{169}Ytterbium Dose Rates.

RAI 5-3. Demonstrate that the ISORAD-TC1 package meets the non-exclusive use regulatory requirements when tungsten is used as the inner container shield material.

Based on a review of the ISORAD-TC1 test plan in SAR Section 2.12.1, the test report in SAR Section 2.12.2 and the half value layer information in SAR Section 5.3.1, staff estimated that the package dose rates would increase by a factor of more than ten if tungsten were used as the shielding material for the package configurations described in the test plan and test report. The estimated dose rates would exceed the non-exclusive use dose rates. Therefore, the staff needs additional information to determine if the package with the tungsten shielding material meets the non-exclusive use dose rate regulatory requirements.

This information is necessary to satisfy the requirements in 10 CFR 71.47 and 10 CFR 71.51(a).

ISO-RAD response to RAI 5-3 is as follows:

1. The Tungsten versions of the ISORAD-TC1 are withdrawn from US Revalidation.

RAI 5-4. Demonstrate that the ISORAD-TC1 package, when transporting either MPIC inner container, meets the non-exclusive use regulatory requirements. The test report in SAR Section 2.12.2 identified that the ISORAD-TC1 prototypes tested used the BPIC – Square and the BPIC – 2835A inner container configurations. The BPIC package configurations place all the source at the center of the package and the shielding material entirely surrounds the source. However, the MPIC package configuration has ten individual sources arranged in either one or two circles within the shielding material. Due to the different configurations of source location and shielding, it is difficult for staff to understand how the ISORAD-TC1 package test results with a BPIC inner container demonstrates that the ISORAD-TC1 package with an MPIC inner container meet the non-exclusive use regulatory requirements. The applicant should provide a shielding analysis which demonstrates that the ISORAD-TC1 package meets the dose rate requirements when transporting an MPIC inner container in non-exclusive use mode. USNRC additional information added in supplemental email dated October 05, 2021, “Will probably need additional clarifying information to authorize DU shielded MPIC packages carrying certain contents”.

This information is necessary to satisfy the requirements in 10 CFR 71.47 and 10 CFR 71.51(a). USNRC Response

ISO-RAD response to RAI 5-4 is as follows:

1. The Shielding Efficiency Test report was supplied with the September 6, 2021 response.

2. An expanded and updated report is being resubmitted with the RAI response.

3. Please see RAI 5-1 response including the three (3) test reports.

4. The actual survey result using Ir-192 was the baseline for the survey. The extrapolation formula used the gamma constant for Ir-192 (0.48 R/hr @ 1 meter) as the starting point and then used the Gamma Constant for Se-75 (0.203 R/hr @ 1 meter) and Yb-169 (0.125 R/hr @ 1 meter) to predict the dose rates. The calculation is assuming the DU HVL for Ir-192 (2.794 mm [0.11 inch]) is the same for Se-75 and Yb-169 produces more conservative dose rate numbers. The analysis provided in the Shielding Efficiency Test report provided a worst case comparison even though the DU HVL for Se-75 and Yb-169 is much lower than for Ir-192. Please see the attached expanded Shielding Analysis Test report.

Package Operations Review

RAI 7-1. Modify the package operating procedures in SAR Chapter 7 to address the use of the optional tungsten insert as necessary.

SAR Sections 1.2.2 and 5.1.1 both identify tungsten insert(s) as an optional feature that, based on information presented in the SAR, would be used with either the BPIC – Square, BPIC – Round, or BPIC – 2835A package configuration. However, the loading instructions for the BPIC package configurations in SAR Sections 7.1.2.1 and 7.1.2.3 only direct the package user to load special form capsules, and they do not address using a tungsten insert. In addition, staff cannot find any criteria (e.g., the radioactivity limit in Curie or Becquerel) indicating when using a tungsten insert is necessary. Additional information is needed for the staff to understand when a tungsten insert is required to be loaded into the package, and the package operating instructions need to address tungsten insert installation to ensure proper package configuration.

This information is necessary to satisfy the requirements in 10 CFR 71.87 and to ensure the package is operated consistent with the application's analyses that demonstrate the package meets the requirements in 10 CFR 71.47.

ISO-RAD response to RAI 7-1 Package Operations Review is as follows:

1. The Tungsten versions of the ISORAD-TC1 are withdrawn from US Revalidation.

RAI 7-2. In the application SAR Chapter 7.0, "Package Operations," in Section 7.1.2.2, "For the Multi Port Inner Container (MPIC)," remove step 6 completely and make existing step 7, step 6.

The step 6 as shown is for the Bulk & PIC Inner Container (BPIC) and this step was incorrectly copied and placed here.

This information is needed to determine compliance with 10 CFR 71.87(f).

ISO-RAD response to RAI 7-2 is as follows:

1. The SAR section has been corrected see attached SAR Section 7 Rev 1.

RAI 7-3. Replace all the fastener qualitative tightening requirement of "bolt" in Section 7.1.2 with specific tightening torque values with allowable tightening tolerances.

In the application SAR Chapter 7.0, "Package Operations," throughout the subsections of Section 7.1.2, "Loading of Contents," there are fasteners (M6x1.0, M8x1.25, M14x2 cap screws, referred to in the application as bolts) that are required to be tightened in various steps. The qualitative term "bolt" is used to describe tightening the fasteners.

This information is needed to determine compliance with 10 CFR 71.87(f).

ISO-RAD response to RAI 7-3 is as follows:

1. This item was discussed with the Canadian Nuclear Safety Commission (CNSC) during the Type B review and agreed that a torque requirement was not necessary. (see RAI 2-1)
   A. ISO-RAD Canada did not specify a torque requirement for the bolts because the transport package is not a sealed package transporting normal form material.
   B. The package does not contain O-rings or other compressible seals that would require compression with a torque value.
   C. The bolted connections are all metal to metal. The Outer Drum M14 x 2 bolts include split lock washers to prevent the bolts from backing out. If the split lock washer is visually inspected flat (fully compressed), the bolt torque (tightness) is sufficient to ensure the bolt is securely tightened. ISO-RAD felt that tightening the bolts down was enough and that most customers would not have access to calibrated torque wrenches.

2. ISO-RAD has provided detailed opening and closing instructions in SAR Section 7 and in the Operating Manual. ISO-RAD does not see where a torque requirement exists in 10 CFR 71.87(f).

3. Many Type B transport containers do not contain torque requirements for screws and bolts with no reported bolt loosening failures. See some examples below:
   A. [redacted]
   B.
   C.
   D.

Editorial

RAI E-1. SAR Section 2.5.1 Lifting Devices.

Reference made to IAEA SSR-1 is listed where IAEA SSR-6 is meant. In addition, the appropriate edition of the reference should be mentioned. In this case, IAEA SSR-6 (2018) to distinguish from other editions.

ISO-RAD response to RAI E-1 is as follows:

1. The SAR was submitted using references to SSR-6 (2018). See Reference Section 2.12.5 Reference Number [2.1]
2. SAR Section 2 has been corrected see attached SAR Section 2 Rev 1.

RAI E-2. SAR Section 2.6.7 Free Drop.

a. It should be Prototype #2 not #1. This is needed to comply with IAEA SSR-6 722(a).

b. Reference made to missing figure, Figure 2.6.7.b.

ISO-RAD response to RAI E-2 is as follows:

1. The section has been corrected see attached SAR Section 2 Rev 1. The figures were combined. The figures are separated, and the correct Prototype references are in place.

RAI E-3. SAR Section 2.6.4 Increased External Pressure.

a. Reference made to IAEA SSR-1 is listed where IAEA SSR-6 is meant.

b. The appropriate edition of the reference should be mentioned. In this case, IAEA SSR-6 (2018) to distinguish from other editions.

c. IAEA SSR-6 Paragraph 617 is listed where Paragraph 616 is meant.

ISO-RAD response to RAI E-3 is as follows:

1. The section has been corrected see attached SAR Section 2 Rev 1

RAI E-4. SAR Section 4.2 Containment Under Normal Conditions of Transport.

a. Reference made for IAEA SSR-6 658(a) where IAEA SSR-6 659(a) is meant,

b. Reference made for IAEA TS-R-1 656(a) where IAEA TS-R-1 657(a) is meant.

ISO-RAD response to RAI E-4 is as follows:

1. The section has been corrected see attached SAR Section 4 Rev 1.

References:

1. IAEA SSR-6 (2018), Regulations for the Safe Transport of Radioactive Material, Revision 1, International Atomic Energy Agency, Vienna, 2018.
2. IAEA SSG-26, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2012 Edition), International Atomic Energy Agency, Vienna, 2018.
3. Title 10, Code of Federal Regulations, Part 71, Office of the Federal Register, Washington D.C.
4. Joint Canada – United States Guide for Approval of Type B(U) and Fissile Material Transport Packages (CNSC RD-364 / USNRC NURERG 1886), USNRC and CNSC, Washington & Ottawa, 2009.
5. [redacted]
6. Bolt Depot - Recommended Torque for Metric Bolts (boltdepot.com)
7. SAE and Metric Fastener Torque Specifications.pdf (gogenielift.com)
8. [redacted]
9. [redacted]
10. Fastenal Engineering Design Support Torque of Metric Stainless Steel.pdf

Documents Included in the Submission:

1. Drawings
   A. RAI R180831-200 BPIC – Square
   B. RAI R180831-300 MPIC – Square
   C. RAI R180831-400 BPIC – Round
   D. RAI R180831-500 BPIC - 2835A
   E. RAI R180831-600 MPIC – Round
   F. RAI R180831-202 Plug Assembly
   G. RAI R180831-508 Plug Assembly
   H. RAI R180831-216 Top Plate and Cavity Assy
   I. RAI R180831-111B-9 ISORAD-TC1 2835A Spacer
   J. RAI R180831-TMD ISORAD-TC1 Thermal Model Drawing

2. SAR Sections
   A. ISORAD-TC1 SAR Section 1 Rev 1
   B. ISORAD-TC1 SAR Section 2 Rev 1
   C. ISORAD-TC1 SAR Section 3 Rev 1
   D. ISORAD-TC1 SAR Section 4 Rev 1
   E. ISORAD-TC1 SAR Section 7 Rev 1

3. Reports
   A. SolidWorks Flow Simulation Validation Report
   B. Burnley Technology, Inc. ISORAD-TC1 Bremsstrahlung Dose Rates Test Report
   C. Burnley Technology, Inc. ISORAD-TC1 Gamma Dose Rates Test Report
   D. Burnley Technology, Inc. ISORAD-TC1 ^{75}Selenium and ^{169}Ytterbium Dose Rates

E. ISORAD-TC1 MPIC Shielding Efficiency Report (Updated) Revision 1
F. Thermal Conductivity and Heat Transfer Analysis Report

Conclusion:

ISO-RAD Canada has answered the RAIs and believes the questions and concerns from the October 4, 2021 RAIs have been thoroughly answered. Please review the attached RAI response data and advise if additional information is needed. I can be contacted by email at kjs@iso-rad.com or by cell phone +1-504-717-7811.

Thank you and I look forward to your response.
Respectfully submitted,

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