



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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October 28, 2021

Mr. Richard W. Boyle
Radioactive Materials Branch
U.S. Department of Transportation
1200 New Jersey Avenue SE
Washington, D.C. 20590

SUBJECT: REQUEST FOR REVALIDATION OF CANADIAN CERTIFICATE OF
APPROVAL CDN/2101/B(U) FOR THE ISORAD-TC1 PACKAGE – REQUEST
FOR ADDITIONAL INFORMATION, DOCKET NO. 71-3099

Dear Mr. Boyle:

By letter dated July 14, 2021 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML21279A216), the U.S. Department of Transportation requested that the U.S. Nuclear Regulatory Commission (NRC) staff perform a review of the Canadian Certificate of Competent Authority CDN/2101/B(U), Rev. 0, for the Model No. ISORAD-TC1 transport package and make a recommendation concerning the revalidation of the package for import and export use.

In connection with our review, this letter is to advise you that the information needed to continue our review, described as a request for additional information, is the enclosure to this letter. Addressing the request for additional information does not preclude the staff from issuing further requests for additional information during the detailed technical review of this application.

In order to complete our technical review on schedule, your response should be provided within 30 days of the date of this letter. If you have any questions regarding this matter, I may be contacted at (301) 415-5196 or at Nishka.Devaser@nrc.gov.

Sincerely,

Nishka Devaser

Nishka Devaser, Project Manager
Storage and Transportation Licensing Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-3099
EPID L-2021-DOT-0006

Enclosure:
Request for Additional Information

SUBJECT: REQUEST FOR REVALIDATION OF CANADIAN CERTIFICATE OF
APPROVAL CDN/2101/B(U) FOR THE ISORAD-TC1 PACKAGE – REQUEST
FOR ADDITIONAL INFORMATION, DOCKET 71-3099 DATE: October 28,2021

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**Request for Additional Information
Docket No. 71-3099
Model No. ISORAD-TC1 Package
Canadian Certificate CDN/2101/B(U)**

By letter dated July 14, 2021 (Agencywide Documents Access and Management System [ADAMS] Accession No. ML21279A216), the U.S. Department of Transportation requested that the U.S. Nuclear Regulatory Commission (NRC) staff perform a review of the Canadian Certificate of Approval CDN/2101/B(U) and associated safety analysis report (SAR), for the Model No. ISORAD-TC1 transport package and make a recommendation concerning the revalidation of the package for import and export use.

This request for additional information identifies information needed by the NRC staff (the staff) in connection with its technical review of the Model No. ISORAD-TC1 package application.

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.

IAEA SSR-6 paragraph 809(b) requires the application for a certificate of compliance of a transportation package to include complete engineering 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 IAEA SSR-6 paragraph 809(b).

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

IAEA SSR-6 paragraph 809(b) requires the application for a certificate of compliance of a transportation package to include complete engineering 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.

Enclosure

This information is necessary to satisfy the requirements in IAEA SSR-6 paragraph 809(b).

- 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 IAEA SSR-6 paragraph 809(b).

- 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 IAEA SSR-6 paragraph 809(b), 527(b) and 659(b).

Chapter 2 – Structural and Materials 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.

- 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. The damage would not impede the safety of the package nor render the package to not be fit for transport.”*

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.

- 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 $217.05 \text{ lbs}/0.13272 \text{ in}^2 = 1,635.4766 \text{ psi}$.”* 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/in^2) by area (in^2) and obtaining pressure (lb/in^2). 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.

- 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.

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.

- RAI 3-2. Provide a detailed description of the thermal model used to perform the thermal evaluation of the ISORAD-TC1 transportation package during normal conditions of transport (NCT) and hypothetical accident conditions (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 NCT and HAC.

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

- 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 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.

- RAI 3-4. 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 conservatism 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).

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, Phosphorus-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.

This information is necessary to satisfy the requirements in IAEA SSR-6 paragraph 809(b), 527(b) and 659(b).

- 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 IAEA SSR-6 paragraph 809(b), 527(b) and 659(b).

- 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 IAEA SSR-6 paragraph 527(b) and 659(b).

- 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.

This information is necessary to satisfy the requirements in IAEA SSR-6 paragraph 527(b) and 659(b).

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 IAEA SSR-6 paragraph 809(d) and to ensure the package is operated consistent with the application's analyses that demonstrate the package meets the requirements in IAEA SSR-6 paragraph 527(b).

- 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 IAEA SSR-6 Paragraph 809(d).

- 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 IAEA SSR-6 Paragraph 809(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.

- 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.

- 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.

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.