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

June 10, 2021

Mr. Mike Rose
Quality Assurance Manager/ARSO
Industrial Nuclear Company, Inc.
14320 Wicks Blvd.
San Leandro, CA 94577

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR THE MODEL NO. OUTER PACK-RAW MATERIAL SHIPPING CONTAINER, REVISION 0 – (EPID NO. L-2020-NEW-0008)

Dear Mr. Rose:

By letter dated December 18, 2020 (Agencywide Documents Access and Management System Accession No. ML20363A167), you submitted an application for a Certificate of Compliance (CoC) for the Model No. Outer Pack-Raw Material Shipping Container transport package. To assist with our review, the U.S. Nuclear Regulatory Commission staff (the staff) needs the information identified in the enclosure to this letter.

We request that you provide this information by July 9, 2021. Inform us at your earliest convenience, but no later than July 2, 2021, if you are not able to provide the information by that date. If you are unable to provide a response by July 9, 2021, please propose a new submittal date with the reasons for the delay.

Please reference Docket No. 71-9387 and EPID No. L-2020-NEW-0008 in future correspondence related to this amendment request. The staff is available to discuss these questions as well as your proposed responses. If you have any questions regarding this matter, feel free to contact me at (301) 415-5196.

Sincerely,

Nishka Devaser

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

Docket No. 71-9387
EPID No. L-2020-NEW-0008

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR THE MODEL NO. OUTER PACK-RAW MATERIAL SHIPPING CONTAINER, REVISION 0 – (EPID NO. L-2020-NEW-0008)

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Request for Additional Information
Docket No. 71-9387
Model No. Outer Pack-Raw Material Shipping Container

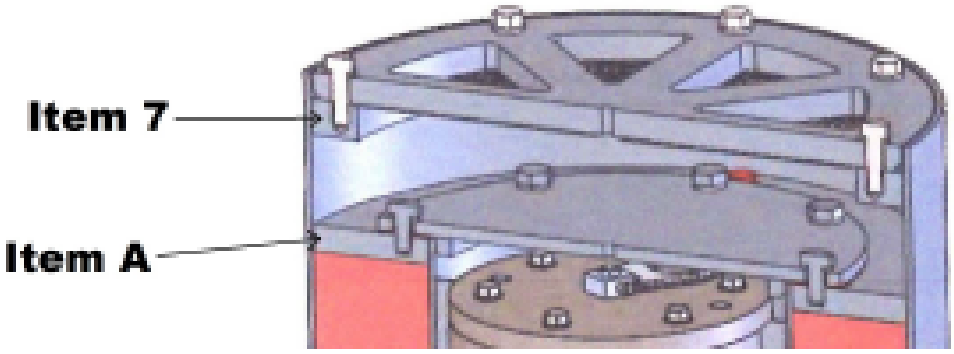
By letter dated December 18, 2020 (Agencywide Documents Access and Management System Accession [ADAMS] No. ML20363A167), Industrial Nuclear Company, Inc. (INC) submitted an application for a Certificate of Compliance (CoC) for the Model No. Outer Pack-Raw Material Shipping Container transport package. This request for additional information (RAI) letter identifies information needed by the staff in connection with its review of the safety analysis report (SAR). NUREG-2216, "Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material," was used by the staff in its review of the application.

Each individual RAI describes information needed by the U.S. Nuclear Regulatory Commission (NRC) staff to complete its review of the application to determine whether the applicant has demonstrated compliance with the regulatory requirements.

General Information Review

1.1. Provide component dimensions.

SAR Drawing OP-RMSC-SAR-TA, page 1 of 4 identifies seven stainless steel plates used to fabricate the Outer Pack-Raw Material Shipping Container (OP-RMSC). Based on staff's review of the drawings, two of the seven steel plates have both an outer diameter and an inner diameter. However, staff only identified one steel plate (i.e., Item 7) with both an inner and an outer diameter listed on drawing OP-RMSC-SAR-TA, page 1 of 4. Since the steel plate in question is also numbered incorrectly on OP-RMSC-SAR-TA, page 2 of 4 (see RAI 1.2), staff has identified the plate in question as "Item A" in the figure below. Staff needs this information to ensure correct fabrication of the package.



This information is necessary to satisfy the requirements in 10 CFR 71.33(a)(5).

1.2. Modify the package drawings, as appropriate, to ensure correctness, clarity and legibility.

a. In Drawing No. OP-RMSC-SAR-TA, multiple packaging components are identified using question marks in lieu of numbers (e.g., Sections A-A and B-B on Sheet 2 of 4). Also, multiple items are identified as item 1 in Drawing No. OP-RMSC-SAR-TA (e.g., Detail Item 1 on Sheet 2 of 4 and Sections C-C and E-E on Sheet 3 of 4). The item identified with a 1 in Section E-E of Sheet 3 of 4 of that drawing cannot be

item 1. Based on the bill of materials on Sheet 1 of 4, the item identified as item 1 in Section E-E must be item 2. Also, the item shown as item 2 in Section E-E must be some other item and appears to be item 5.

b. Drawing No. OP-RMSC-SAR-TA identifies where item 14 is used on the packaging. The bill of materials for that drawing includes an item 14; however, the drawing does not show the locations of that item on the packaging.

c. The outer diameter of item 3 in Drawing No. OP-RMSC-SAR-TA is 8.63 inches. The dimension shown in the drawing's bill of materials is difficult to read, making the dimension unclear.

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

1.3. Modify Drawing No. OP-RMSC-SAR-TA to define the following dimensions as non-reference dimensions, or show they can be determined from non-reference dimensions:

a. the outer diameter of the tungsten body shield and its thickness below the cavity containing the capsule, and

b. the length and outer diameter of the tungsten cavity shield.

c. on Sheet 3, provide the length of item 8.

It is the staff's understanding that dimensions designated as reference dimensions (by enclosing the dimensions with parentheses) means that either the dimension may be determined from others on the drawing or the dimension is considered unimportant and so does not require inspection. However, the staff is unable to determine the dimensions of the identified components from other non-reference dimensions given on the drawings. In addition, the staff expects that gaps will exist between the tungsten and steel components; therefore, the steel components' dimensions do not translate into the tungsten components' dimensions.

The package drawings submitted with the application are incorporated by reference into the certificate of compliance that defines the authorized package design. The licensee using the package must maintain a copy of and follow the terms and conditions of the certificate, including those incorporated by reference (see 10 CFR 71.17(c)), and the terms and conditions of the certificate specify the components, contents, and operations of the package that assure the package meets the performance requirements in the regulations. Other information in the package application, of which the safety analysis is part, is not typically considered a condition of the package approval and simply provides the information that demonstrates the design meets the performance standards in the regulations.

Thus, the approval conditions, of which the package drawings are part, need to include sufficient information to ensure the package as fabricated and operated in accordance with the package approval will meet the performance requirements in the regulations. The drawings do not meet this standard of sufficient information with the dimensions identified in (a) and (b) above as reference dimensions only. They and the components to which they apply are important for shielding purposes to show compliance with the regulatory limits. Thus, the identified dimensions should be provided in the drawings but

not as reference dimensions only. Alternatively, the applicant should evaluate the impacts on compliance with the shielding requirements due to variations that would be allowed in the affected components with these dimensions being specified as reference only.

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

1.4. Clarify the proposed content quantity specification for the package.

The applicant is requesting 2 Ci of Co-60 and 16,000 Ci for Se-75 and Ir-192, with a maximum of 4,000 Ci per capsule for the latter two nuclides. Unless indicated and evaluated otherwise, the staff will specify the contents' activity limits within the certificate of compliance to be based on their assigned activity as opposed to an activity determined by measurement, which includes the impact of self-attenuation and attenuation by the source's capsule. Note, that the activity determined by this latter method is often referred to as output activity and is only allowable for Ir-192 per Note c of Table A-1 of Appendix A to 10 CFR Part 71. The activities of the other two nuclides must be the assigned value, often referred to as content activity, which does not credit self-attenuation by the source or attenuation by the capsule.

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

1.5. Address the following for the two tungsten alloys:

a. provide the allowable minimum densities, allowable minimum tungsten weight fractions, and the allowable dimensional tolerances (both over and under tolerances),

b. update the drawings, and

c. modify the shielding evaluations, if necessary, using the information provided in (a) above or address their impacts.

Unlike for most of the RMSC's steel components, Drawing No. OP-RMSC-SAR-TA provides a product or brand name for the material specifications and not a materials standard(s) for the two tungsten alloys components. ASTM B777 specifies ranges of densities as well as nominal compositions for tungsten alloys. Based on ASTM B777, it appears that the densities and compositions identified by the applicant and used in the applicant's shielding evaluation are nominal values. The applicant needs to provide the tungsten alloys' minimum densities and minimum compositions (i.e., tungsten alloy compositions with the minimum allowable weight fraction of tungsten for each alloy). Also, with no other specification of tolerances in the package drawings, those given in the drawings' title block apply to the tungsten alloy components' dimensions. The applicant's shielding evaluations should use the minimum properties and dimensions based on the drawing tolerances for the two tungsten alloy components (see RAIs 5.2 and 5.3). With regard to the materials specification, one option is to specify on the drawings the ASTM standard (B777) and the applicable alloy class from that standard for each of the tungsten alloys used in the package. If no materials standard and class is specified in the drawings, the appropriate density and composition specifications for both alloys should be specified directly in the drawings. Specifying the ASTM standard

and alloy class for each alloy will also help ensure the acceptance tests as described in SAR Section 8.1.1 are adequate to assure the fabricated components meet the specifications regarding composition and density.

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

Materials Review

2.1. Provide additional information to explain how the evaluation of the package under hypothetical accident conditions (HAC) was determined to meet the acceptance criteria of 10 CFR 71.51(a)(2), without first conducting the penetration test for normal conditions of transport (NCT) described in 10 CFR 71.71(c)(10).

SAR Section 2.6.10 of the application states that the penetration tests for NCT specified in 10 CFR 71.71(c)(10) were not conducted because the OP-RMSC package was puncture tested more severely in accordance with the HAC required by 10 CFR 71.73(c)(3). As stated in NUREG-2216, Section 2.4.6, and Regulatory Guide 7.9, Section 2.7, the NCT testing conducted under the specified conditions in 10 CFR 71.71 must not affect the package's ability to withstand the HAC tests. It is not clear how the effects of NCT testing conditions were accounted for in the HAC tests without conducting the NCT penetration test described in 10 CFR 71.71(c)(10).

This information is needed to determine compliance with the requirements of 10 CFR 71.51(a).

2.2. Provide the following additional information to explain how the evaluation of the package was determined to meet the HAC acceptance criteria of 10 CFR 71.51(a)(2) without conducting the HAC thermal test that meets the requirements of 10 CFR 71.73(c)(4).

1. Provide an evaluation of the package component temperatures during and after the HAC thermal test assuming a payload with an initial steady state temperature of 752 °F (400 °C) based on the maximum decay heat load, as described in Sections 2.6.1 and 3.3.1 and Table 3.3.1-1 of the application.

2. Provide mechanical properties for the RMSC lid bolts including yield and tensile strength, allowable stress values and thermal expansion coefficient as a function of temperature. Provide test data or an analysis to show that the RMSC lid bolts would remain intact during and after the HAC thermal test. Include measured or calculated temperatures for the RMSC lid and the lid bolts.

3. Revise SAR Section 2.7.4 of the application to cite the correct regulatory requirement. SAR Section 2.7.4 currently states that the OP-RMSC package satisfies the requirements of 10 CFR 71.73(c)(4). The regulatory citation in this statement is incorrect. The regulatory requirements of 10 CFR 71.73(c)(4) pertain to the HAC thermal test conditions. The acceptance criteria for the performance of a non-fissile Type B package are in 10 CFR 71.51(a)(2).

SAR Section 2.7.4 of the application provides a justification for not conducting the thermal test based on the results of the free drop and puncture tests, and because the structural and shielding materials have melting temperatures greater than the fire

temperature requirements of 71.73(c)(4). However, the justification provided in SAR Section 2.7.4 of the application does not include an analysis of the maximum temperatures of the components during and after the HAC thermal test with the maximum total decay heat load, nor does it provide sufficient information to address thermal effects other than melting such as differences in thermal expansion coefficients for the packaging component materials. ASME B&PV Code, Section II, Part D, Table TE-1 shows that the thermal expansion coefficient for the RMSC lid bolts is lower than the thermal expansion coefficient for the RMSC lid top plate. The difference in thermal expansion coefficients may result in thermal stresses and failure of the lid bolts at elevated temperatures.

This information is needed to determine compliance with the requirements of 10 CFR 71.33(a)(4) and 71.51(a)(2).

2.3. Provide additional information such as test data or an analysis to show that the operating temperature for the stainless steel components will be limited to a maximum temperature of 400 °F (204 °C) for NCT. Alternatively, revise SAR Table 3.3.1-1 to include material properties over the range of temperatures expected for all stainless steel components under NCT.

SAR Table 3.3.1-1 provides a summary of the maximum NCT component temperatures but it is not clear if this is limited to the OP-RMSC stainless steel components as described in Section 3.3.1 of the application, or if this summary also includes the stainless steel RMSC payload components. The thermal profiles provided in SAR Figures 3.3-3 and 3.3-4 suggest that the RMSC stainless steel shell, lid and baseplate may exceed 400 °F (204 °C) under NCT.

This information is needed to determine compliance with the requirements of 10 CFR 71.51(a).

2.4. Provide additional information on the safety function of Item No. 11 in SAR Drawing OP-RMSC-SAR-TA and the range of operating temperatures for this component.

The bill of materials in sheet 1 of 4 identifies that this component could be fabricated from either ASTM A276 or ASTM A479. ASME Section II Part D does not include mechanical properties as a function of temperature for the A276 specification.

This information is needed to determine compliance with the requirements of 10 CFR 71.31(c).

2.5. Provide additional information on the safety function of the tungsten heavy alloys in the RMSC as follows:

a. Provide additional information on the elevated temperature performance of the tungsten heavy alloys used in the RMSC. SAR Sections 2.7.4, 3.2.1, 3.2.2, and 3.2.4 of the application states that tungsten has a melting temperature of 6,191°F. The melting temperature of pure tungsten is not applicable to the liquid phase sintered tungsten heavy alloys used in the RMSC.

b. Clarify the apparently contradictory statements in the application regarding the structural function of the tungsten heavy alloy shielding materials. Section 2.2.1 states, "Typical room temperature properties are provided in Table 2.2-2. Since the tungsten gamma shields are not a primary structural material for the RMSC payload, these typical properties are provided for information only." Section 3.2.2 states, "The two primary structural materials are austenitic stainless steel and the tungsten gamma shielding." If the tungsten heavy alloys are primary structural materials as stated in Section 3.2.2 of the application, provide the mechanical properties of these alloys as a function of temperature over the range of temperatures expected during NCT.

This information is needed to determine compliance with the requirements of 10 CFR 71.33(a)(5) and 71.51(a).

2.6. Provide additional information to support the statement that the tungsten shielding material is not subject to brittle fracture at low temperatures.

Application SAR Sections 2.1.2.2.1 and 3.2.2 state that the tungsten shield material is not susceptible to brittle fracture at temperatures as low as −20 °F (−29 °C) and that, based on the low temperature testing of the OP-RMSC package, brittle fracture of the tungsten gamma shields in the RMSC payload is not a concern. Based on the information provided in the application, it is not clear to the staff if the performance of the tungsten heavy alloy shield materials are a result of acceptable impact toughness of these materials or a result of impact absorption by the packaging including the foam used for impact protection of the RMSC.

Information provided by the alloy manufacturer shows that the notched impact strength of the Densimet-Tungsten alloys decreases with temperatures and is below 3 J/cm^2 (14 ft lb/in^2) at temperatures of 0 °C (32 °F)[1]. The fracture toughness and impact toughness of liquid phase sintered tungsten heavy alloys has been shown to be a function of processing and alloy composition.[2,3]

This information is needed to determine compliance with the requirements of 10 CFR 71.31(c) and 71.51(a).

2.7. Provide additional information to justify the classification of the foam as a not important to safety (NITS) component. SAR Section 2.1 identifies the foam as one of the four major fabricated components of the OP-RMSC. In addition, SAR Section 2.1.1 states that the rigid polyurethane foam provides limited impact protection of the payload. If the polyurethane foam is an important to safety component, provide a material specification and properties for the foam and update the bill of materials in Drawing OP-RMSC-SAR-TA.

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[1] Plansee, "Refractory Metals for the Foundry Industry," http://www.foundry-planet.com/uploads/tx_browserdirectory/Download_Brochure_Refractory_metals_for_the_foundry_industry.pdf.

[2] Gurwell, W.E., Nelson, R.G., Dudder, G.B., and Davis, N.C, "Fabrication and Properties of Tungsten Heavy Metal Alloys Containing 30% to 90% Tungsten," PNL-5218, September 1984.

[3] Spencer. J.R. and. Mullendore, J.A., "Relationship Between Composition, Structure, Properties, Thermo-Mechanical Processing and Ballistic Performance of Tungsten Heavy Alloys," MTL-TR-91-44, GTE Products Corporation, Towanda, PA, November 1991.

This information is needed to determine compliance with the requirements of 10 CFR 71.33(a)(5).

2.8. Provide additional information to show that there will be no detrimental galvanic reactions between the tungsten heavy alloy shielding and the stainless steel components.

The information provided in SAR Section 2.2.2 appears to have incorrectly compared tungsten to active stainless steel rather than passive stainless steel. In the passive state, there is a significant difference between tungsten and stainless steel with tungsten being the anodic material.[4]

This information is needed to determine compliance with the requirements of 10 CFR 71.43(d).

Thermal Review

3.1 Clarify how the maximum decay heat limit was determined for the OP-RMSC package.

The applicant states, in Section 3.1.2 “Content’s Decay Heat,” of the SAR, that the OP-RMSC package may contain up to 16,000 Ci of Ir-192 in special form and that the maximum decay heat allowed for this content is 100 W. However, with a radiolytic decay heat of 7.03×10^{-3} W/Ci for Ir-192, the total decay heat in the package would be 112.5 W (i.e., 7.03×10^{-3} W/Ci x 16,000 Ci = 112.5W). The applicant should clarify the inconsistency between the prescribed decay heat limit (i.e., 100 W) and the allowed Ir-192 amount limit of 16,000 Ci in the OP-RMSC package.

This information is necessary to satisfy the requirements in 10 CFR 71.33(b)(7).

3.2 Provide information on the personnel barrier configuration and the derivation of the maximum accessible package surface temperature from the thermal analysis with the personnel barrier installed. Include a description of how the minimum open area of the personnel barrier is determined and verified prior to shipment.

The applicant stated in SAR Section 3.3.1, “Heat and Cold,” that “…an expanded metal personnel barrier with a minimum open area of 75% is installed over the OP-RMSC after the package is secured to the transport pallet. With the personnel barrier installed, the maximum accessible surface temperature is 115 °F (46 °C) which allows the package to be shipped as a non-exclusive use shipment.” However, the applicant did not provide details on how the personnel barrier allowed the package to meet the non-exclusive use transport temperature limits.

[4] Forman, C.M. and Verchot, E.A., “Practical Galvanic Series,” Report No. RS-TR-67-11, U. S. Army Missile Command, Redstone Arsenal, Alabama, October 1967.

The applicant should provide additional information about how the maximum accessible surface temperature of 115 °F (46 °C) is determined from the thermal analysis (computer code or hand-calculation). The description provided should include the configuration of all components, materials used, the personnel barrier dimensions, and personnel barrier modeling assumptions.

Provide a description of how the minimum open area of the personnel barrier is determined and verified prior to shipment.

This information is necessary to satisfy the requirements in 10 CFR 71.43(g).

Shielding Review

5.1 Clarify the condition of the bolt hole in the RMSC's tungsten cavity shield as prepared for transport. Ensure the package description, package operations descriptions, and package evaluations (e.g., shielding) are consistent with that condition.

It is unclear from the SAR whether or not the bolt hole in the RMSC's tungsten cavity shield is filled or empty in the package's transport configuration. The descriptions and drawings in SAR Chapter 1 are not clear in this regard but seem to indicate the bolt hole is empty. The package operations description in SAR Chapter 7 also indicates this space is empty during transport (e.g., SAR Section 7.1.2, paragraphs 3-4 and 6-7 and SAR Section 7.2.2, paragraphs 8-9). However, SAR Figure 5.3-1 and SAR Appendix 5.5 indicate that the shielding analysis assumes this space is filled with steel.

The SAR descriptions and evaluations need to be clear and consistent with the package design and how it is operated for shipments. If the bolt hole in the tungsten cavity shield is empty, then the shielding analysis should also model that space as empty. While the steel bolt of the RMSC's hoist ring is present in design, the drawings provide no information on its dimensions and appear to show it does not extend through the full thickness of the RMSC lid. Thus, it is not clear that it provides the same amount of steel that would be necessary to fill the empty bolt hole in the tungsten cavity shield and the RMSC lid thickness. The staff's evaluations indicate that package radiation levels for the top surface above this location, when also accounting for the dimensional tolerances and minimum density of the tungsten alloy, could result in surface radiation levels that exceed the regulatory limit for non-exclusive use. If the bolt hole is filled during transport, the drawings should clearly show this and provide the information for the component filling the hole. Also, the package operations descriptions should correctly reflect the use of that component.

This information is necessary to satisfy the requirements in 10 CFR 71.33(a), 71.47, 71.51(a), and 71.87.

5.2 Provide the following information regarding the measurements of package radiation levels that were used to demonstrate compliance with the non-exclusive use limits in 10 CFR 71.47(a) and NCT and HAC limits in 10 CFR 71.51(a) for a package with Ir-192:

a. description of the methods used to perform the radiation measurements for a package containing Ir-192 sources.

The SAR shielding chapter should sufficiently describe the measurement methods, equipment, and techniques to demonstrate that they are appropriate for the

measurements. The description should also address any geometric correction factors for ensuring the results are for the surface and show appropriate considerations have been made related to detector size and averaging radiation levels over the detector probe area. Sections 5.4.4.1 and 5.4.4.4 of NUREG-2216 provide a discussion on information that should be included to describe the measurement methods.

b. confirmation of the package configuration and conditions for which the radiation levels in SAR Table 5.1-1 were measured.

   SAR Chapter 5 should clearly indicate the test conditions (NCT and HAC tests) the package experienced prior to the radiation measurements as well as the package components that were present or included in the radiation measurements. While there are some indications in the SAR that at least some measurements were done on packages that had experienced both NCT and HAC tests, and that the measurements were with the RMSC only, the descriptions for all the radiation measurements should be clear and consistent.

c. ensure radiation levels reported in SAR Table 5.1-1, and in other locations of the SAR, are correct and consistent.

   SAR Sections 2.12.1.7.1.5, 2.12.1.7.2.6, and 5.4.4 include radiation level measurement results that have some differences versus the SAR Table 5.1-1 radiation levels even though they appear to be measurements for the same package configuration and conditions.

d. source strength used in the measurements.

   Typically, the source used in the measurements has a lower activity than the maximum authorized activity proposed for a package; however, it should be an activity for which scaling measured radiation levels to represent radiation levels for the maximum authorized contents is appropriate. The shielding evaluation chapter should provide information about the source strength used in the measurements for demonstrating the package meets the regulatory requirements for shielding.

e. maximum radiation levels for package top, bottom, and side surfaces and at one meter from each of those surfaces as well as information that clearly identifies the location of the maximum radiation level on each package top, bottom, and side surface and at one meter from each surface.

   SAR Table 5.1-1 only provides a single radiation level for the package surface and at one meter from the package, but it does not identify the package surface for which these radiation levels were measured. While SAR Sections 2.12.1.7.1.5 and 2.12.1.7.2.6 provide multiple surface and one meter radiation levels, they do not identify the package surfaces for which they were measured or whether they are different points of the same package surface. Given the axial and radial variations in the package's shielding (in the RMSC), and the lack of information about the measurements, it is not clear that the maximum package radiation levels have been identified and measured for the package. The information should be adequate to demonstrate that, as stated in the regulations, the radiation levels at any point on the package surface and at one meter from the package surface will not exceed the stated limits for non-exclusive use.

f. descriptions of dimensional and material properties (e.g., tungsten alloy components' densities and weight fractions of tungsten in the alloys) of the prototypes used in the measurements and how dimensional and material property tolerances could impact the measured radiation levels.

The shielding evaluation should consider the impacts of the allowed material property variations and dimensional tolerances, as defined in the drawings, of the packaging components (e.g., the tungsten alloy components) present in the measurements. Staff evaluations indicate that consideration of these items could lead to significant increases in radiation levels versus a prototype that was fabricated with nominal properties and had the measured radiation levels stated in the SAR. The increases could be large enough that the non-exclusive use dose rate limits are exceeded.

g. description of how source capsule position is accounted for if movement of the source capsules within the RMSC cavity is possible. Source position changes may also contribute to increased package radiation levels in addition to the impact of the items described in (e) above.

SAR Chapter 5 indicates that the applicant measured radiation levels on package prototypes to demonstrate regulatory compliance with the package radiation level limits for the Ir-192 contents and, by extension, Se-75 contents. However, Chapter 5 provides very little information regarding these measurements and the package prototype(s) on which the measurements were performed. Since Chapter 5 is for evaluating the package's shielding function, this chapter should include the necessary information, as identified in (a) through (g) above, to describe the measurements and to clearly demonstrate that the measurements address compliance with the limits and requirements in 10 CFR 71.47(a) for non-exclusive use shipments and 10 CFR 71.51(a) for NCT and HAC.

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

5.3 Modify the shielding analysis for the proposed Co-60 contents to address the following:

a. identify and justify the locations of the maximum radiation levels on each surface of the RMSC (i.e., top, side, and bottom) and at one meter from each surface.

The applicant's analysis needs to demonstrate compliance with the regulatory radiation level limits for non-exclusive use shipments in 10 CFR 71.47(a). These limits apply to any point on the external surface of the package. While the applicant conservatively neglects the outer components of the packaging (the OP-RMSC) and applies the evaluation of these limits to the RMSC, the applicant's analysis does not provide information that identifies where the maximum radiation level for each surface of the RMSC is located. Given the non-uniform shielding (both radially across the top and axially along the side), it is not clear that the applicant has identified the maximum radiation levels for each surface and at one meter from each surface or where those locations are.

b. account for the impacts of dimensional tolerances, minimum density and composition specifications for the tungsten alloy components.

The applicant's analysis uses nominal tungsten alloy densities and composition for the analysis. For the composition, the alloying metals (iron and nickel) are assumed to be in equal amounts. The dimensional tolerances applied in the model are also much smaller in magnitude than appear to be allowed by the drawings. Staff evaluations indicate that accounting for the appropriate minimum values of these aspects of the tungsten alloy components can result in package radiation levels that are significantly higher and that exceed the non-exclusive use limits. The staff evaluations also indicate that assuming the alloying metals in the tungsten alloys to be all iron further increases package radiation levels.

c. analyze the top surface radiation levels for the source positioned at the top of the RMSC cavity and directly underneath the bolt hole in the tungsten cavity shield, with the bolt hole modeled correctly as empty or void (see RAI 5.1).

   The applicant modeled the bolt hole in the tungsten cavity shield as filled with steel whereas the package operations indicate that the spot is empty in the package's transport configuration. It is also not clear that the applicant considered the source positioned at the top of the RMSC cavity under that bolt hole. Thus, maximum radiation levels at the top surface of the RMSC could be significantly higher than the applicant's analysis indicates.

d. account for the impacts of modeling the source as a cylinder with capsule materials credited, considering the dimensions and thicknesses of the smallest source and capsule for which shipment with this package is anticipated.

   Dimensions of the source and capsule also affect package radiation levels. The applicant states that the assumed specifications are based on typical values. However, dimensionally smaller sources and capsules could be transported in the package. A point source would bound the variation in source and capsule geometry and dimensions for potential Co-60 source contents. With very little margin to the regulatory limit (about one percent), a source and capsule specification that appropriately bounds the authorized source configurations should be used.

e. revise the azimuthal, or rotational, tally subdivision to appropriately calculate the maximum radiation level for the side, top, and bottom surfaces and at one meter from those surfaces with the Co-60 source.

   The applicant has divided the detector tallies rotationally (i.e., azimuthally) into 90° segments. Such wide azimuthal tally divisions cannot appropriately capture the maximum radiation levels on the RMSC side, top and bottom surfaces for a source that is fairly confined in terms of cross-sectional area for each of these surfaces. Such wide azimuthal tally divisions would artificially reduce maximum radiation levels by averaging the radiation levels over too large an area.

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

5.4. Modify the shielding acceptance test in SAR Section 8.1.6 of the application to adequately demonstrate performance of the tungsten shielding components as described below.

SAR Section 8.1.6 describes an acceptance test for the tungsten shielding components. It indicates that a radiation profile is performed on each component. The results are

ratioed to determine the expected radiation levels for the proposed Ir-192 source, with the acceptance criteria being that the results show the radiation levels for the maximum authorized contents will not exceed the limits in 49 CFR 173.441 (the same as in 10 CFR 71.47).

It is not clear that this test is adequate to demonstrate the tungsten shielding components perform their function as designed for all the proposed contents. First, the test description does not include enough information about the source that is used for the radiation profile measurement. For the described ratioing to be appropriate it would seem this source should be an Ir-192 source of adequate source strength vs. the allowable limit so that measurements and ratioing are appropriate and don't introduce error.

Second, the proposed acceptance criteria do not relate to these components' shielding performance as designed and evaluated. The applicant's shielding analysis shows the maximum radiation levels for the RMSC are significantly below the non-exclusive use regulatory limits for the proposed Ir-192 source. The same is true for the Co-60 source except for the location of maximum surface radiation level, which the current analysis shows to be nearly equal to the regulatory limit. In all other instances, the maximum radiation levels for the RMSC, as designed, are significantly below the limits. The acceptance test should use acceptance criteria that are based on the performance of the RMSC as designed and evaluated. Thus, appropriate acceptance criteria would be more like the radiation levels and associated radiation profiles in the applicant's shielding analysis (adjusted to neglect the steel RMSC components if those are not present in the test), with the components at their minimum allowed properties and dimensions. Also, based on the applicant's shielding analysis, the RMSC with the proposed Ir-192 could pass the currently proposed test and acceptance criteria but fail with the proposed Co-60 source.

Alternately, if the applicant specifies a materials standard for the tungsten alloys in the package drawings and can show the standard adequately controls material composition and porosity and precludes voids in fabricated tungsten alloy components, it may be possible for the confirmation of compliance with the material and dimensional specifications in the package drawings to adequately fulfill the purpose of the shielding acceptance test.

This information is needed to confirm compliance with 10 CFR 71.85 and ensure the package will perform as designed to demonstrate that it meets the requirements of 10 CFR 71.47.

5.5. Revise the acceptance criteria for the shielding maintenance test in SAR Section 8.2.5 to use radiation levels that are consistent with the as-designed performance of the tungsten shielding components.

The shielding maintenance test described in SAR Section 8.2.5 specifies the regulatory limits for radiation levels in 49 CFR 173.441 (the same as in 10 CFR 71.47) as acceptance criteria to confirm the continued performance of the tungsten shielding components. As described in RAI 5.4 for shielding acceptance tests, the regulatory limits are not adequate to confirm the performance of the as-fabricated components versus the design. Acceptance criteria should be based on the performance of the as-designed components similar to the acceptance test criteria as discussed in RAI 5.4. Alternatively, if the applicant determines that a maintenance test is not needed for the

tungsten shielding components, then the applicant should provide adequate justification for not having a shielding maintenance test for these components.

This information is needed to confirm the maintenance program is adequate to ensure the package will be maintained consistent with the design to meet the requirements in 10 CFR Part 71 Subparts E and F.

Package Operations Review

7.1 Modify the package operations descriptions in SAR Chapter 7 to address the following:

a. include a step in Section 7.1.1 to check the condition of the OP-RMSC cavity after removing the RMSC. This check is needed to ensure compliance with 10 CFR 71.87(b) to confirm the package is in unimpaired physical condition,

b. clarify or define the “acceptable limits” for RMSC radiation levels in Section 7.1.2 paragraph 9; based on the shielding analysis; these limits should be the same as the analyzed radiation levels in the SAR,

c. clarify or define “acceptable” for both the RMSC radiation levels and the smear test in Section 7.2.2 paragraph 5; for the radiation levels; it would seem that the limits should be the same as for Section 7.1.2 paragraph 9 as noted in item (b) above,

d. clarify or define “acceptable” for both the RMSC radiation levels and the smear test in Section 7.2.2 paragraph 13; if this step is in preparation for shipping the package as an empty package, the limits of 49 CFR 173.428 would be the criteria for determining acceptability,

e. include operations with the silicone seal that is associated with the OP-RMSC’s inner closure lid; it appears that activities related to this seal should be included in Section 7.1.1 paragraph 3 or 4, Section 7.1.3 paragraph 2, and Section 7.2.2 paragraphs 3 and 15. Per 10 CFR 71.87(c), the package operations should include steps that ensure that each closure device, including any gasket, is properly installed, secured and free of defects,

f. include a smear test, or contamination check, of the RMSC in Section 7.1.2 upon removal from the hot cell and prior to loading into the OP-RMSC similar to what is done in Section 7.2.2. The operations should also define the criteria for what is “acceptable” for this test. Contamination from loading of the RMSC in a hot cell could be a concern,

g. include in Section 7.2.2, between existing paragraphs 10 and 11, an operations step to re-install the tungsten cavity shield into the RMSC and to remove the package user’s lifting device from the RMSC after the radioactive contents have been removed. The operations steps appear to be missing from among those steps that are necessary to return the package to its designed transport configuration, and

h. include appropriate operations descriptions in Section 7.3. It would appear that operations similar to those in Section 7.1.3 paragraphs 5 through 7 and 9 through 11 are necessary, with appropriate regulations cited for an empty package. Section 8.4.3 of NUREG-2216 includes a discussion of the kinds of information that should be included.

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.

Acceptance and Maintenance Review

8.1 Modify the acceptance tests described in SAR Section 8.1.1 to include verification that the package components' dimensions meet the specifications in the package drawings and, for the tungsten alloy components, to include verification that there are no visible defects (e.g., cracks or pinholes).

SAR Section 8.1.1 includes confirmation that the materials of construction meet the requirements in the package drawings. However, that is only one part of the checks needed for ensuring the package's safety functions. The components' dimensions are also important and should be verified to conform to the requirements, including tolerances, in the package drawings as part of the acceptance tests described in SAR Section 8.1.1. SAR Section 8.1.1 should be clear and explicit regarding dimension verification. Additionally, for the tungsten alloy shielding components, it seems that the visual inspections and measurements should include a visual check to confirm that there are no visible defects (e.g., cracks or pinholes).

This information is necessary to satisfy the requirements in 10 CFR 71.85.

Quality Assurance Review

9.1 Provide a quality assurance program description, as required by 10 CFR 71.37, or a reference to a previously approved quality assurance program in the transportation package application.

This information is necessary to satisfy the requirements in 10 CFR 71.31(a)(3).