May 25, 2016

Ms. Sarah Bryson
Licensing Engineer
Croft Associates Limited
Building 4F, Culham Science Centre
Culham Abingdon
Oxfordshire, OX14 3DB, United Kingdom

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR REVIEW OF THE MODEL NO. 3977A PACKAGE

Dear Ms. Bryson:

By letter, dated March 21, 2016 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16081A142), Croft Associates Limited submitted an application for amendment of Certificate of Compliance No. 9338 for the Model No. 3977A package. To assist with our review, the U.S. Nuclear Regulatory Commission staff needs the information identified in the enclosure to this letter. Discussion of this request for additional information (RAI) and a response date occurred on May 25, 2016.

We request that you provide this information by June 24, 2016. Inform us at your earliest convenience, but no later than June 17, 2016, if you are not able to provide the information by that date. If you are unable to provide a response by June 24, 2016, please propose a new submittal date with the reasons for the delay.

Please reference Docket No. 71-9338 and TAC No. L25100 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) 415-6877.

Sincerely,

/RA/

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

Docket No. 71-9338
TAC No. L25100

Enclosure: Request for Additional Information

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Enclosure: Request for Additional Information

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Request for Additional Information
Docket No. 71-9338
Model No. 3977A Package

By letter, dated March 21, 2016 (ADAMS Accession No. ML16081A142), Croft Associates Limited submitted an application for amendment of Certificate of Compliance No. 9338 for the Model No. 3977A package. This RAI letter identifies information needed by the staff in connection with its review of the application.

Each individual RAI describes information needed by the 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 a redacted copy of the Mallinckrodt gas generation calculation.

Although the applicant marked the gas generation calculation per the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390(b)(1)(i)(A), the applicant did not provide a version of the gas generation calculation which can be viewed by the public as required by 10 CFR 2.390(a).

This information is necessary to satisfy the requirements in 10 CFR 2.390(b)(1)(i)(B).

1.2 Identify the maximum mass of Molybdenum-99 (Mo-99) for transport in insert Design No. 4081.

Table 1-3-8 in the SAR identifies the maximum mass of contents as 808 grams while Table 2 in PCS 038 identifies the maximum mass of contents as 807 grams.

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

1.3 Clarify the shipping configuration and mass of insert Design No. 4081.

Table 1-1 in the safety analysis report (SAR) indicates that the tungsten liner is used in conjunction with insert Design No. 4081 similar to the description of insert Design No. 3987. However, Table 2 in PCS 038 only identifies insert Design No. 4081 while the description of insert Design No. 3987 in the same table also includes the PTFE liner. If the shipping configuration for insert Design No. 4081 does not include the tungsten insert, provide the mass of insert Design No. 4081 alone in Table 1-1 of the SAR.

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

Enclosure

Materials Review

2.1 Identify any significant reaction(s) between the liquid Mo-99 content and the HS-50x85-SS insert and discuss the impact of these reaction(s) on the performance of the package.

Drawing No. 2C-7508 identifies the materials of construction for the insert top, and the insert body as SS Type 430, and SS Type 316 respectively. Literature suggests SS 316 is a good material for handling strong bases like sodium hydroxide, which is a main component of the Mo-99 content, below 80 degrees Celsius (^{o}C), up to the limit of solubility. Literature also indicates that the risk of stress corrosion cracking for SS 316 increases if service temperatures exceed 95^{o}C. Table 3-1 identifies the maximum temperature for the shielding insert under normal conditions of transport (NCT) is slightly greater than 80 ^{o}C and Table 3-2 indicates that the maximum temperature reached by the shielding insert exceeds 95 ^{o}C. In addition, staff could not identify the service characteristics of SS 430 in relation to sodium hydroxide.

This information is needed to ensure compliance with 10 CFR 71.43(d).

2.2 Identify O-ring materials of construction for the HS-50x85-SS insert within the text of the SAR.

Drawing No. 2C-7508 identifies the confinement seal/O-ring as EPM/EPDM. However, silicone is the only insert O-ring material listed in Table 2-10 and Table 3-2.

This information is needed to ensure compliance with 10 CFR 71.33.

Thermal Review

3.1 Confirm the maximum and minimum allowable temperature range for the Viton GLT containment boundary seal and the shielding insert seal.

Table 3-3 lists a maximum allowable Viton GLT O-ring temperature. Although pages 3-10 and 3-12 in the SAR indicate that -40 ^{o}C is within the O-ring minimum temperature, no data (e.g., vendor data sheets) was provided for verification. Similar data should be provided for the EPM/EPDM shielding insert seal.

This information is needed to determine compliance with 10 CFR 71.51 and 10 CFR 71.71.

3.2 Confirm that the results from the experimental NCT test and the furnace test on a package with the standard containment vessel lid bound the results for a package with the split lid design.

Page 3-11 states that the NCT test and furnace test were based on the standard containment vessel lid but the relevance of the test results to the split lid design was not discussed.

This information is needed to determine compliance with 10 CFR 71.71 and 10 CFR 71.73.

3.3 Provide pressure calculations for the containment vessel under NCT that account for the vapor pressure of the Mo-99 liquid mixture at 80 °C.

Page 3-15 states that "there is no pressure increase due to vapour pressure of the liquid contents" because the liquid is below the boiling point. However, the vapor pressure of water increases with temperature between loading (presumably at 20 °C) and prior to the boiling point.

This information is needed to determine compliance with 10 CFR 71.33(b)(5).

3.4 Confirm that the Mo-99 product bottle/product container has adequate space (i.e., ullage), or other specified provision, for expansion of the liquid during the heat and cold test for NCT and the hypothetical accident conditions (HAC) fire test.

It is not clear whether the package systems are adequately designed to accommodate expansion of the liquid Mo-99.

This information is needed to determine compliance with 10 CFR 71.33(b)(3) and 10 CFR 71.87(d).

3.5 Confirm the gas generation report results bound the gas generated during transport and specify the product bottle material.

The materials mentioned in the radiolytic gas generation report ("Radiolytic gas formation in Mallinckrodt produced Mo99 solutions") were SS and glass. Because the product bottle material used during transport is not specified in the application, it is unclear if the gas generation report adequately accounts for the potential radiolysis of the product bottle. For example, plastics have radiolysis generation rates greater than the materials mentioned in the gas generation report.

This information is needed to determine compliance with 10 CFR 71.33(b)(5) and 10 CFR 71.43(d).

3.6 Provide radiolysis (i.e., flammable gas concentrations) and pressure calculations that account for NCT temperatures.

a. Section 6.1 of the gas generation report ("Radiolytic gas formation in Mallinckrodt produced Mo99 solutions") indicated that the test temperature varied from 28.1 °C to 33.8 °C. However, SAR page 3-15a states the assumed gas temperature is 80.1 °C. This higher temperature would increase the amount of gas/hydrogen generated by radiolysis and would result in a greater pressure within the package.
b. The vapor pressure of the liquid should consider the temperature due to self-heating of the Mo-99 content; the decay heat of the radioactive material, if high enough, could cause the content temperature to be greater than the 80 °C surrounding air within the containment vessel at NCT. Self-heating should also be considered in the pressure calculations for HAC.

This information is needed to determine compliance with 10 CFR 71.33(b)(5) and 10 CFR 71.43(d).

3.7 Clarify if there is a limited transportation period associated with the Mo-99 content.

SAR Section 2.6.1.1 generically states that the 7 bar (gauge) pressure is based on a one year period, and SAR Section 3.3.2 indicated a 28-day period for radiolysis associated with the Iodine-131 content. However, a transportation time period was not provided for the Mo-99 content.

This information is needed to determine compliance with 10 CFR 71.33(b)(5).

Containment Review

4.1 Identify the acceptable pre-shipment leakage test leakage rate.

The applicant described the pre-shipment leakage test in SAR Section 7.1.4 without identifying the acceptable leakage rate. The applicant should identify the acceptable leakage test leak rate per ANSI N14.5 not only for completeness and as an aid to the test personnel, but also to incorporate it by reference in the certificate of compliance.

This information is needed to determine compliance with 10 CFR 71.43(f), and 10 CFR 71.51(a).

Shielding Review

5.1 Justify the assumption that a 3.5% dose rate increase from the top source due to beta emission is conservative.

The applicant provided report AMEC/CRM42622/TN_001 which found there was a 3.5% increase in dose rate associated with the side and bottom sources. The report also assumed a similar dose rate increase for the top source. However, the applicant provided no correlating justification for that assumption.

This information is required to determine compliance with 10 CFR 71.47.

5.2 Explain how the changes in distance from the source to package surface due to denting and buckling from the HAC tests described in AMEC/CRM42622/TN_001 have been determined to alter surface dose rates.

The applicant discusses a 5% change in dose rates at the side in Chapter 5, but it is not clear if this was taken into account in the maximum dose rates presented in Tables 5-12 and 5-13. There is further mention of buckling after the top drop but no statement as to whether there is or isn't a change to the distance between the lid and source. While the applicant states that shielding material is not lost, insufficient information was provided to verify that changes in geometry would not also change the external dose rate.

This information is necessary to determine compliance with 10 CFR 71.51(a)(2).

5.3 Identify the “cavity” referenced in Tables 5-12 and 5-13.

Tables 5-10 and 5-11 provide data for the situation in which the source is positioned at the inside surface of the containment vessel; i.e., no insert. Therefore, it is not clear to staff if the cavity referenced in Tables 5-12 and 5-13 is the insert cavity or the containment vessel cavity. In addition, staff noted that the applicant has duplicate Tables 5-12 and 5-13. One set of tables presents dose rate information for Iodine-131 and one set of tables presents dose rate data for Mo-99.

This information is necessary to determine compliance with 10 CFR 71.47.

Operations Review

7.1 Clarify what equipment should be used to handle the containment vessel.

Step 5 of Section 7.1.1 recommends a 12 mm eyebolt be used to remove the containment vessel. However, both step 3 of Section 7.2.2 and step 3 of Section 7.2.3 directs the user to install a 12 mm eyebolt to remove the containment vessel from the keg. The language in these instructions is not consistent, and should be revised to assist the user in developing procedures and ensuring the appropriate equipment is available.

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

7.2 Clarify the certification level of the personnel developing/approving the helium leakage rate testing procedures.

Although ANSI/ASNT CP-189-2006, “Standard for Qualification and Certification of Nondestructive Testing Personnel”, states that a nondestructive testing personnel Level III examiner has the qualifications to develop and approve written instructions for conducting the leak testing, the applicant described the leakage tests in SAR Chapters 7 and 8 without identifying the certification level of the personnel developing/approving the helium leakage rate testing procedures.

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

7.3 Identify equipment needed to handle the containment vessel shielding plug.

Step 8 of Section 7.1.1 states that the shield plug lifting point shall be used to remove the shield plug. Drawing 1C-7507 indicates the containment vessel shielding plug lifting point is a threaded connection. However, step 8 does not identify what lifting equipment, if any, is need to remove the containment vessel shielding plug. If lifting equipment is required, the loading instructions in Section 7.1.3 should be revised to reference the equipment for loading.

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

7.4 Clarify if the tungsten liner is transported separate from insert Design No. 4081.

Step 3 of Section 7.3.2 directs the user to install the containment vessel shielding plug after placing the tungsten liner into the containment vessel. The instructions also identify that loading the insert and payload is optional. Since shielding analysis AMEC/CRM42622/TN_001 assumes insert Design No. 4081 sits within the tungsten liner, the applicant should identify situations in which the tungsten liner is transported separately from insert Design No. 4081.

This information is needed to ensure compliance with 10 CFR 71.33(a)(5) and 10 CFR 71.87(f).

7.5 Identify how positive closure of insert Design No. 4081 is ensured.

Insert Design Nos. 3982, 3985 and 3987 employ match marks to identify positive closure and ensure the radioactive contents remain inside the insert. Identify how the current design both ensures positive closure of insert Design No. 4081 and ensures the radioactive contents remain inside the insert as assumed in shielding analysis AMEC/CRM42622/TN_001. Alternatively, the applicant should modify both the insert licensing drawing to show match marks and the operating instructions to reference match marks.

This information is needed to ensure compliance with 10 CFR 71.33(a)(5) and 10 CFR 71.87(f).

7.6 Identify the appropriate insert Design number for the split CV lid in Section 7.1.3.

Section 7.1.2 provides the appropriate insert Design numbers for the standard lid. There is no corresponding input in Section 7.1.3 for the split CV lid.

This information is needed to determine compliance with 10 CFR 71.33.

In addition to the information requests above, staff identified the following editorial items:
1. Mass of steel insert for Mallinckrodt insert should be 1,615 versus 1.615 in PCS 038,
2. References to gaseous shielding limits were deleted in PCS 038,
3. Table 10 is consistently omitted in Sections 1 and 2 of PCS 038,
4. The assumed maximum temperature is missing in the table located on page 3-12,
5. Incomplete sentence in item 2 in Section 7.1.3, and
6. The final unloading instruction in Section 7.2.3 is not numbered.