

July 30, 2010

Dr. Robert A. Vaughan
Managing Director
Croft Associates Limited
Building 4F, Culham Science Centre
Culham, Abingdon
Oxfordshire, OX14 3BD, United Kingdom

SUBJECT: SECOND REQUEST FOR ADDITIONAL INFORMATION FOR REVIEW OF THE
MODEL NO. 3979A PACKAGE

Dear Dr. Vaughan:

By application dated July 30, 2009, as supplemented October 15, 2009 and March 31, 2010, Croft Associates Limited requested that the Nuclear Regulatory Commission approve the Model No. 3979A package as a Type B(U) package for the transport of radioisotopes and radiochemicals used in a wide range of therapeutic and diagnostic applications and research.

In connection with our review, we need the information identified in the enclosure to this letter. To assist us in scheduling staff review of your response, we request that you provide this information by August 30, 2010. Inform us at your earliest convenience if you are unable to provide a response by that date.

Please reference Docket No. 71-9337 and TAC No. L24361 in future correspondence related to this request. The staff is available to meet to discuss your proposed responses. If you have any questions regarding this matter, please contact me at (301) 492-3292.

Sincerely,

/RA/

Michele M. Sampson, Sr. Project Manager
Licensing Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-9337
TAC No. L24361

Enclosure: Second Request for Additional Information

cc w/encl: E. Redmond, NEI

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Request for Additional Information
Croft Associates Limited
Docket No. 71-9337
Model No. 3979A

By application dated July 30, 2009, as supplemented on October 15, 2009, and March 31, 2010, Croft Associates Limited requested approval of the Model No. 3979A as a Type B(U) transportation package. This request identifies additional information needed by the Nuclear Regulatory Commission staff in connection with its review of the application. The requested information is listed by chapter number and title in NUREG-1609, "Standard Review Plan for Transportation Packages for Radioactive Material," which was used by the staff in its review of the application. This request describes information needed by the staff for it to complete its review of the application and to determine whether the applicant has demonstrated compliance with regulatory requirements.

1.0 GENERAL INFORMATION

- 1-1** Clarify the net and gross weight for the package in Section 1.2.1.1, of the application. These weights should correspond to the weight of the tested prototype, or the application should be revised to provide analytical justification that the results of the test conditions bound the weight in Section 1.2.1.1.

In Section 1.2.1.1, CTR 2008/10, Rev. 1, the applicant stated that the gross weight of the package is 68 kg (150 lbs), and the net weight (without contents) is 62.1 kg (137 lbs). These weights are also reflected in Table 2-7, CTR 2008/10, Rev. 1.

The gross weight of the tested prototype package was tabulated as 61.72 kg (136 lbs), and the net weight was 56.16 kg (124 lbs) in Section 2.2 of CTR 2009/21, Issue B. The comparison to the calculated mass of the package in CTR 2009/21 indicates that the tested package was 3% lighter than the design weight; however in comparison to Section 1.2.1.1, the weight difference is nearly 10% lighter, and no justification is provided to support the proposed 68 kg gross weight.

This information is required to assess compliance with 10 CFR Parts 71.71 and 71.73.

- 1-2** Revise Drawing Nos. 0C-6042, 1C-6045, and 1C-6046, and Section 2.3.1, of the application to establish the appropriate section of the Code with applicable version/date(s) for the welder and welding operator qualifications.

The applicant has provided the welding requirements and acceptance criteria in notes on the drawings. However qualification of personnel performing the welding has not been specified. In Section 2.3.1, the application states "All qualified welds shall be carried out by welders holding a valid qualification in accordance with the appropriate part of ASME Section VIII." The drawings and Section 2.3.1 should be revised to reflect the appropriate Code for welder and welding operator qualification.

This RAI is a result of the response to RAI 1.1-2 and 1.1-2 sent on February 26, 2010.

This information is required to assess compliance with 10 CFR 71.31.

- 1-3** Revise Tables 1-3-6 to reflect the maximum quantity of material, by radionuclide, which can be shipped in the package and meet the hypothetical accident condition test containment requirement for release of material in a one week period.

Section 4.3.4.2 notes that containment of gases is based upon the assumption that the gas material will leak from the containment system at the given leakage rate. Report CS 2009/06 calculates the size of a single leak and the maximum activity in the package which will result in a leak at the regulatory limit. This quantity is a limit which should be reflected in Table 1-3-6, since transport of a quantity greater than this limit would result in the package failing to comply with the requirements for a Type B package. (See also RAI 4-3).

This information is required to assess compliance with 10 CFR 71.51(a)(2).

2.0 STRUCTURAL

- 2-1** Update the drawing to provide the critical characteristics of the O-ring compound used to demonstrate the package performance, or limit the reference for the material used for the containment vessel (CV) O-ring to Parker Compound E0740-75.

Sheet 1 of licensing Drawing No. 1C-6044 lists British Standard (BS) 4518 0895-30, American Society for Testing and Materials (ASTM) D2000 and Parker Compound E0740-75.

It appears that the seal used for demonstrating the package's compliance with the Hypothetical Accident Conditions was made of Parker Compound E0740-75. Although this compound meets the requirements of ASTM D2000, some elastomers which also meet ASTM D2000 may not be adequate for the application. The exact O-ring compound intended for use in the package should be listed on the licensing drawings. To reduce ambiguity, the applicant could retain the reference to Parker Compound E0740-75 and remove the ASTM and BS standards.

This Request for Additional Information (RAI) is a result of the response to RAI 1.1-8 sent on February 26, 2010.

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

- 2-2** Clarify the application to provide verification of the maximum pressure after the hypothetical accident condition tests. Consideration should be given to the effects of degradation (charring) of the shielding insert O-ring and the potential release of volatiles.

The application lists the maximum pressure for the hypothetical accident condition tests as 1000 kPa gauge in Sections 2.7.4.1, and 3.4.3. The effects of degradation of the shielding insert O-ring, and potential for release of volatiles is not addressed in either section.

This RAI is a result of the response to RAI 1.2-3 sent on February 26, 2010.

This information is needed to determine compliance with 71.73(c)(4).

- 2-3** Provide an engineering calculation to demonstrate the maximum pressure inside the containment vessel after the hypothetical accident condition tests, if contents of the package are gaseous and the gas-filled vessel is breached.

Table 1-3-6 limits the maximum amount of gas to 25 bar-cc. The application does not indicate the expected maximum pressure after the hypothetical accident conditions, taking into consideration release of the gas inside the containment vessel.

This RAI is a result of the response to RAI 1.2-5 sent on February 26, 2010.

This information is needed to determine compliance with 10 CFR 71.43(c).

- 2-4** Clarify if the melting point of all solid contents (not just elemental forms) will be above the maximum temperature of the package contents.

The maximum temperature of the package contents may exceed the maximum temperature of the containment boundary. The restrictions on the melting points of the solids are limited to pure elements (not compounds) and may result in the need for operating limits specified as a condition in the Certificate of Compliance.

This RAI is a result of the response to RAI 1.2-1 sent on February 26, 2010.

This information is needed to determine compliance with 71.73(c)(4).

- 2-5** Provide revised analytical analyses of the package. Some of the ABAQUS outputs may have been incorrect due to erroneous input data in VECTRA report, 925-3272/R1, Rev 4.

Perform a detailed review of all ABAQUS input files for their accuracy/correctness, and rerun the ABAQUS files that may have erroneous input data to determine the correct stress intensity levels at the selected locations shown in Figure 7 in the VECTRA report, 925-3272/R1, Rev 4.

Staff has performed a cursory review of the ABAQUS input files for their accuracy/correctness, and identified a concern that erroneous input data may have been used to determine the stress intensity levels at the selected locations shown in Figure 7 in the VECTRA report, 925-3272/R1, Rev 4 -- e.g., LS_CV1_NCT11_HAC5.inp and LS_CV1_NCT12_HAC6.inp erroneously list a GRAV $1.1772\text{E}+06$ mm/s² acceleration, which corresponds to a 120g acceleration.

However, (1) for the normal conditions of transport (NCT) free drop case on page 2-33 in Section 2.6.7 of the application (CTR2008/10, Rev. 1) states, "A body force was applied to the model which was equivalent to an upward vertical acceleration of 120 g plus an additional factor of 50% to ensure conservatism." (2) And for the hypothetical accident conditions (HAC) free drop case on page 2-41 in Section 2.7.1 of the application (CTR2008/10, Rev. 1) states "Once the load conditions had been applied a body force of 300g was applied to the vessel which was equivalent to the deceleration of impact."

Similarly, on page 8 of VECTRA report, 925-3272/R1, Rev 4 states, "Bounding values were used for the accelerations applied to the model for the impact cases. A value of

300g was used for the HAC free drop cases from 9m and a value of 180g was used for the NCT free drop cases from 1.2m.”

This information is required to assess compliance with 10 CFR Parts 71.71 and 71.73.

- 2-6** Check tabulated displacement values of CV in CTR 2009/21, Issue B, Table 8, “Acceleration data for drop test” for correctness and provide a description of how the displacement values were determined.

Displacements of CV at the end of acceleration pulse in millimeters (mm) are tabulated in Table 8, “Acceleration data from drop tests” in CTR 2009/21. Those displacement values may have been erroneously listed, if they were to be compared with the dimensional differences tabulated in Table 9, “Dimensions taken before NTC and HAC tests.” There is no discussion of the displacement values in the text for Section 5, in conjunction with the discussion of the peak acceleration data.

This information is required to assess compliance with 10 CFR Part 71.71 and 71.73.

- 2-7** Provide analyses/evaluation to ensure the containment boundary is maintained due to reduction in closure screw preload of CV at cold conditions.

The effect of reduction in closure screw preload of CV for the integrity of the containment boundary need to be performed due to the difference in the thermal expansion coefficient of Type 304L stainless steel vessel lid and SA-A320/A320M, Grade L43 alloy steel closure screw at cold temperature levels.

This information is required to assess compliance with 10 CFR Part 71.71(c)(2).

- 2-8** Review the following calculation for the CV screw force based on the torque value, and provide reason(s) for the discrepancy between the calculation provided in the response for RAI 2-9.

Using the following common industry approach, the staff was not able to confirm CV screw tension force similar to the one presented in the response for RAI 2-9.

Torque: (given)

$T = 10 \text{ Nm} = 7.376 \text{ ft-}\#$

Nut factor: for Alloy or Mild Steel (assumed) -- experimentally derived constant

$K = 0.2$

Nominal diameter of the closure screw: (given - item 4, from Drawing No. 1C-6044, Rev. A)

$D = 10 \text{ mm} = 0.394 \text{ inch}$,

Formula for bolt force:

Taken from the following Referenced Documents:

- NUREG/CR-6007 “Stress Analysis of Closure Bolts for Shipping Casks,”
- EPRI, NP-5067 “Good Bolting Practices”

$$F = T / (K \cdot D) = [(7.376 \text{ ft-}\#) \cdot (12 \text{ in/ft})] / [(0.2) \cdot (0.394 \text{ in})] = 1,123 \text{ }\#_{\text{force}}$$

$$= 509 \text{ kg}_{\text{force}} = 4,995 \text{ N}$$

The difference in CV screw forces are: ~5.0 N vs. 8.12 N

Note that for higher K values, the difference in screw force would be even larger.

Furthermore, the calculated CV screw force from the torque value is directly related to previous RAI (see RAI 2-8).

This information is required to assess compliance with 10 CFR 71.71 and 71.73.

3.0 THERMAL

- 3-1** Clarify Section 3.2.2 of the application to identify the type of O-ring material used for low-temperature testing. Provide a specific reference to the section of the supporting documentation or analysis to verify that the containment vessel remained leak-tight at -40°C.

Section 3.2.2 should be revised to provide a specific reference within report CTR 2009/21, Issue A, for the low-temperature testing of the containment vessel. Additionally, the description of the O-ring material should be revised to reflect the O-ring material must be as described on Drawing No. 1C-6044.

This question is a result of the response to RAI 1.1-8 sent on February 26, 2010. The staff wants to confirm that Parker Compound E0740-75 was used to demonstrate a leak-tight configuration at -40°C.

This information is needed to determine compliance with 10 CFR 71.71(c)(2).

- 3-2** Revise the application to provide the maximum temperature of the package contents and the O-ring of the shielded inserts under HAC.

The maximum temperature of the containment vessel is stated in the application, but it is not clear if the temperature of the package contents and the O-ring on the shielded inserts exceed the maximum temperature of the containment vessel. Also, the effect of temperature on contents was not evaluated since some content like cesium have a relatively low melting and boiling point.

This RAI is related to the response to RAI 1.2-1 sent on February 26, 2010.

This information is needed to determine compliance with 71.73(c)(4).

- 3-3** Remove the temperature limit of 204°C from Table 3-3 for the containment vessel lid seal and replace it with the batch test temperature of 200°C from Chapter 8. Also, Note 1 associated with this seal temperature limit should reference the batch testing requirements for this seal.

This information is needed to determine compliance with 10 CFR 71.73(c)(4).

4.0 CONTAINMENT

- 4-1 Revise Section 4.1 of the application to correct the statement that there are no welds that are a part of the containment boundary or to provide a detailed explanation of why lid welds are not considered to be part of the containment boundary.

Section 4.1 of CTR 2008/10, Rev. 1 states, "There are **no welds**, valves, or pressure relief devices present in the containment boundary and the package does not rely on any filter or mechanical cooling system to meet the containment requirements.

Detail A of Drawing No. 1C-6044, Issue B and Detail B of Drawing No. 1C-6045 illustrate a bevel weld on the containment vessel lid, which is directly on the containment boundary indicated in Figure 4-1 of CTR 2008/10, Rev. 1.

This information is required by the staff to assess compliance with 10 CFR 71.51.

- 4-2 Revise Section 8.1.4 of the application to ensure that the entire containment boundary is leak tested per ANSI N14.5 - 1997, "American National Standard for Radioactive Materials – Leakage Tests on Packages for Shipment".

ANSI 14.5-1997, Table 1, "Containment boundary test requirements" requires that "Entire containment boundary including welds, seals, closures valves," are required to be evaluated during the fabrication leak testing. The leak test requirement is intended to include leak testing of the base material.

Per CTR 2008/10, Rev. 1, the applicant has committed to using the evacuated envelope method to perform the acceptance (fabrication) leakage test.

Upon further review of CP 390, TR 09/03/17, and TR 09/03/30 the staff is unsure of how the current leak test, as required in Step 8.1.4, of Section 8 of the application, will provide leak testing of the entire containment boundary, including the base material. As described, the mass spectrometer leakage detector (MSLD) is only placed in the closure vicinity to indicate a containment seal (item 5 of Drawing No. 1C-6044 Issue B) leak.

This information is required by the staff to assess compliance with 10 CFR 71.51.

- 4-3 Clarify Section 4.3.4.2, and the calculations provided in CS 2009/07, Issue A, for the maximum activity for each radionuclide intended to be shipped as a gas.

The text in Section 4.3.4.2 notes krypton-85 as the radionuclide to be shipped as a gas, however Table 1-4-6 and report CS 2009/07, both identify the material as krypton-79. The specific radionuclide is important because the regulations in 10 CFR 71.51 allow the release of 10 times the A_2 value for krypton-85 in a one week period. This 10 times limit does not apply to krypton-79.

Additionally, the A_2 value used in report CS 2009/07 for krypton-79, $2.00E+12$ becquerels, is not the current A_2 value for this radionuclide in the U.S. regulations, 10 CFR Part 71 and 49 CFR Part 173. The U.S. regulations do not have a specific value assigned for krypton-85, therefore, the default value from 10 CFR Part 71, Table A-3, "General Values for A_1 and A_2 " should be used to calculate the maximum quantity of material that can be released from the package. The U.S. has not adopted the 2003 or

newer editions of TS-R-1, "Regulations for the Safe Transport of Radioactive Material" which contain a higher A_2 value for krypton-79. This higher value cannot be used for transport until it has been incorporated into the U.S. regulations. The applicant may petition both the Commission and the Associate Administrator for Hazardous Materials Safety, in the Department of Transportation's Pipeline and Hazardous Materials Safety Administration for authorization to use an A_1 or A_2 value other than as listed in the regulations.

The volume used to calculate the quantity of xenon-133 released in a one week period appears to exceed the bounding free volume. If the bounding free volume were used to calculate the density, the amount released would exceed one A_2 per week.

This information is required by the staff to assess compliance with 10 CFR 71.51.

8.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM

8-1 Correct Table 8-1, "Package Maintenance Summary" of the Safety Analysis Report.

The fasteners on the outer keg and containment vessel are visually inspected prior to loading, as described in Section 7.1.1(8) and 7.1.1(13).

This RAI is a result of the response to RAI 7-3 sent on February 26, 2010.

This information is needed to determine compliance with 10 CFR 71.37(a).

8-2 Revise section 8.1.5.2 to describe the "test rig" used to test the O-ring responsible for containment and provide the acceptance criteria for the batch testing to show that the containment vessel will maintain a leak-tight configuration after the containment vessel has been heated to 200°C for 24-hours, as specified on Drawing No. 1C-6044, sheet 1.

The sealing surface of the "test rig" should have the exact dimensions (within the specified dimensional tolerances) and configuration, and be made of the same materials, as the containment vessel. The leak test sensitivity and acceptance rate should be specified for the test. This information is not adequately described for the acceptance test in Section 8.1.5.2.

This RAI is a result of the response to RAI 3-8 sent on February 26, 2010.

This information is needed to determine compliance with 10 CFR 71.43(f).

EDITORIAL

E-1 Revise the application to remove the truncated formatting comment boxes from the right-hand margin.

Chapters 2, Structural Evaluation, and 3, Thermal Evaluation, submitted on March 31, 2010, have formatting "track changes" boxes in the right hand margin. These were cut off in the conversion to .pdf format, resulting in text that runs off the page. While these do not affect the review, staff would prefer to have these chapters resubmitted so it does not appear that there is missing information in the application.

- E-2** Revise Figure 3-1 to provide the missing text from the “Materials” color key (legend).

As submitted on March 31, 2010, in Figure 3-1, the color identifiers are truncated on the “Materials” legend.

- E-3** Provide the descriptive name for the first use of the acronym NCR in Chapter 7 of the application.

In Section 7.1.1, step 7, it is noted that mismatched components should be removed from service and action taken in accordance with the users NCR system. For clarity, staff would prefer to have NCR spelled out in this first usage. The acronym may continue to be used throughout the remainder of the chapter.

- E-4** Revise the introductory material in Section 7, to require package users to file a report in accordance with 10 CFR 71.95, for any instance in which there is a significant reduction in the effectiveness of the package, where any defect with safety significance is identified after the first use of the packaging, or any instance in which the conditions of approval in the Certificate of Compliance were not observed in making a shipment.

In addition to notifying the Certificate holder when a condition of the Certificate is not met, package users are required to provide a written report to the Commission in accordance with 10 CFR 71.95. Staff notes that the licensee should obtain the Certificate holder’s input, but that it is the licensee who is required to submit the report. This regulatory requirement is not clearly identified in the Package Operations chapter of the application.