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

SAFETY EVALUATION REPORT

Docket No. 71-9338
Model No. 3977A
Certificate of Compliance No. 9338
Revision No. 2

SUMMARY

By letter dated December 14, 2015, as supplemented on May 23, and September 9, 2016, January 26, March 22, and May 12, 2017, Croft Associates Limited submitted an amendment request to revise the certificate of compliance (CoC) for the Model No. 3977A (Safkeg-HS) package. The applicant provided both shielding and gas generation analyses as well as both new and revised drawings to authorize the transport of liquid Iodine-131 (I-131). For this amendment request, staff reviewed Chapters 1 thru 5, 7 and 8 of the application using the guidance in NUREG-1609, "Standard Review Plan for Transportation Packages for Radioactive Material" and associated Interim Staff Guidance. Based on the statements and representations in the application, as supplemented, staff agrees that these changes do not affect the ability of the package to meet the requirements of 10 CFR Part 71.

1.0 GENERAL INFORMATION

The applicant requested authorization to ship I-131 in a stainless steel insert designated insert Design No. 3987. The applicant stated the I-131 would be shipped as normal form liquid salts in either alkaline or acidic solutions, and identified the maximum curie content of the material, the maximum mass of material as well as the maximum allowable decay heat of the contents. The applicant also provided dimensions and materials of fabrication for insert Design No. 3987. The applicant identified a PTFE liner as a component of insert Design No. 3987 in the original submittal (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15351A323). However, as a result of questions raised by staff on the impact of radiation on the PTFE liner performance, the applicant changed the liner material to titanium (ADAMS Accession No. ML16147A127), provided the necessary design information, and updated the necessary design documents. Based on a review of the statements and representations in the application, staff concludes that the package has been adequately described to meet the requirements of 10 CFR Part 71.

2.0 STRUCTURAL

2.1 Structural Evaluation

For this amendment, the applicant proposed the use of ASTM A479/A479M UNS designation S21800 material as an optional material for the keg closure studs because package users had experienced galling issues with the previously approved ASTM A479/A479M Type 304L material, and introduced a new design insert for transporting liquid I-131. Due to sourcing issues, the applicant also requested approval to use Loctite 263 adhesive as an option to the previously approved Loctite 270 adhesive. Since only the keg closure studs and the adhesive affect the structural evaluation of the package, staff only reviewed those changes with regard to the structural integrity of the package.

Staff evaluated the keg closure studs and determined that S21800 type material has a yield strength that is twice that of the 304L material, and a minimum elongation value (ductility) which is greater than 304L material. In addition, staff determined that the bolts are not fracture critical components because multiple load paths exist. With regard to the use of Loctite 263, staff determined that the bonding strength for Loctite 263 is equivalent to the bonding strength for Loctite 270. Based upon a review of the information submitted in the application, staff determined that the structural changes to the package are acceptable.

2.2 Materials Evaluation

2.1.1 Packaging Components

For this amendment, the applicant proposed the use of an austenitic SS alloy, ASTM A479/A479M UNS designation S21800, as an optional material for the keg closure studs along with the previously approved ASTM A479/A479M Type 304L SS material. For the new design insert, Design No. 3987, the applicant fabricated the design insert top from ASTM A276, Type 431 SS, and the design insert body from ASTM A479, Type 304L SS. The applicant also utilized ASTM B348 Grade 5 titanium liners in both the design insert top and design insert body as well as a silicone O-rings in the design insert top. In addition, the applicant added Loctite 263 to licensing drawing 0C-5942 for use in positioning and repositioning the keg studs.

Staff finds the use of SS and silicone acceptable since these materials have been widely employed to fabricate packaging components. Staff reviewed information on ASTM A479/A479M UNS designation S21800 and found its temperature dependent mechanical properties, including yield strength, tensile strength, allowable strength, modulus of elasticity, and coefficient of thermal expansion, acceptable because they conform to ASME Code, Section II, Part D. Staff also reviewed literature describing titanium's temperature dependent mechanical properties and concluded that the use of titanium is appropriate for the conditions of transport identified in the application. Staff compared Loctite 263 to the previously approved Loctite 270 and determined that both are designed for locking and sealing threaded fasteners where either high strength or high temperature applications are required. Therefore, staff finds the Loctite 263 to be acceptable for use as a permanent adhesive based on an evaluation of the contact material, and material specifications which describe the chemistries of both compounds to be essentially the same under similar operating conditions and temperatures.

2.1.2 Chemical or Galvanic Reactions

The applicant requested the inclusion of I-131 as authorized contents in dilute caustic form, and identified the chemical form of the I-131 as Sodium Iodide (NaI) with possible buffers of Sodium Hydroxide (NaOH) and Sodium Thiosulfate ($Na_2S_2O_3$) at concentrations below 0.1 M within a glass vial with crimp neck, rubber stopper, and aluminum crimp. Although NaOH may adversely impact the SS design insert, the applicant utilized a titanium alloy liner in its design to preclude any interaction between the caustic radioactive content and the design insert material. The applicant also asserted that the titanium alloy liner was compatible with the SS material used to fabricate the design insert. Staff reviewed various literature describing both titanium's resistance to chemical attack, and it's compatibility with SS. Consequently, staff determined that the titanium liner will provide adequate protection for the SS design insert and will not adversely react with the SS design insert.

In evaluating the chemical characteristics of Loctite 263, staff reviewed material specifications and material safety data sheets. Based upon its review of this literature, staff determined that the Loctite 263 will not cause adverse chemical reactions with package components and will adequately protect the binding surfaces from corrosion based on an evaluation of the contact material, material specifications and material safety data sheets which describe the chemistries of both compounds to be essentially the same under similar operating conditions and temperatures.

2.1.4 Radiation Effects on Materials

The applicant indicated that the proposed I-131 content emitted either beta or gamma radiation, and that these types of radiation will adversely impact neither the SS nor the titanium liner used to fabricate the design insert. Because electrons in metals are mobile and not attached to any particular atoms, when ionizing radiation displaces an electron within the metal's molecular structure, the free movement of electrons allows the displaced electron to be readily replaced within the metal. Therefore, staff finds the use of these metals in fabricating the package acceptable.

The applicant revised the SAR operating instructions to clarify that the design insert O-rings are tested prior to shipment of liquids. However, staff reviewed literature discussing the impact of radiation on silicone seals and determined that the properties of silicone change when exposed to greater than 10^6 rad. As discussed in Section 5.3 of this safety evaluation report, the applicant identified that the highest dose rate occurred at the radial surface at an elevation approximately where the silicone O-rings are located. Therefore, although these seals are leak tested prior to shipment, staff felt it prudent to impose a CoC condition to replace the silicone O-rings after each use. Staff notified the applicant of their intent to impose this condition (ADAMS Accession number ML17165A489) and obtained the applicant's agreement (ADAMS Accession number ML17173A157). Consequently, staff finds that radiation emitted by the proposed liquid I-131 contents will not adversely affect the package materials of construction based upon a review of the information submitted in the application, information obtained through independent research and independent analyses.

2.5 Conclusion

Based on a review of the statements and representations in the application as well as staff's independent evaluations, staff concludes that the Model No. 3977A transportation package meets the requirements of 10 CFR Part 71, and is constructed with materials in accordance with acceptable industry codes and standards.

3.0 THERMAL EVALUATION

Staff reviewed the Model No. 3977A transportation package application to verify that the thermal performance of the package has been adequately evaluated for the tests specified for normal conditions of transport (NCT), hypothetical accident conditions (HAC) and that the package design satisfies the thermal requirements of 10 CFR Part 71. The application was also reviewed to determine whether the package is consistent with the acceptance criteria listed in Section 3 of NUREG-1609, "Standard Review Plan for Transportation Packages for Radioactive Material," as well as associated Interim Staff Guidance documents.

The applicant sought approval to transport liquid I-131 in a SS insert, as listed in Contents Type 5 (SAR Table 1-4-3). The addition of this content affected the package thermal performance by changing the maximum normal operating pressure (MNOP) through the generation of hydrogen gas as a radiolysis product. The applicant calculated that one vial of liquid I-131 will generate 53.4 cm^3 of hydrogen over 10 days as detailed in the proprietary technical note listed in SAR Section 3.5.2 (CS 2017/02 "Maximum Pressure in Containment Vessel 3978 Under NCT and HAC for I-131 Contents"). If two vials are shipped, as the applicant proposed, this equated to 106.8 cm^3 of hydrogen. In a free volume of 216.4 cm^3, 106.8 cm^3 of hydrogen, along with heating of the gases on loading, resulted in a MNOP of 2.61 bar gauge which is well below the MNOP allowable limit for NCT shown in SAR Table 3-4. The applicant asserted that the generation of Xe-131 only leads to a very small increase in pressure, and neglected it in calculating the MNOP.

From the revised hydrogen generation calculations, the applicant predicted a hydrogen concentration of 26% for a shipment time of 10 days. Although this concentration exceeds the recommended limit in NUREG-1609, the applicant stated that under NCT all hydrogen will be trapped in the product container within the insert. The applicant also asserted that no ignition source exists. However, if the product container failed allowing the hydrogen to escape into the insert and subsequently leak into the containment vessel (CV), the applicant calculated that the total energy release would be about 966 Joules if ignition were to occur. The applicant asserted that this combustion energy content of evolved hydrogen is negligible compared to the heating of the cask from the I-131 decay. For example, the applicant calculated a decay heating rate of 200 Ci of I-131 to be 0.656 W or 0.656 Joules/sec which would release 966 Joules of energy in less than one-half hour. Thus, the applicant stated that the heating created by ignition of all of the hydrogen generated over 10 days would be negligible compared to the heating of the package by the decay of I-131.

For liquid contents emitting 5 W, the applicant determined the CV HAC maximum temperature to be 132°C and the maximum temperature of the insert to be 134°C per SAR Table 3-1. Assuming the NCT pressure is 2.61 bar gauge, the calculated pressure increased to 3.01 bar gauge at the CV maximum temperature. Using a vapor pressure 2.0 bar gauge from steam tables for the liquid contents, the maximum pressure within the CV during HAC increased to 5.01 bar gauge which is well within the design pressure shown in SAR Table 3-4.

Staff reviewed the application, assumptions, and analysis results to determine consistency with NUREG-1609. Staff noted that the hydrogen concentration predicted by the applicant, for a shipment time of 10 days, exceeds the NUREG-1609 recommended limit. Staff evaluated the applicant's statements regarding lack of ignition source and unlikely probability of hydrogen release into the CV. Based on the applicant's explanation and justification, as well as the package design, staff agreed that both the probability of hydrogen release and ignition is very small. Also, staff evaluated the applicant's statements regarding the energy release and the consequences from a hydrogen ignition. Based on the applicant's analysis and explanation, the package design, and the small volume of released hydrogen, staff agrees that the released energy from a hydrogen ignition is small with little or no consequence. Staff determined that the small quantity of energy released from a hydrogen ignition would be self-contained by the CV resulting in neither property damage nor radiation release. Based on this evaluation, staff imposed a CoC condition limiting the transport of I-131 to a maximum of 10 days. Staff also concluded that hydrogen generation in concentrations exceeding the NUREG-1609 recommended limit is acceptable for the small Safkeg-HS transportation package.

Based on its review of the application, staff concludes that the Model No. 3977A transportation package thermal design has been adequately described and evaluated, and that the thermal performance of the package meets the thermal requirements of 10 CFR Part 71.

4.0 CONTAINMENT EVALUATION

The objective of the containment review of the Model No. 3977A system is to verify that the package design satisfies the containment requirements of 10 CFR Part 71 under NCT and HAC. The objective includes review of changes to the containment design characteristics and containment analyses for the Model No. 3977A proposed by this amendment request. The applicant requested several changes to the Model No. 3977A system design and only those changes that affect the containment system are discussed in this section. Staff reviewed the Model No. 3977A system containment analyses submitted with the amendment request to ensure that the system continues to meet the regulatory requirements of 10 CFR 71 under NCT and HAC.

The applicant proposed to slightly increase the containment seal O-ring groove dimensional tolerance upper limit to 2.9+0.3/-0.1 mm from the original dimensional tolerance of 2.9±0.1 mm to allow for the use of two CV lids in which the O-ring groove widths were inadvertently machined slightly oversize during the manufacture of the first Model No. 3977A production batch. This change only affected the groove width as shown in the applicable proprietary licensing drawings. In responding to information request 4.1 (ADAMS Accession No. ML16147A127), the applicant stated that the groove depth is the vital performance characteristic regarding sealing and that this dimension remained unchanged. Therefore, the minimum fill ratio of the O-ring in the groove remained the same and the O-ring still meets the design standards necessary to meet NCT and HAC; therefore, there are no changes to the previously accepted NCT and HAC analyses. The applicant stated that the containment ability of the units manufactured with the increased groove width had been demonstrated through successful pressure and helium leak testing. Consequently, staff finds that the change in O-ring groove width will not affect either the sealing system or containment of the package, and that the proposed relaxed O-ring groove dimensions for the containment system are acceptable.

As discussed in the thermal chapter of this SER, staff noted that the hydrogen concentration predicted by the applicant, for a shipment time of 10 days, exceeds the NUREG-1609 recommended limit. Staff evaluated the applicant’s statements regarding the energy release and the consequences from a hydrogen ignition and determined that the small quantity of energy released from a hydrogen ignition would be self-contained by the CV resulting in neither property damage nor radiation release. Based on this evaluation, staff concluded that hydrogen generation in concentrations exceeding the NUREG-1609 recommended limit is acceptable for the small Safkeg-HS transportation package.

Based on its review of the application, staff concludes that the containment design has been adequately described and evaluated and that the package design meets the containment requirements of 10 CFR Part 71.

5.0 SHIELDING EVALUATION

The objective of this review is to verify that the addition of iodine-131 in a liquid solution as authorized contents in the Model No. 3977A Type B(U) transportation package continues to meet the external radiation requirements of 10 CFR Part 71 under NCT and HAC. Staff reviewed the application to ensure that the applicant provided adequate information to evaluate the shielding features and show that they provide adequate protection from the radioactive contents within. Staff evaluated the applicant’s assumptions, methods, and calculations to verify the expected radiation dose rates at locations near the cask surface and at specific distances away from the cask.

5.1 Shielding Design Description

5.1.1 Design Features

The applicant proposed no shielding-significant changes to the Model No. 3977A CV or outer keg from previously reviewed and approved amendments. The applicant sought authorization to transport liquid I-131 in a new SS insert, the HS-55x128-SS Design No. 3987, fitted with a liner. The applicant specified that the maximum total weight of the contents within this insert is 1810 g. The applicant also specified that the total weight, including the contents, insert, and any other containers and packing, may not exceed 3.62 kg. Cork dunnage filled the space surrounding the CV and keg cavity liner to maintain position during NCT. The applicant conservatively ignored the presence of this material in the shielding evaluation. The applicant also took no credit for the product container in shielding and containment analyses.

5.1.2 Summary Table of Maximum Radiation Levels

SAR Tables 5-1 and 5-2 reported the maximum NCT and HAC dose rates. The applicant planned to transport the package via exclusive use shipments.

5.2 Radiation Source Specification

SAR Tables 1-4-1 through 1-4-4 listed all authorized contents. For this amendment, as listed in SAR Table 1-4-3, the applicant only proposed to add 200 Ci of I-131 in solution as authorized contents for the Model No. 3977A. Given a maximum specific activity of 124.3 kCi/g, this limited the total mass of I-131 isotope to 1.61 mg.

The applicant referenced report AMEC/CRM37327/TN_001, "HS Container Shielding Assessment with I-131," which describes the three-dimensional Monte Carlo analysis of the Model No. 3977A (see section 5.4.1 of this SER). Since I-131 emits both photons and electrons (beta particles), the method used in the referenced report conservatively accounted for Bremsstrahlung radiation by assuming all beta particles were emitted with the maximum possible energy. The applicant non-conservatively ignored low-intensity photons which are emitted by the meta-stable daughter product, Xe-131m, 1.96% of the time. However, considering the margin between the expected dose rates and the limits in 10 CFR 71.47, staff determined this to be acceptable for this specific application.

The applicant used two separate shielding models to determine the expected dose rates from I-131 in the Model No. 3977A. The applicant initially developed two reference configurations with a 3000 Ci source of solid Cs-137 in equilibrium with Ba-137m in the CV cavity with the HS-31x114-Tu and HS-12x95-Tu tungsten inserts (applicant's reference AMEC/SF6652/001). The applicant developed dose rate corrections from these references by using MicroShield. The applicant then applied these correction factors to a separate I-131 model using a 200 Ci point source. This analysis conservatively ignored self-shielding by concentrating the point source at a location closest to an external surface rather than distributing it throughout the insert cavity. SAR Table 5-5 listed activity limits by nuclide, whereas SAR Tables 1-4-1 through 1-4-4 grouped nuclides by source material state, type, and package insert required for shipment.

5.3 Shielding Model

Aside from the HS-55x128-SS insert, the applicant's shielding model remained unchanged from previously reviewed applications. Staff previously accepted the applicant's assumptions and model changes for both NCT and HAC. The applicant ignored the shielding provided by the liner for the final dose rate correction, but relied on the liner to provide geometric separation from the insert cavity wall in the three-dimensional analysis. The applicant explicitly modeled the insert in both the three-dimensional Monte Carlo model and included the insert material in the one-dimensional MicroShield evaluation.

The applicant's Monte Carlo models only determined the bounding point-source location for shielding analysis, and not actual dose rates, by using a 200 Ci I-131 point source modeled at four locations: centered at the liner bottom; at the vertical mid-plane of the liner cavity side; centered at the liner top; and offset at the top against the liner cavity side. The applicant determined that placing the source at the top side of the empty liner cavity corresponded to the location of maximum external dose being on the outer side surface of the package at roughly the elevation of the CV lid.

Staff determined that the shielding model is described in sufficient detail to conduct a review of the package shield design.

5.4 Shielding Evaluation

5.4.1 Methods

The applicant used MCBEND version 11 and determined the source spectra for I-131 from the JEF2.2 data. Amec Foster Wheeler prepared the reports detailing the Monte Carlo analysis which used a continuous cross-section library based on the UK Nuclear Data Library. Since MCBEND is widely used for Monte Carlo shielding calculations and the JEF2.2 nuclear data is appropriate for the I-131 source spectra, staff determined these analytical tools are appropriate as used. The applicant also used the ANSI/ANS-6.1.1 1977 dose conversion factors to determine surface dose rates.

The applicant listed supporting documents containing the discussion and model specifications for the applicant's shielding evaluation in SAR Section 5.5.6. Enclosures AMEC/SF6652/001, "Monte Carlo Modelling of Safkeg HS Container," and AMEC/CRM37327/TN_001 contained the details of the Monte Carlo analysis. The three-dimensional Monte Carlo analysis modeled all relevant shielding design features of the Model No. 3977A in both the reference and I-131 sources.

The applicant performed subsequent MicroShield analyses to determine the relative dose rates from I-131. The applicant initially used MicroShield with the reference 3000 Ci Cs-137 source and compared the dose rates from the MicroShield calculation to the calculated MCBEND dose rates for the bottom of the package to determine a correction factor. The location resulting in the highest external dose rate in the reference configurations with the two tungsten inserts is the bottom center of the container cavity. The applicant initially expected this to hold true with the I-131 point source and used the dimensions from the bottom surfaces of the 3977A components for the MicroShield dose rate evaluation. The results of this Monte Carlo analysis are presented in SAR Tables 5-12 and 5-13. The applicant discovered that the location of maximum dose rate was not where expected. As a result, the applicant scaled this calculated dose rate based on the comparative difference between the dose rates at the location of maximum dose and the package bottom.

5.4.2 External Radiation Levels

SAR Table 5-1 presented a summary of the exclusive-use radiation levels under NCT on the surface of the package, the conveyance surface and 2 m from the conveyance edge. SAR Table 5-2 presented the dose rates under HAC.

5.4.3 Confirmatory Analyses

Staff reviewed the applicant's shielding models and determined that, aside from the treatment of the meta-stable Xe-131m daughter product, the applicant's assumptions are conservative and analysis methods are appropriate to the shielding design of this package.

Staff performed a confirmatory Monte Carlo analysis using the MAVRIC module in SCALE 6.1. Staff used continuous energy cross-sections based on the ENDF/B-VII data, and also included the ANSI/ANS-6.1.1 1977 dose response function in its Monte Carlo model. Staff confirmed the location of maximum dose.

Staff modeled the HS-55x128-SS insert, the CV, and the outer keg. Staff conducted a comparative evaluation with and without the presence of a titanium liner. Regardless of the presence of a liner, staff modeled the point source such that it would be located on the inner surface of the liner. Whenever staff opted to simplify the model, staff used reduced dimensions or conservatively omitted components (e.g., the CV flange bevel). Staff only included stainless steel, titanium, and DU components; staff modeled all other material as air. In addition, staff shifted the insert, the CV, and the CV lid toward the dose rate location being analyzed to minimize the distance between the point source and the detector.

Staff's evaluation resulted in dose rates which reasonably agreed with those determined by the applicant. Staff's evaluation confirmed that Bremsstrahlung radiation from the titanium liner would have negligible effect on external dose rates. Staff's evaluation also confirmed the maximum dose location on the radial surface of the keg.

5.5 Findings

Staff concludes that the design of the shielding system for the Model No. 3977A package is in compliance with 10 CFR Part 71 and the applicable design criteria have been satisfied. The evaluation of the shielding system provides reasonable assurance that the Model No. 3977A will provide safe transportation of radioactive materials. This finding is based on staff confirmation of relative dose rates, confirmation of the reference source dose rate, as well as considerations of the applicant's conservative analyses and modeling assumptions in the SAR.

6.0 PACKAGE OPERATIONS

The applicant revised the loading instructions to more clearly specify the performance of a leak test of the insert seal for insert Design No. 3987 for shipments of liquid contents. The applicant also revised the unloading instructions to ensure an explosive atmosphere will not exist when opening the package after transporting liquid I-131. Staff reviewed the proposed changes and determined that they ensure the package will satisfy the requirements in 10 CFR Part 71 during operation. Based on a review of the statements and representations in the application, staff concludes that the operating procedures meet the requirements of 10 CFR Part 71 and that these procedures are adequate to assure the package will be operated in a manner consistent with its evaluation for approval.

7.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM REVIEW

The applicant modified the maintenance instructions to identify when keg closure studs should be replaced. Staff reviewed the proposed changes and determined that they will ensure the package is maintained in a manner which will allow the package to satisfy the requirements of 10 CFR Part 71. Based on review of the statements and representations in the application, staff concludes that the acceptance tests for the packaging meet the requirements of 10 CFR Part 71, and that the maintenance program is adequate to assure packaging performance during its service life.

CONDITIONS

The CoC includes the following condition(s) of approval:

Condition 5(a)(2) was revised to incorporate the description of the stainless steel shielding insert Design No. 3987.

Condition 5(a)(3) was revised to incorporate the latest revisions to the drawings.

Condition 5(b)(1)(v) was added to incorporate the type and form of material authorized for transport.

Condition 5(b)(2) was revised to identify the maximum amount of I-131 authorized for transport.

New Condition 6 was added to specify the transit time of I-131 shall not exceed 10 days and CoC Conditions were re-numbered as necessary

Condition 7(a) was revised to address design insert O-ring replacement for shielding insert Design No. 3987.

The references section was updated to include this request.

Minor editorial corrections were made.

CONCLUSIONS

Based on the statements and representations contained in the application, as supplemented, and the conditions listed above, staff concludes that the design has been adequately described and evaluated, and the Model No. 3977A package meets the requirements of 10 CFR Part 71.

Issued with Certificate of Compliance No. 9338, Revision No. 2
on July 21, 2017.