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SAFKEG-LS – DEVELOPMENT AND LICENSING OF A SMALL 6M REPLACEMENT PACKAGE

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ABSTRACT

In 2007 the University of Missouri Research Reactor (MURR) contracted with Croft to develop two Type B packages in accordance with 10CFR71 [1]. These packages were required to serve the medical, research and industrial isotope market and to replace the 6M and 20 WC DOT Spec packages in use by MURR at that time.

This paper details the development of the smaller, lightly shielded package – the Croft Safkeg-LS – which is to replace the DOT 6M package. The larger, heavily shielded package – the Croft Safkeg-HS – which is to replace the DOT 20WC package is currently at the SAR review stage.

The paper covers development to a very tight specification, prototype manufacture, testing under low temperature conditions, data collection for stress analysis and stress analysis to support the test program.

The paper also covers the process of developing the design expressly to facilitate approval by the NRC. The process of discussing options with the NRC to determine the most prudent approach to design of specific details, and approaches to be included in the SARP preparation is also covered. The benefits of preparation before SARP submission are given, and the speedy process of SARP review that resulted is described.

Croft decided to have the Safkeg-LS manufactured in the USA by CHT, NC. Planning for manufacture included review of Croft's Quality Management System (QMS) by the NRC – this presented particular challenges (which are covered) as Croft's ISO 9001 QMS did not cover certain issues required by the NRC – issues not detailed in 10CFR71 Subpart H on Quality Assurance (QA) – these issues are covered by the paper.

The paper also covers the issues that arose in the manufacture of the production packages, NRC QA inspections of manufacture, and how these issues were managed with respect to the licensing process.

The total time for development, licensing and supply of packages is given, which despite the relatively short licensing time was 5 years: comments are made on how this process can be accelerated.

INTRODUCTION

The Missouri University Research Reactor (MURR) produces of a wide variety of radioisotopes which are used in research, medicine and industry. Each year, MURR makes well over a thousand shipments of radioisotopes all across North America and Europe. A significant portion of these shipments are of Type B quantities and were made in the DOT approved 6M and 20WC-1 packages.

On the 1st October 2008 part 71.20 of title 10 of the Code of Federal Regulations allowing the use of the DOT 6M or 20WC packages was removed by the Nuclear Regulatory Commission (NRC) and Department for Transport (DOT) in order to align with the IAEA regulations [2]. In order for MURR to continue shipping it had to replace its existing packages with an NRC approved package, in accordance with 10 CFR 71. MURR contracted Croft Associates to design, test, manufacture and gain approval of the 6M and 20WC replacement designs by the Nuclear Regulatory Commission.

CUSTOMER DESIGN SPECIFICATIONS

The brief provided by MURR [3] required the design to meet certain operational requirements. These requirements were:

- the weight of the loaded package could not exceed 68 kg (150 lbs) to facilitate shipping;
- the shielding had to be at least as good as the existing 6M package;
- operational requirements had to be similar to the 6M package;
- the containment vessel had to have a cavity to fit the existing MURR lead pots;
- a stainless steel containment vessel with a leak testable closure was required; and
- the package design had to meet the requirements of 10 CFR 71 to gain NRC approval.

Due to the nature of their work, MURR require a fleet of flexible shipping containers with a large number of nuclides approved for shipment. The MURR contents are activated solids contained within quartz vials, aluminium cans or septum bottles, liquids in quartz vials or a septum bottle and gases in quartz vials [4]. Therefore the package had to accommodate 55 nuclides, all in solid form and a limited number in liquid and gaseous form. The package had to allow the maximum amount of each nuclide to be carried as limited by the shielding, mass, heat or leakage rate with regards to gases. The package also had to be able to carry a mixture of these nuclides.

THE LS PACKAGE DESIGN

Croft has extensive experience of designing packaging for the medical and research sectors. When designing it is prudent to base the design on those already tested and approved by a Competent Authority. This provides confidence in the ability of the design to meet all the requirements of the regulations. Croft chose to base the new MURR 6M replacement on its Safkeg 2799E package shown in Figure 1.

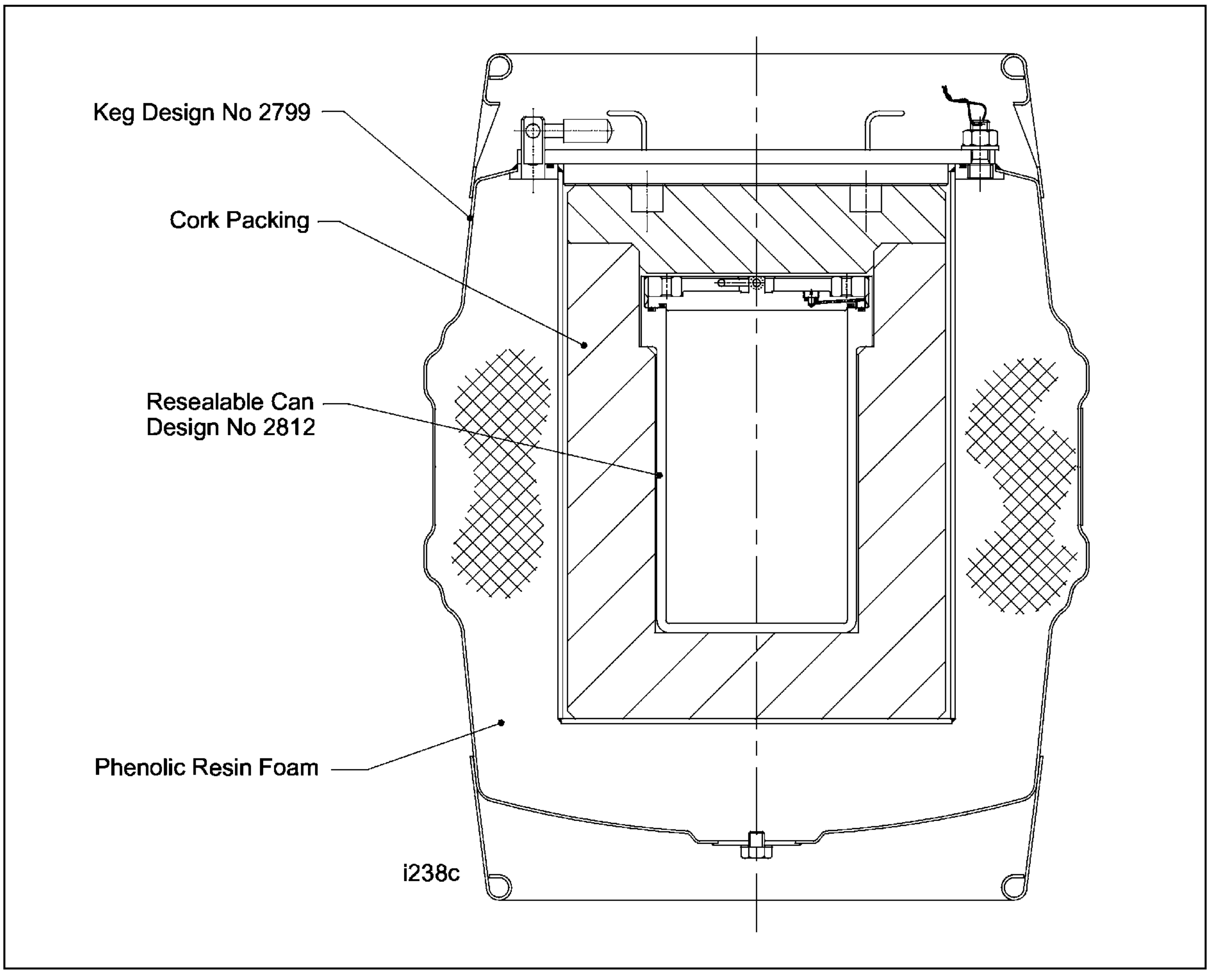

Figure 1. 2799E Package

The MURR design brief required a package that was substantially different to the 2799E design. The 2799E package has no built in shielding whereas lead shielding was required to be built into the MURR containment vessel (CV). The phenolic resin foam is novel to the NRC so it was decided to use cork in its place. To simplify tooling and manufacture, the keg was redesigned with straight sides and end walls and with hollow hoops at the top and bottom of the keg. The final design of the SAFKEG-LS package is shown in
Figure 2.

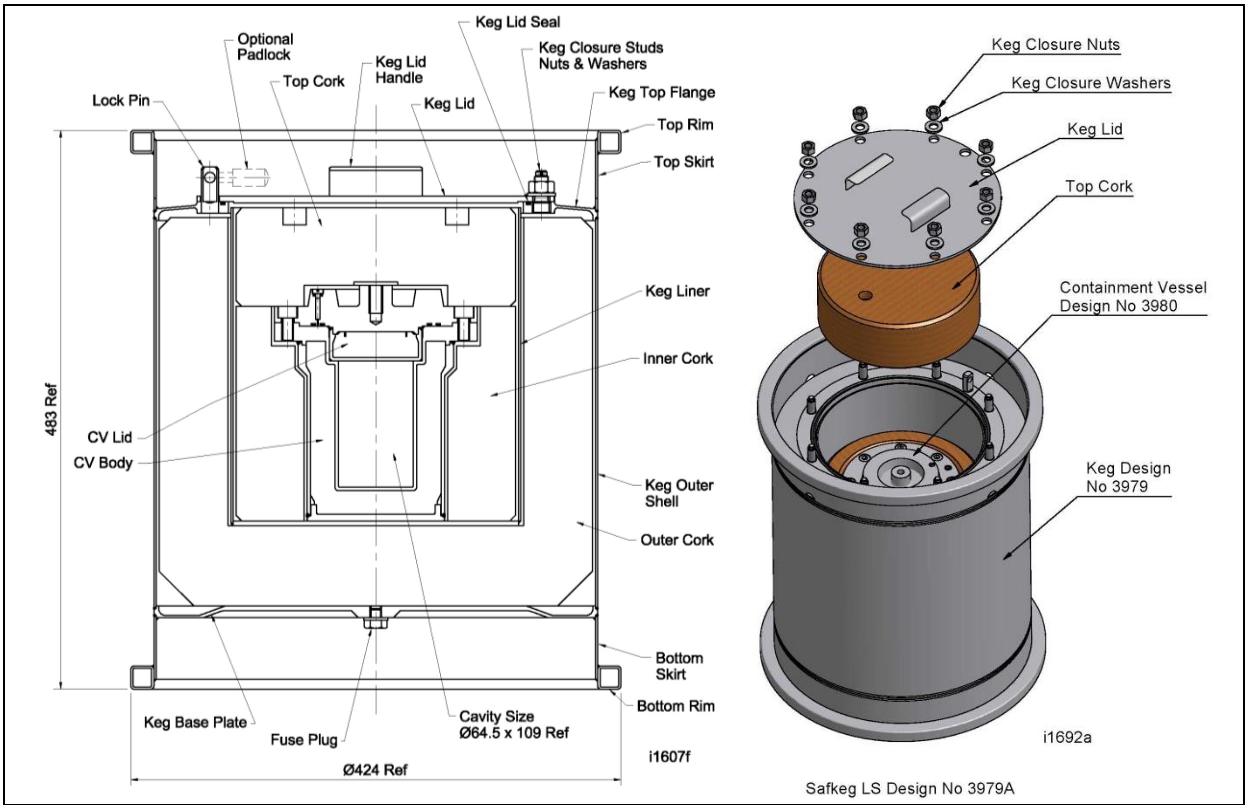

Figure 2. SAFKEG-LS Package Design

This package design allowed Croft to meet the MURR requirements because:

- the package has a maximum gross weight of 64.8 kg (143 lbs);
- the containment vessel has a double O-ring closure to allow leak testing on loading;
- 4% antimony lead is present in the CV to provide a similar level of shielding as that in the 6M package. Antimony lead was chosen because it prevents lead slumping; and
- the cavity within the CV could fit all the required MURR product containers.

Early in the design process it was concluded that the movement of the contents must be limited. Initial meetings with the NRC indicated that the MURR lead pots would not be suitable for use in the LS package therefore two inserts were designed and manufactured from tungsten. The design of these inserts provided confinement of the contents under Normal Conditions of Transport (NCT) and Hypothetical Accident Conditions (HAC) and also provided extra shielding for the contents.

Each tungsten insert had a different sized cavity, one 12 mm diameter by 65 mm high (see Figure 3) and the other 31 mm diameter by 73 mm high (see
Figure 4). They also allowed the variety of product containers to be accommodated with increased shielding. A further stainless steel insert was added with an initial cavity of 50 mm diameter and 103 mm high (see
Figure 5) which allowed the larger aluminium product cans to be accommodated as the cans themselves could not be assumed to meet NRC requirements.

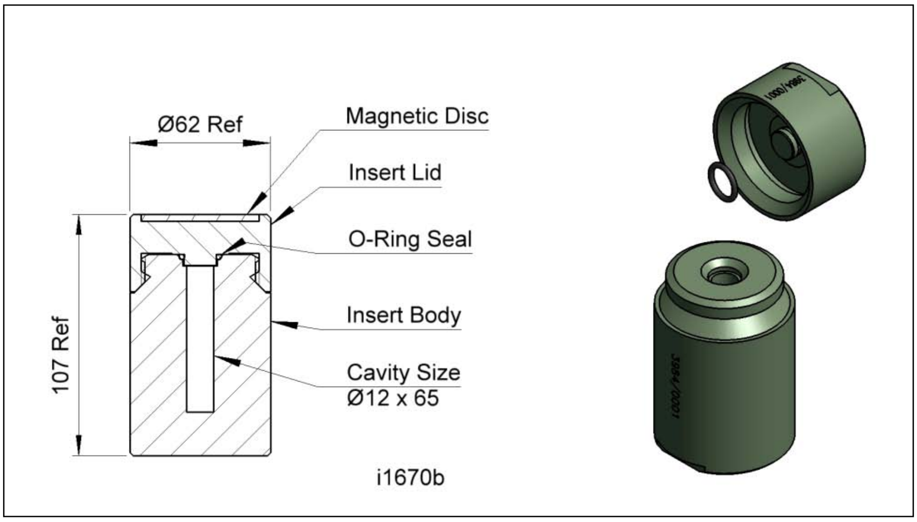

Figure 3. LS-12x65-Tu Insert Assembly

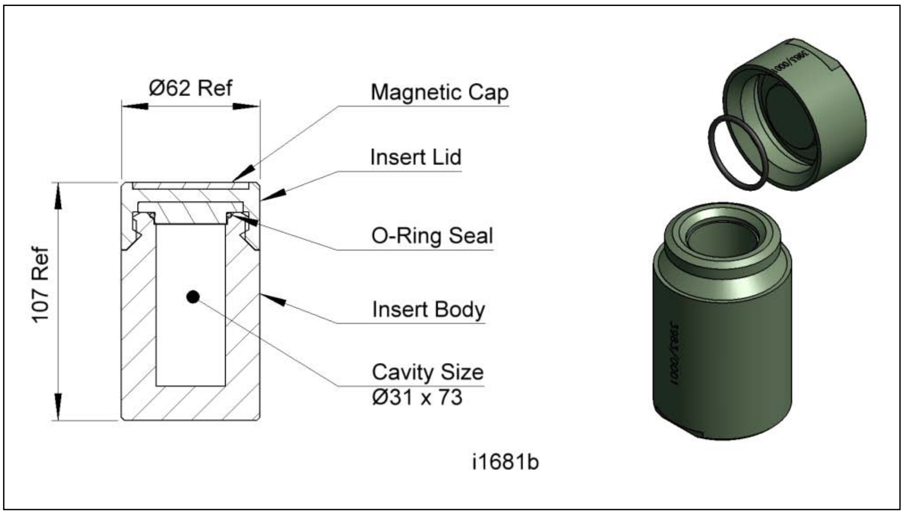

Figure 4. LS-31x73-Tu Insert Assembly

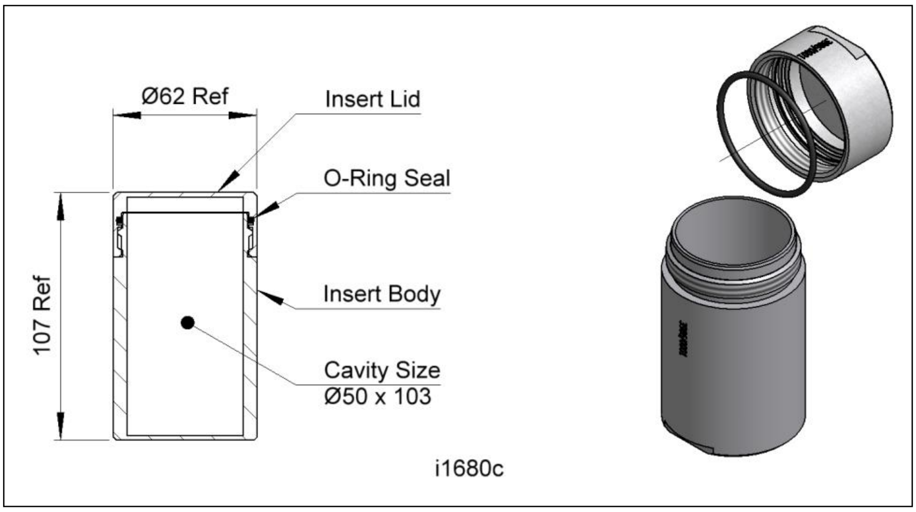

Figure 5. LS-50x103-SS Insert Assembly

TESTING

Prototype Testing

The Croft packages are designed with an outer sacrificial keg which is designed to absorb impacts, provide protection during handling operations and insulate the containment vessel during the HAC thermal test. The keg and cork are designed to deform in order to protect the containment vessel within.

The change to the outer keg design provided no assurance from existing designs that the outer keg and the cork packing would perform as required. Therefore an outer keg prototype with two different dummy lead containment vessels was built and tested. These tests also allowed an opportunity to determine how to perform the regulatory drop tests, to test the accelerometers, data recording and the method of filtering the data.

The prototype package was initially configured as illustrated in Figure 6. Spring loaded shock indicators were fitted to the lid of the containment vessel to indicate the accelerations involved as shown in
Figure 7. This package then underwent three 11.2m drop tests in different orientations, on the bottom, on the side and on the bottom edge of the package, all at ambient temperatures.

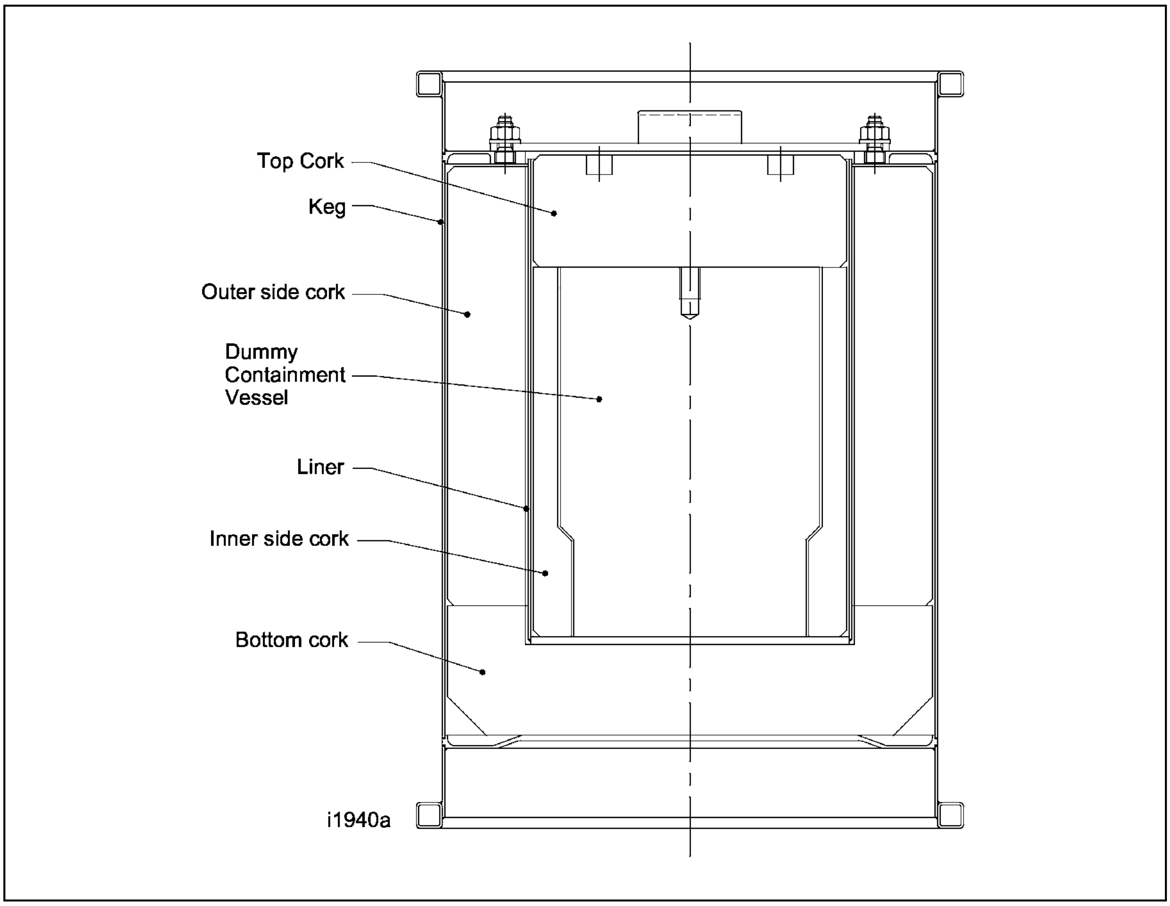

Figure 6. Protoype Configuration for Initial Drop Tests

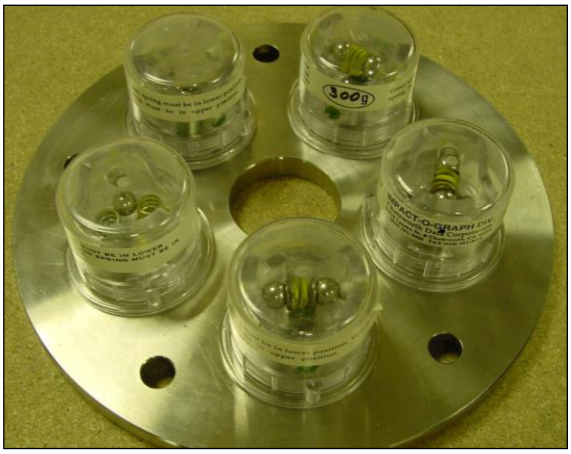

Figure 7. Shock Indicators attached to Lid

A second prototype package was then configured according to Figure 8. The containment vessel was fitted with an accelerometer in order to measure the actual g values and to determine the best method to log and filter the g data. The package was cooled to -40°C and then underwent 1 drop from 11.2m onto the package side. 4 drops from 1.2 m onto the top, side and 2 onto the top edge of the package and then 2 drops from 9m onto the top and top edge of the package.

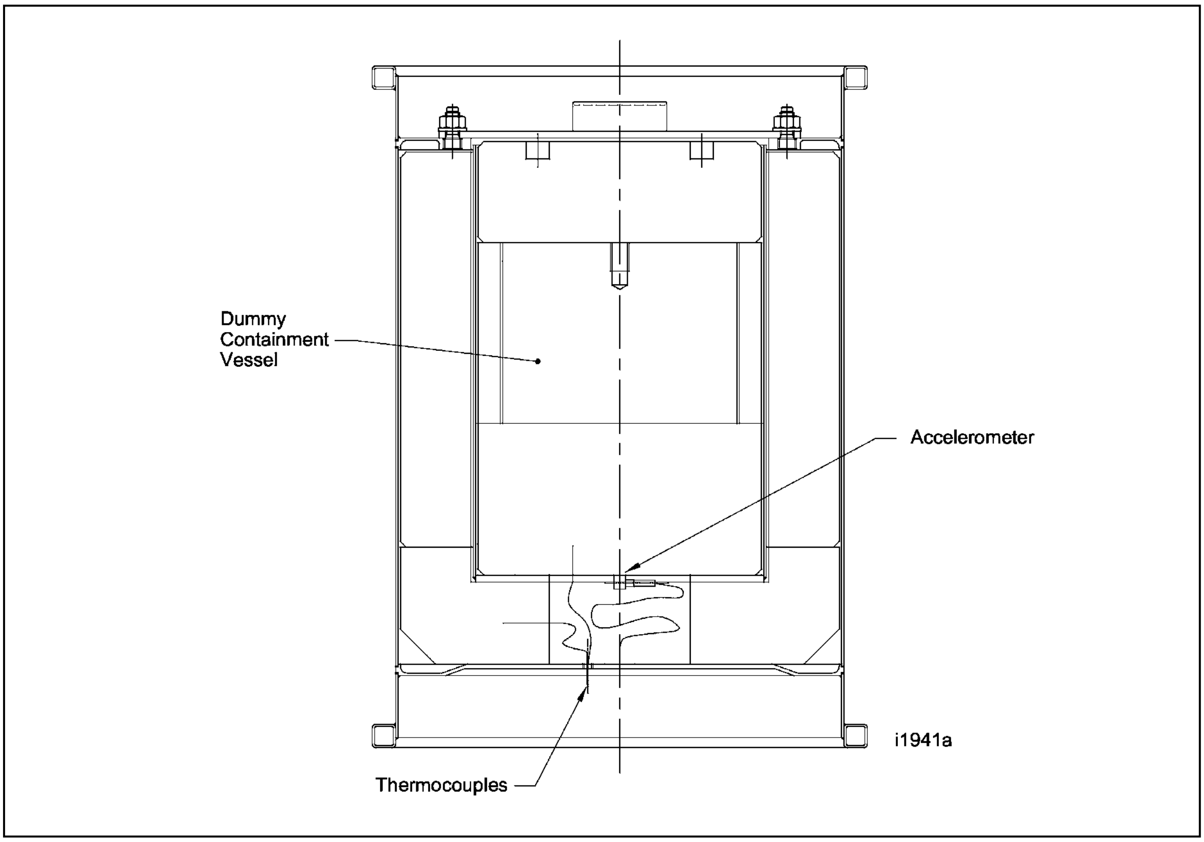

Figure 8. Second Prototype Configuration

The results of these tests demonstrated that the outer keg performed as required. It also identified refinements required during the prototype testing such as returning the package to the freezer between each -40°C drop test to ensure the package remains at the correct temperature. It also allowed the best method to measure and filter the acceleration data to be determined.

Regulatory Testing

On completion of the prototype testing a package meeting the required design specifications was fabricated to undergo the testing required to demonstrate compliance with 10 CFR 71. The heaviest Tungsten insert LS-12x65-Tu was filled with lead shot to simulate the contents.

Normal Conditions of Transport tests

The package underwent the following NCT tests:

- steady state thermal test;
- compression test;
- penetration test;
- 1.2 m drop test centre of gravity (C of G) over the side of the package;
- 1.2 m drop test C of G over the top end of the package; and
- 1.2 m drop test C of G over the top rim edge of the package.

The water spray test was not carried out because the materials both inside and out are made from materials that are water resistant. Therefore the water spray test would have no effect on the structural design of the package.

The steady state thermal test was carried out with a 10W electrical heat source. This provided the benchmark test for the thermal FEA work. After the thermal test the package was disassembled and the compression test was carried out on the keg with a 500 kg weight which was in excess of the 340 kg required. Once the compression test was completed the package was dimensionally assessed, the containment vessel was closed and leak tested. The package was then assembled as shown in Figure 9, in order to begin the penetration, drop tests, puncture tests and the thermal test. All the NCT drop tests were carried out at ambient conditions.

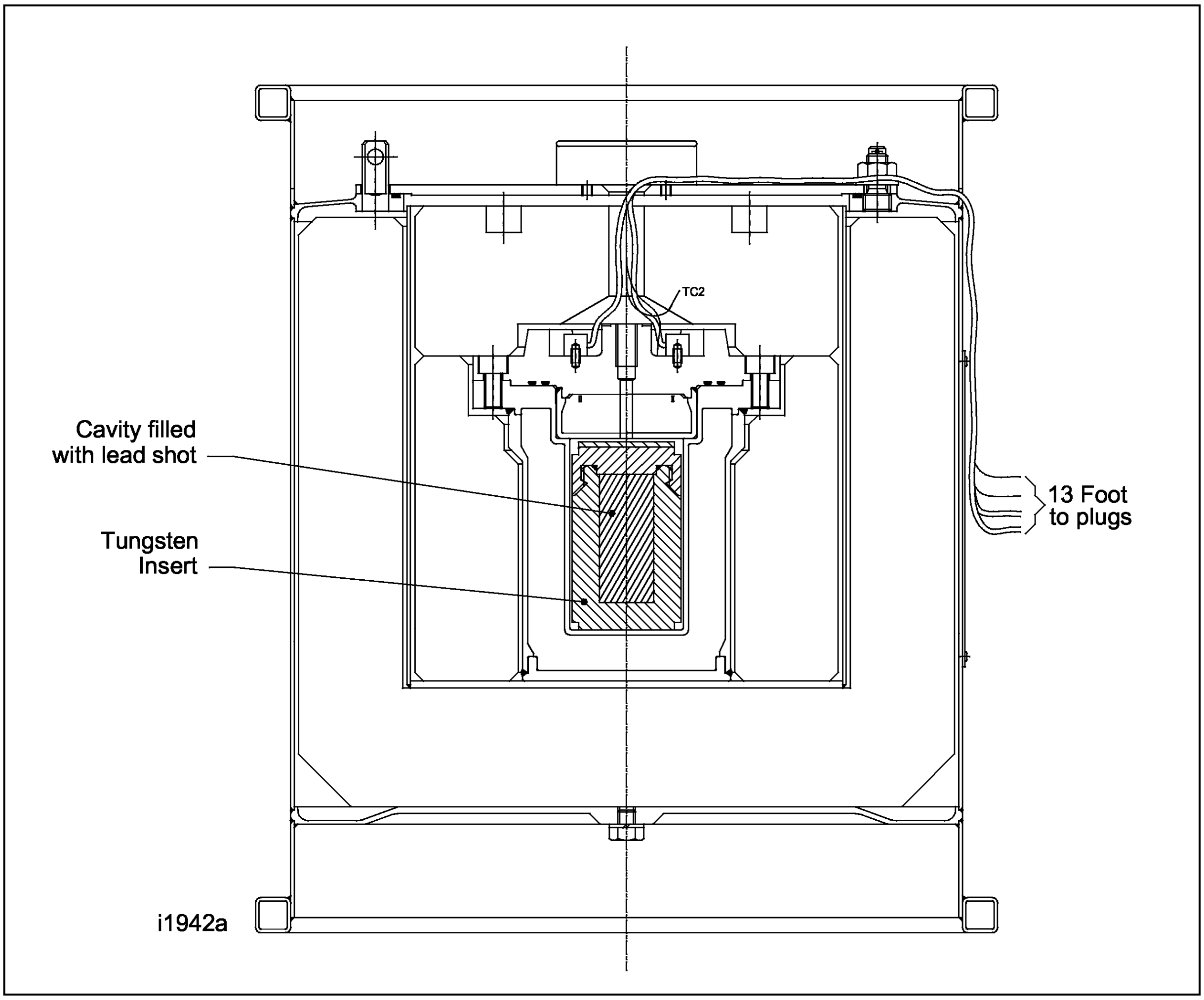

Figure 9. Package Prior to NCT and HAC test series

Hypothetical Accident Condition Tests

On completion the of the NCT drop tests the package then underwent the HAC tests. The package was not opened or dissembled prior to this testing. The following tests were carried out in the order listed:

- 1m puncture test on side impact point at ambient;
- 1m puncture test on bottom end impact point at ambient;
- 1m puncture test on top rim edge impact point at ambient;
- 10.2m drop test 1 at -40°C, C of G over side;
- 10.2m drop test 2 at -40°C, C of G over top rim edge;
- 10.2m drop test 3 at -40°C, C of G over top end;
- 1m puncture test on top end at -40^{o}C; and
- 800°C thermal test.

The crush test was not carried out on the package because its density was greater than 1000 kg/m^3.

The initial puncture tests were carried out at ambient temperatures from 1m in the orientations shown in Figure 10. A further 1m puncture test was added after the 10.2m drop tests. The package was at a temperature of -40°C and was dropped with the C of G over the top of the package onto the punch. This ensured that the package was tested at the worst case conditions for the puncture test.

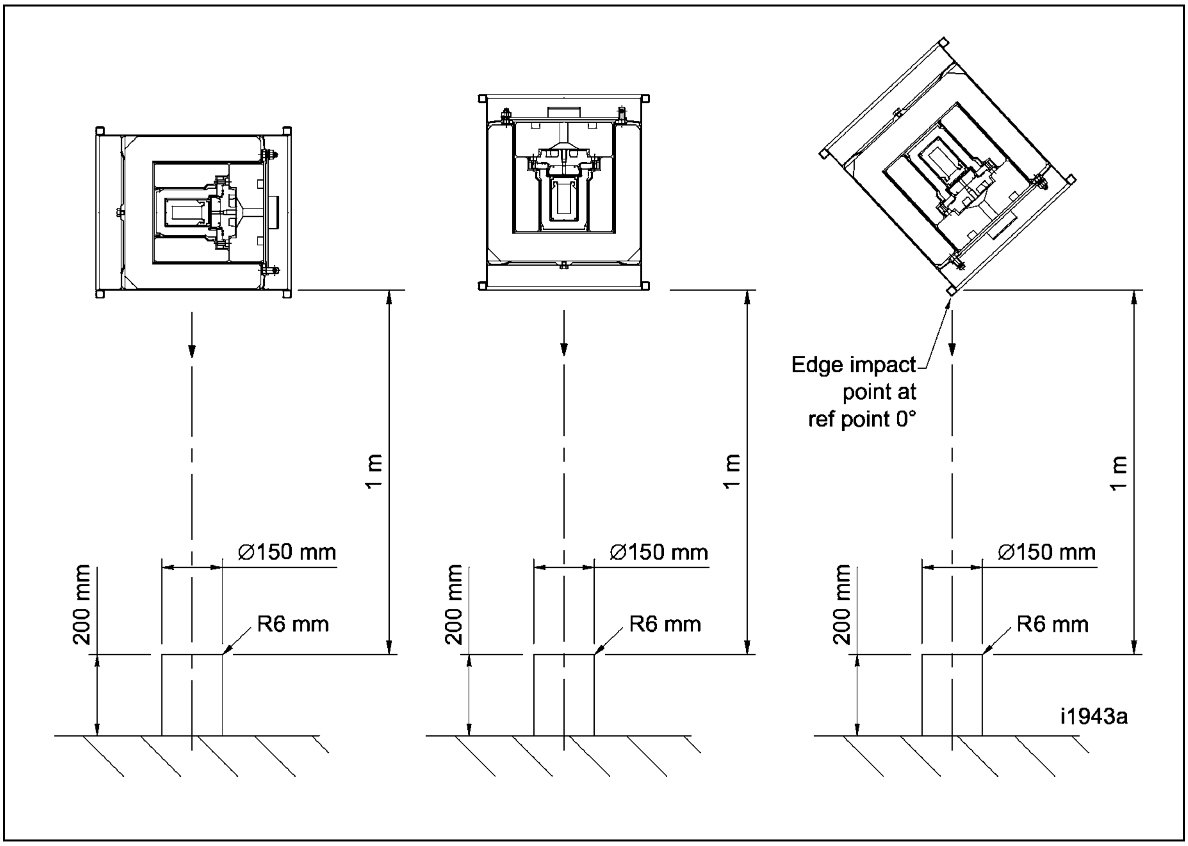

Figure 10. Initial Puncture Tests Drop Orientations for the SAFKEG-LS Package

All the drop tests occurred with the C of G over the top, top edge and the side as shown in Figure 11 for the 10.2 m drop tests. These were considered the most challenging orientations to the package integrity. The package experiences the maximum deceleration in the side drop orientation. The top and top edge orientation challenges the integrity of the keg and CV closure.

The HAC drop tests were carried out from a height of 10.2 meters, a combination of the 9 meter and 1.2 meter test heights. This height allowed a degree of variation within the package weight to account for differences between the prototype weight and the nominal weight. For the 10.2m drops the package was cooled to -40°C by placing it into a freezer prior to the test. Temperature probes were attached to several points in and on the package to confirm it had reached -40°C prior to the drop test. The -40°C temperature of the package ensured that the effects of brittle fracture were investigated.

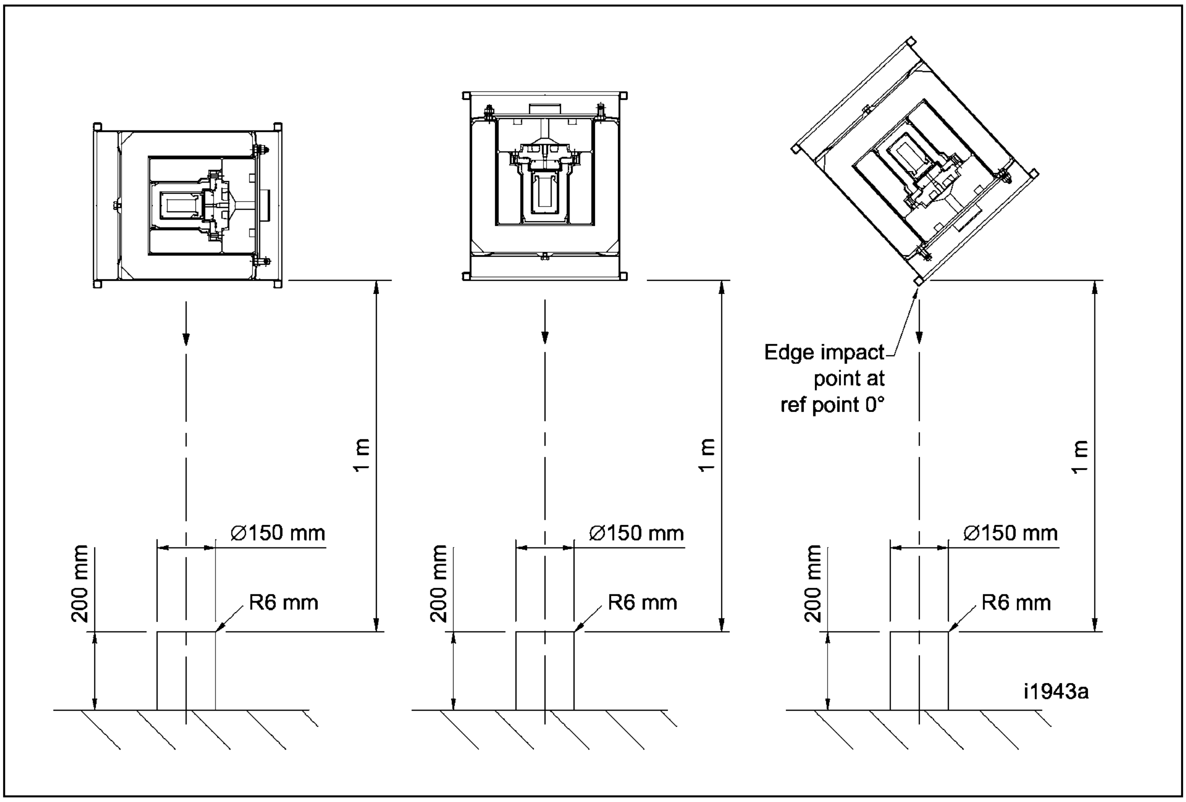

Figure 11. 10.2m Drop Orientations for the SAFKEG-LS Package

During all the drop tests the g values were determined from the accelerometers attached to the package. Two accelerometers were attached to the lid of the containment vessel. They were both attached in similar positions on the CV lid top to essentially measure the same acceleration as shown in Figure 12. Two were used as this allowed redundancy should one of the accelerometers fail during the test. The accelerometers used were DYTRAN Model Number: 3023A, mini triaxial accelerometers.

The reason for positioning the two accelerometers on the CV lid top was that this is deemed to be the most vulnerable part of the package. Triaxial accelerometers were chosen as they provide data for all directions and therefore for all impact orientations. The accelerometers were fixed such that channel 3 (z axis) was aligned with the principle axis of the package. Channels 1 and 2 were orientated with the x and y axis of the package and were used to determine the acceleration in the radial direction by vector summation.

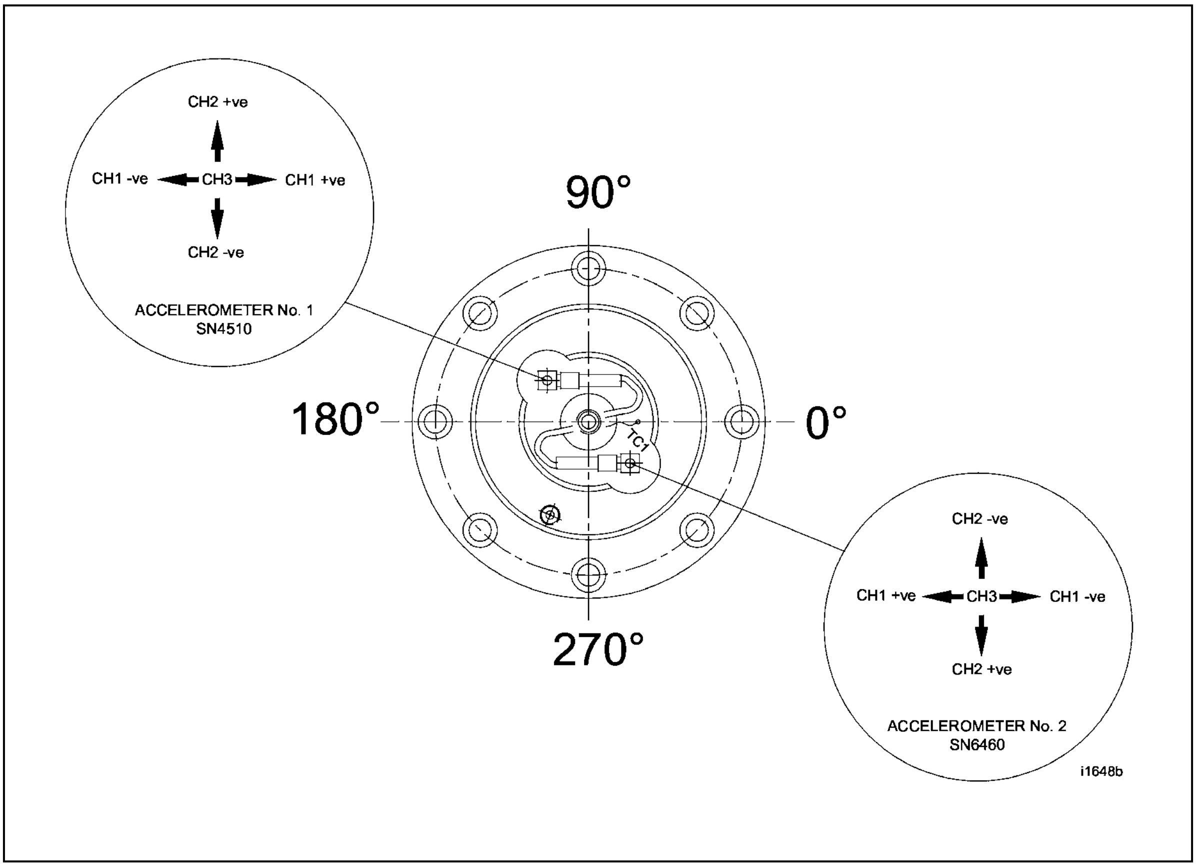

Figure 12. Accelerometer Location on CV Lid

The acceleration data was captured using National Instruments Signal Express version 2.5. The sample frequency was 100,000 samples per second. The raw acceleration response data was filtered using a low pass digital 4th order Butterworth filter, with a cut off frequency of 500Hz to remove any high frequency hash. From the g graphs the peak g values were obtained and then used in the Finite Element Stress Analysis (FEA) of the containment vessel.

The thermal test was carried out by placing the package in a furnace heated to 800°C. Thermocouples were attached on and in the package and these indicated that the package surface remained at ≥ 800°C for more than 30 minutes.

Results of Testing

On completion of the testing the containment vessel remained leak tight and dimensionally unaltered as shown in
Figure 13. The cork was cracked from the drop tests and charred from the thermal test. The keg skin suffered minor denting however it was not penetrated and the welds did not tear. The majority of the damage was deformations of the rims and skirt, however the keg remained intact and the lid was still in place as shown in
Figure 14.

Figure 13. Containment Vessel on Completion of Testing

Figure 14. Damage to Top Rim and Skirt of Keg after Testing

PRODUCTION AND NRC REVIEW OF THE SAFETY ANALYSIS REPORT

The Safety Analysis Report (SAR) is comprised of 8 sections. Each section is used to address various aspects of the design, manufacture and operations. The NRC provides two very comprehensive guides discussing in depth the requirements of each section of the SAR, Regulatory Guide 7.9 [5] and NUREG-1609 [6].

Croft chose to start the SAR production in the initial design stages because the production of the SAR helps guide the design to ensure it meets all the requirements of 10 CFR 71. This section will not fully detail the contents of every section but it will discuss the items that were most challenging within the design process.

Section One – General Information

Section one provides the general information about the package but crucially it lists out the allowable contents and provides the licensing drawings for the package.

With 55 nuclides and several different inserts, classification of the contents was a challenge. In order to simplify the process for the package users and the NRC reviewers, it was decided that the contents would be split up into several types as shown in Table 1. This method then allowed the limits for weight, shielding and heat to be set for each insert and material form.

The package design had to be flexible with regards to the contents because MURR may be asked to produce and ship any activity and type of nuclide. There are no standard contents, as with most other approved packages. Therefore rather than specify an actual activity to be carried Croft specified the maximum content of each nuclide that may be carried for each contents type. This maximum content was derived from the lowest activity provided by the shielding limit, heat limit and mass limit.

Table 1. Contents Types for the SAFKEG-LS Package

Contents Type Designation	Material Form	Shielding Insert
CT-1	Solid	LS-12x65-Tu Design No 3984
CT-2	Solid	LS-31x73-Tu Design No 3983
CT-3	Solid	LS-50x103-SS Design No 3986
CT-4	Liquid	LS-31x73-Tu Design No 3983
CT-5	Liquid	LS-50x103-SS Design No 3986
CT-6	Gas	LS-31x73-Tu Design No 3983
CT-7	Solid/ Fissile Normal Form	LS-50x103-SS Design No 3986
CT-8	Solid/ Fissile Special Form	LS-50x103-SS Design No 3986

Section 1 also contains the licensing drawings; note that these are not manufacturing drawings. The licensing drawings only detail those items that are important to safety. These drawings allow analysis of the design by all the NRC review groups. They do not detail any items that are not important to safety but which are required for manufacturing drawings.

During the design process we assessed the licensing drawings against the manufacturing drawings to ensure both matched. The fabrication of the test package allowed these drawings to be compared against the process of fabrication. Design requirements can be difficult to fulfil in reality when materials are difficult to source or inappropriate tests are listed. Fabrication can identify these problems. These drawings were also assessed prior to final approval by our US fabricator of the production units to identify any further issues that could arise in manufacture.

Section Two – Structural Evaluation

This section defines the materials, fabrication methods and assesses the design against the testing requirements for Normal Conditions of Transport and Hypothetical Accident Conditions.

As discussed in the testing section, Croft chose to test the package to prove regulatory compliance. However early meetings with the NRC suggested that FEA analysis would be of benefit alongside the testing data. The NRC felt that an FEA analysis would be required to demonstrate the response of the package at all angles. Movement of the package during the testing may mean that the package does not land in the intended orientation. Croft took the decision to carry out the FEA on the containment vessel only; damage to the keg was adequately demonstrated by testing.

On completion of the prototype testing the highest g value measured during each drop orientation was taken and used in the FEA work at the equivalent orientation. This allowed Croft to determine if the stresses on the CV during the drop tests remain below the allowable limits, as defined in Regulatory Guide 7.6 [7]. The FEA and testing demonstrated that the design did meet all the testing requirements of 10 CFR 71.

Section 3 – Thermal Evaluation

The thermal evaluation identifies the heat reached by the components of the package and the maximum operability limits for these items.

The chosen maximum heat load of the package was 10W. This value allowed Croft comfort in the early design process that the package would perform during the NCT and HAC conditions.

Testing of the package at the steady state condition and the 800^{o}C thermal test provided actual temperatures throughout the package. The thermal FEA model was produced and benchmarked against the thermal testing carried out on the package. This model then allowed the temperatures throughout the package to be determined for all conditions and for all components.

Section 4 – Containment

This section details the containment boundary and how its effectiveness is tested. Croft took a decision early in the process that no welds would be present in the containment boundary. Therefore the flange and body of the containment vessel were manufactured from a solid piece. This removed onerous requirements for weld tests. Very early seal designs had a seal on the plug to prevent liquid moving into the gap between the plug and the body. However in drafting the SAR it was realised that this design would not be suitable and therefore it was changed to the standard double seal on the flange.

Section 5 – Shielding Evaluation

Section 5 details the shielding evaluation of the package. As previously discussed, the contents needed to be defined as the maximum contents that may be carried; there was not a specified content to model. Therefore the location of the source that produces the highest surface dose was identified using a point source in a Monte Carlo analysis. Using this location a Microshield model, also with a point source, was produced and benchmarked against the Monte Carlo analysis. This Microshield model was then used to calculate the surface dose rate for 1 Curie of each nuclide at its highest dose time to take into account daughter products. The activity of the nuclide was then increased to determine the activity which provided a surface dose rate of 2 mSv/hr under NCT.

Section 6 – Criticality Evaluation

This section details the criticality evaluation of the package. This was not required for the SAFKEG-LS package as only fissile material under exemption 10 CFR 71.15 could be carried.

Section 7 – Package Operations

This section details the package operations such as loading, unloading and shipping an empty package. Writing this section during the design process allowed the design to be reviewed to determine how easy it would be to load, unload and test.

Section 8 – Acceptance Tests and Maintenance Program

This section details the tests carried out during fabrication, final release and during service to ensure that the fabricated packages meet the design intent. This section also details the checks and replacements carried out during maintenance to ensure the package continues throughout its life to fulfil the design intent.

Writing this section during the design process helped to determine all the tests that needed to be undertaken and the best point in the fabrication process at which to carry out these tests. It also helped to identify any items that required further testing such as the containment vessel O-rings. The material used did meet the temperature requirements however the manufacturer could not guarantee the material would operate at the maximum temperature for the time indicated in the thermal tests. Therefore we introduced our own tests for the O-rings to ensure they would operate at the temperatures required.

NRC REVIEW PROGRAM

In order to obtain a Certificate of Compliance for the SAFKEG-LS package a SAR must be submitted to and assessed by the NRC. Using the information in the SAR the NRC produces a Safety Evaluation Report (SER) which determines if the package design meets the requirements of 10 CFR 71.

The SAR was initially dispatched to the NRC on the 30th of June 2009. The NRC carried out its initial acceptance review. From this review it Requested Supplementary Information (RSI). Once the NRC received this information from Croft it started the official review process. During this process it made 2 Requests for Additional Information (RAI).

After each RAI had been issued, the NRC held a teleconference with Croft to help determine the requirements of each question and if the Croft responses were satisfactory to the NRC. All responses were provided in a review matrix which helped to clearly identify the responses to each question. The help the NRC provided during the review process enabled Croft to find the best answers to the questions asked.

During the review process, the liquids posed questions for which Croft could not obtain answers for within the required timeline. Therefore the liquids contents were removed from the required contents specification. The NRC did allow the liquids to remain within the SAR which means liquids can be easily added at a later date when further work has been completed to allow their inclusion.

The initial license was issued on the 24th of January, 2011 therefore the entire licensing process excluding the liquid contents took 1 year and 7 months.

NRC QUALITY ASSURANCE (QA) PROGRAM

In order to manage, design, fabricate and maintain a B(U) package, Croft is required to have an NRC approved QA program in accordance with 10 CFR part 71.

Initially the NRC began the review of Croft’s QA system with a desktop review of the Croft QA manual. An NRC audit then followed from the 14th to the 20th May 2008. This focused on the entire Croft Quality Management System (QMS). The Croft QMS at the time the NRC came to audit was approved under ISO 9001:2000. ISO 9001 focuses on the customer and continual improvement via measurement, analysis and improvement of supplied services and products. Audits are and were regularly carried out by British Standards Institute (BSI) and the UK Competent Authority.

The NRC audit however made several observations regarding the QA policy. The issues identified were linked to the fact Croft didn’t discriminate between items that were important to safety and those that were not. All items were treated as if they were all important to safety and therefore required a large quantity of documentation and auditing. This led to a complicated and difficult to follow system, in which errors were more likely to occur.

The NRC audit allowed Croft to take actions to simplify its QA system by introducing a graded approach to quality for the purchasing, fabrication and testing of items and the auditing of suppliers. The introduction of this graded approach provided a clear understanding of the needs when managing the supply chain and allowed Croft to apply objectivity to the understanding and auditing needs. This graded approach was based on the NRC document NUREG/CR-6407 [8]. Items that are important to safety are categorised as A to C and the requirements for fabrication, suppliers, tests etc. change according to their category.

The NRC also allowed Croft to implement the idea of Significant Conditions Adverse to Quality (SCAQ) with regards to non conforming items. This introduction to the Croft QA system allowed a substantial improvement in its effectiveness.

A follow up audit occurred on the 7th to the 10th of December 2009. The NRC reviewed the changes implemented to the Croft QMS. They concluded that overall Croft had adequately addressed the concerns raised in the 2008 audit and that the quality program met the requirements of 10 CFR part 71. During the audit the NRC team mentioned that Croft's plans for packaging fabrication needed further development and strengthening particularly with regard to Croft's QA oversight plans in the identification of SCAQ and the commercial dedication process. The NRC did allow Croft to start manufacture on completion of the second audit.

The NRC audited Croft and CHT (the US based manufacturer) during the fabrication of the SAFKEG-LS package. As part of the audit, they verified that the QA Program operated by CHT met the requirements of an NRC approved QA program. The NRC ensured that the manufacturing process met the requirements laid down in the Certificate of Conformity. The NRC reviewed the welding processes from the keg to ensure performance in accordance with the approved methods and procedures. They reviewed procurement to ensure it met the design requirements and checked non conformance control, training of personnel and the auditing program. No findings of significance were identified.

FABRICATION

The manufacturer of the SAFKEG-LS packages has to have an NRC approved quality program. Initially it was decided that Croft would manufacture the packages in the UK. However if Croft were the fabricator it would have been responsible for ensuring that all the suppliers met the requirements of the NRC quality program. Croft determined that this was not a viable approach as the manufacturing quantity is not large enough for a fabricator in the UK to develop the necessary systems to meet the QA requirements of 10 CFR Part 71. Therefore Croft decided to use a US supplier with an NRC approved quality system.

This supplier was CHT who already had an approved NRC quality system. Croft provided the drawings, manufacturing and test procedures based on the SAR and its quality system. CHT then produced its travellers and work instructions. Hold points were introduced at various points in the process for Croft to examine the manufactured product and the associated paperwork.

During manufacture issues with the SAR were identified. These related to minor drawing errors, errors in specifications in the SAR and the ability to source larger quantities of some materials to the requirements listed. These issues only became apparent when manufacturing multiple units. To ensure that the packages matched the requirements of the SAR, Croft had to apply for an update to the Certificate of Compliance. This involved updating the SAR and reapplying to the NRC for a new certificate. This process involved one RAI and took 7 months to complete.

ACCELERATING THE DEVELOPMENT PROCESS

The process from initial design to manufactured and approved package was 5 years. This is a relatively short time for a B(U) package. However this process could have been accelerated by being more conversant with all the NRC guidance. The guides produced by the NRC cover most areas of the design and if they are followed this reduces the review process. There are a large number of NUREG's and Regulatory Guides available, so it is useful to spend time considering the areas in which they can provide guidance.

Engaging the NRC as early in the design process as possible helps expedite the SAR; this is also true if problems are encountered, and speaking to the NRC during the review process assists greatly in ensuring your response will be satisfactory.

Within the manufacturing process, checks and hold points must be carefully considered where they are required and if they add value to the process. In some instances Croft introduced more checks than were required and this slowed the manufacturing process considerably.

CONCLUSIONS

Croft Associates successfully designed, tested, manufactured and gained NRC approval of the LS-SAFKEG, a 6M replacement design, in a timescale of 5 years which is relatively short. The timescale was aided by producing the SAR during the design process and carrying out testing on early prototypes. Productive interactions with the NRC during the early design stages, testing and SAR review helped to reduce the review time. The NRC audit of the Croft Quality System helped to Croft to simplify and therefore produce a more effective Quality System for the manufacture of the packages.

REFERENCES

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