



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

June 12, 2024

Robert Petre  
Quality Assurance Manager  
Croft Associates Limited  
Building F4, Culham Campus  
Abingdon  
OX14 3DB  
United Kingdom

SUBJECT: CROFT ASSOCIATES LIMITED – U.S. NUCLEAR REGULATORY  
COMMISSION INSPECTION REPORT NO. 71-0939/2024-201

Dear Robert Petre:

On April 29, 2024, through May 3, 2024, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an announced onsite inspection at the Oxford Engineering Limited (OEL) facility in Abingdon, England in the United Kingdom. Croft Associates Limited (Croft) has contracted with OEL to fabricate important to safety components of the 3979A (Safkeg-LS) transportation packaging.

The purpose of the inspection was to verify and assess the adequacy of Croft's implementation and compliance with the NRC requirements for the design, modification, fabrication, assembly, testing, and procurement of Safkeg-LS packaging components. Croft is the certificate of compliance (CoC) holder for the Safkeg-LS packaging.

The inspection scope included reviews of records and interviews with personnel to determine whether the transportation packagings, fabricated by an offsite entity, are fabricated in accordance with the commitments and requirements specified in the applicable safety analysis report for packaging, the NRC's corresponding safety evaluation report, Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71 and the CoC; and to determine whether fabrication and related quality activities are conducted in accordance with NRC approved quality assurance program requirements. The enclosed report presents the results of this inspection, which were discussed with you and other members of Croft and OEL staff on May 3, 2024.

Based on the results of this inspection, the NRC inspection team determined that two Severity Level IV violations of NRC requirements occurred. The NRC is treating these violations as Non-cited Violations (NCVs), consistent with Section 2.3.2 of the Enforcement Policy. The NRC inspection team described these NCVs in the subject inspection report.

If you contest these violations, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Director, Office of Nuclear Material Safety and Safeguards; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," a copy of this letter, its enclosure, and your response (if any) will be available electronically for public inspection in the NRC Public Document Room (PDR) or from the Publicly Available Records component of the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. The PDR is open by appointment. To make an appointment to visit the PDR, please send an email to [PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov) or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

Sincerely,



Signed by Rodriguez-Luccioni, Hector  
on 06/12/24

Hector Rodriguez-Luccioni, Chief  
Inspection and Oversight Branch  
Division of Fuel Management  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 71-0939

Enclosure:  
NRC Inspection Report No.  
71-0939/2024-201

SUBJECT: CROFT ASSOCIATES LIMITED – U.S. NUCLEAR REGULATORY  
COMMISSION INSPECTION REPORT NO. 71-0939/2024-201

DOCUMENT DATED: June 12, 2024

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**U.S. NUCLEAR REGULATORY COMMISSION  
Office of Nuclear Material Safety and Safeguards  
Division of Fuel Management**

Docket: 71-0939

Report.: 71-0939/2024-201

Enterprise Identifier: I-2024-201-0015

Certificate Holder: Croft Associates Limited

Facility: Oxford Engineering Limited

Location: Abingdon, England

Inspection Dates: April 29, 2024, through May 3, 2024

Inspection Team: Jeremy Tapp, Transportation and Storage Safety Inspector, Team Leader  
Marlone Davis, Senior Transportation and Storage Safety Inspector  
Raju Patel, Transportation and Storage Safety Inspector

Approved By: Hector Rodriguez-Luccioni, Branch Chief  
Inspection and Oversight Branch  
Division of Fuel Management  
Office of Nuclear Material Safety  
and Safeguards

Enclosure

**U.S. NUCLEAR REGULATORY COMMISSION  
Office of Nuclear Material Safety and Safeguards  
Division of Fuel Management**

**EXECUTIVE SUMMARY**

Croft Associates Limited  
NRC Inspection Report 71-0939/2024-201

On April 29, 2024, through May 3, 2024, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an announced onsite inspection at the Oxford Engineering Limited (OEL) facility in Abingdon, England in the United Kingdom. Croft Associates Limited (Croft) has contracted with OEL to fabricate important to safety (ITS) components of the 3979A (Safkeg-LS) transportation packaging.

The purpose of the inspection was to verify and assess the adequacy of Croft's implementation and compliance with the NRC requirements for the design, modification, fabrication, assembly, testing, and procurement of Safkeg-LS packaging components. Croft is the certificate of compliance (CoC) holder for the Safkeg-LS packaging.

**Quality Assurance Program**

- The team determined that Croft conducted quality related activities for their transportation packaging fabrication of the Safkeg-LS in accordance with their NRC approved quality assurance program (QAP). (section 1.1)

**10 CFR Part 21**

- The team determined that Croft required OEL meet the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 through the purchase order (PO) and that Croft and OEL personnel were familiar with the reporting requirements of 10 CFR Part 21. OEL also complied with the 10 CFR 21.6, "Posting requirements." (section 1.2)

**Design Control**

- The team concluded that Croft is effectively implementing its design control program and has adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements. (section 1.3)

**Fabrication, Maintenance, and Testing**

- The team determined, for the items selected for observation and review that Croft performed fabrication, maintenance, and testing in accordance with approved safety analysis report for packaging (SARP), written procedures, and specifications, as applicable. (section 1.4)

**Procurement**

- The team concluded that overall, Croft had adequate procurement controls. However, the team identified Croft's commercial-grade dedication (CGD) as an area of improvement as evidenced by the three examples where Croft failed to establish traceability and perform adequate CGD, including critical characteristic identification, to ensure the ITS category A

item will

perform its safety function. The team identified three examples of inadequate CGD as a violation of 10 CFR 71.107, "Package Design Control," and 10 CFR 71.115, "Control of Purchased Material, Equipment, and Services," requirements. (section 1.5)

### **Nonconformance and Corrective Action**

- The team determined that Croft and OEL effectively implemented their nonconformance and corrective action programs (CAPs) and has adequate procedures in place to ensure compliance with the applicable regulations and quality assurance (QA) requirements. (section 1.6)

### **Personnel Training and Quality Assurance Oversight**

- The team determined that Croft and OEL had trained and qualified individuals performing activities affecting quality and that Croft management provided appropriate oversight of quality related activities, as applicable. However, Croft failed to ensure a lead auditor that performed audit of OEL, an ITS category A supplier, was qualified in accordance with Croft procedure CAP 13-09. See section 1.8 of this report for details of the violation. (section 1.7)

### **Audit Program**

- The team concluded overall that for the items selected for review that Croft and OEL were performing oversight and audits in accordance with their QAP. However, the team identified Croft's audit program as an area for improvement as evidenced by the identification of one violation of 10 CFR 71.137, "Audits," for inadequate implementation of its audit procedure for performing external audits by an unqualified lead auditor. (section 1.8)

## REPORT DETAILS

### 1.0 **Applicable portions of Inspection Procedure 86001 – Design, Fabrication, Testing, and Maintenance of Transportation Packagings**

#### 1.1 **Quality Assurance Program**

##### 1.1.1 Inspection Scope

The team reviewed Croft's and OEL's quality management system (QMS) and associated implementing processes and procedures to verify how Croft and OEL implemented their QAPs for the fabrication activities associated with transportation packaging of the Safkeg-LS. Specifically, the team focused on how Croft implemented their NRC approved QAP at OEL. The team reviewed Croft's Quality Assurance Report (QAR) 144, "Quality Assurance Program Description Manual for 10 CFR Part 71, Subpart H," issue E, implementing procedures, work instructions, and quality assurance guidelines (QAG) developed to comply with specific NRC requirements and guidance activities subject to 10 CFR Parts 71 and 21 requirements. This included a review of Croft's and OEL's QMSs and implementing documentation to verify if Croft and OEL clearly defined and documented the quality program authorities and responsibilities and that the QA organizations functioned as independent groups.

The team also reviewed Croft's QAG for the use of a graded approach for identifying ITS components and whether Croft applied this graded quality level to documents provided to OEL for the fabrication of the Safkeg-LS.

##### 1.1.2 Observation and Findings

The team assessed that Croft and OEL have adequate QAPs in place that included applicable implementing processes and procedures to conduct effective quality activities in accordance with the SARP for the Safkeg-LS, and 10 CFR Parts 21 and 71 requirements. The team verified that Croft and OEL clearly defined and documented the QAP authorities and responsibilities and that both quality assurance organizations functioned as independent groups as described in their QAPs. The team also found that Croft used a graded approach to categorize ITS components in its transportation packaging for the Safkeg-LS.

No findings of significance were identified.

##### 1.1.3 Conclusions

The team determined that Croft conducted quality related activities for transportation packaging fabrication of the Safkeg-LS in accordance with their NRC approved QAP.

## **1.2 10 CFR Part 21**

### **1.2.1 Inspection Scope**

The team verified that provisions are in place for reporting defects which could cause a substantial safety hazard, as required by 10 CFR Part 21. Croft imposed the requirements of 10 CFR Part 21 within their purchase order to OEL. The team reviewed OEL procedure CP/116, "Reporting of Defects and Noncompliance in Accordance with 10 CFR Part 21," issue 1 to verify that OEL had provisions in place for reporting defects that could cause a substantial safety hazard and whether OEL would complete the required evaluation and notification in a timely manner. The team requested a list of 10 CFR Part 21 evaluations and notifications associated with the fabrication activities and interviewed personnel to verify if OEL was familiar with the implementing procedure. The team also verified if OEL complied with 10 CFR 21.6, "Posting requirements."

### **1.2.2 Observation and Findings**

The team assessed that OEL has provisions in place for evaluating deviations and reporting defects that could cause a substantial safety hazard, as required by 10 CFR Part 21. There was no closed or open Part 21 reports related to the Croft Safkeg-LS work. The team also noted that the 10 CFR Part 21 posting at OEL fabrication shop and office met the applicable requirements of 10 CFR Part 21.

No findings of significance were identified.

### **1.2.3 Conclusions**

The team determined that OEL implemented the provisions of 10 CFR Part 21 and that OEL's personnel were familiar with the reporting requirements and complied with 10 CFR 21.6, "Posting requirements."

## **1.3 Design Control**

### **1.3.1 Inspection Scope**

The team reviewed selected design documentation to determine that adequate design controls are implemented. Specifically, the team reviewed Safkeg-LS packaging licensing drawings against the fabrication drawings and specifications to verify consistency of critical parameters and material specifications. Specifically, the team focused on design commitments and requirements for ITS components from the Safkeg-LS packaging SARP to fabrication drawings. The team reviewed Croft's QAR 144, procedural guidance, and the implementation process for commercial-grade item dedication activities. Specifically, the team reviewed the implementing procedures, commercial-grade surveys, receipt inspections, visual and dimensional inspection reports that govern Croft's implementation of CGD activities.

Within the scope of this area of the inspection, the team reviewed the following procedures and records:

- CAP 05-14, "Graded Approach to Quality," issue F



- CAP 02-03, "Project Control," issue M
- CAP 02-04, "Project Specifications," issue E
- CAP 02-05, "Project Plan," issue D
- CAP 03-02, "Design Review," issue K
- CAP 03-03, "Design Control," issue J
- CAP05-18, "Commercial Grade Dedication," issue F
- OEL CP25, "Compilation and Control of OE Drawings"
- Manufacturing Specification (MSP) 155, "Manufacturing Specification LS Safkeg Packaging Assembly Design No. 3979A," issue F
- Drawing No. 0C-6041, "SAFKEG LS Design No. 3979A (Licensing Drawing)," issue C
- Drawing No. 0C-6042, "Keg Design No. 3979 (Licensing Drawing)," issue F
- 1C-6041, "Safkeg LS Design No. 3979A," issue C
- 1C-6044, "Containment Vessel Design No. 3980, (Licensing Drawing)," issue F
- 1C- 6045, "Containment Vessel Lid," issue E
- 1C-6046, "Containment Vessel Body," issue E

The team selected components classified as ITS category B and C to determine if the component was classified in accordance with the guidance in NUREG/CR-6407 and the justification provided for the quality classification was appropriate. The team reviewed OEL's control of design requirements passed down by Croft into OEL's drawings and works orders (WOs) for ITS category A and B items.

### 1.3.2 Observation and Findings

No findings of significance were identified.

### 1.3.3 Conclusions

The team concluded that Croft is effectively implementing its design control program and has adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements.

## 1.4 **Fabrication, Maintenance, and Testing**

### 1.4.1 Inspection Scope

The 3979A (Safkeg-LS) Type B package, CoC No. 71-9337, revision 5, has been developed for the transport of radioisotopes used in a wide range of therapeutic and diagnostic applications and research. The packaging consists of an outer stainless-steel keg and an inner containment vessel (CV) surrounded by insulating cork packing. Containment is provided by the inner CV, and shielding is provided by the inner CV and shielding insert.

The team observed drawings, procedures, and records, and observed selected activities related to the inner CV and outer keg to determine if fabrication, assembly, and testing activities met SARP, revision 8, dated November 2021, design commitments and requirements documented in CoC 71-9337.

The team interviewed selected personnel and reviewed the fabrication specification, drawings, and works orders (travelers) to determine whether Croft and OEL implemented adequate instructions, requirements, and testing and acceptance criteria controls. The team reviewed the following documents:

- MSP 155, "Manufacturing Specification LS Safkeg Packaging Assembly Design No 3979A," issue F
- MSP 156, "Manufacturing Specification LS Keg Assembly Design No 3979," issue F
- MSP 154, "Manufacturing Specification LS Containment Vessel Design No 3980," issue G
- WO 21165755 for CV body shell
- WO 21164344, issue E, for CV outer wall
- WO 21164343, issue F, for CV flange/cavity wall
- WO 21165758, issue F, for CV body shell welded
- WO 21165684 for keg body assembly
- Drawing No. 1C-6059, "CV Body Shell Machined," issue F
- Drawing No. 0C-6002, "Keg Body Assembly," issue E

Specifically, the team observed activities such as welding, assembly, and nondestructive testing (NDT) of the inner CV and outer keg to verify that OEL performed these tasks in accordance with approved methods, procedures, and specifications. The team reviewed the fabrication process through observations, examinations of records, and personnel interviews in the areas of fabrication, assembly, inspection, and testing, along with control of measuring and test equipment (M&TE). The team reviewed and observed the following shop activities:

- Gas tungsten arc welding (GTAW) of keg outer shell to bottom and top skirts (weld joints 3, 4, 5, 8, 9, and 14)
- Machining of the inner CV body assembly to fabrication drawing specifications
- Mass spectrometer leak testing of inner CV base material with helium
- Dimensional inspection of inner CV lid using coordinate measuring machine (CMM)
- Dye penetrant testing (PT) report review of inner CV body shell

The team also reviewed the control of M&TE program to evaluate how OEL identified, specified, and controlled tools and equipment in accordance with their standard procedures. The team selected a sample of the M&TE used during the assembly and testing of the inner CV. The sample included a review of WOs that identified the use of specific M&TE that the team selected such as a screw plug gauge, digital depth gauge, digital caliper, optical projector, welding machines, thermocouple, helium reference leak, and vacuum pressure gauge. The team reviewed the calibration records to verify calibration dates, testing standards, and traceability of the associated M&TE. The team verified that personnel used M&TE within their rated capacities and sensitivities as documented in calibration records. The team also reviewed the purity of the helium used to perform mass spectrometer leak testing to determine if it met procedure requirements.

The team reviewed the following documents and records specific to welding, testing, NDT, and M&TE:

- Welding Procedure Specification (WPS) 005 for manual GTAW
- Welder Performance Qualification welder identification/stamp number 802, GTAW
- Welding Procedure Approval Certification for WPS 005
- Welder Approval Test Certificate, BES/NDT 00543236/OE for WPS 005/002/001
- NDT and nondestructive examination reports:
  - PT report no. OE1184, dated February 19, 2024
  - PT report no. OE1200, dated March 11, 2024
  - Visual testing (VT) report no. OE1183, dated February 19, 2024
  - VT report no. OE1199, dated March 11, 2024
  - Quality assurance inspection reports from WO 21165758 for CV body shell welded, dated March 12, 2024
- M&TE:
  - Screw plug gauge, ID no. SP-040, calibration dated June 13, 2023
  - Digital depth gauge, ID no. OE-1330, calibration dated March 13, 2024
  - Optical projector, ID no. OE663, calibration dated May 30, 2023
  - Digital caliper, ID no. OE-1818, calibration dated March 13, 2024
  - CMM reference ball, ID no. OE-1884, calibration dated August 2, 2021
  - Welding machine, ID no. OE 1167, calibration dated July 20, 2023
  - CMM, ID no. OE-1879, calibration dated February 8, 2024
- OE procedures:
  - CP/06, “Raw Material and Issue Procedure,” issue 1, dated August 2021
  - C/P09, “Production Control Procedure,” issue 1, dated August 2021
  - C/P12, “Identification & Traceability Procedure,” issue 1, dated August 2021
  - C/P11, “Customer Supplied Material Procedure,” issue D, revision 1, dated November 2019
  - CP/14, “Handling, Storage, Packing, & Delivery Procedure,” issue 2, dated November 2023
  - CP/23, “Welding Control Procedure,” issue 1, dated August 2021
  - C/P110, “Dye Penetrant Testing Procedure in accordance with ASME Article 6: 2013,” issue 1, dated May 2014
  - PM/06, “Calibration Procedure,” issue 6, dated November 2012
  - CSD/420, “Personal Stamp Declaration”
  - SNT WP001, “Written Practice for the Control and Administration of NDT Personnel, Training, Examination and Certification,” dated April 7, 2022
- Croft procedure MSLT–CV3980-CHT, “Helium Mass Spectrometer Leak Test Procedure Hood Technique,” dated April 17, 2024
- Croft goods received checklist no. 3463 for helium cylinder, dated August 15, 2022

#### 1.4.2 Observation and Findings

The team assessed that OEL established appropriate means to control Safkeg-LS fabrication activities and special processes for those activities observed. The team noted that OEL implemented their QAR 144, quality procedures, and special processes with qualified personnel, using approved procedures for assembly, welding, and testing. The team determined that OEL provided the appropriate information on WOs in accordance with approved procedures, and the WOs identified applicable drawings, operations, and procedures applicable to the manufacturing activity.

The team observed keg outer shell welds were made in accordance with the applicable drawings using qualified procedures and qualified welding personnel and that inner CV

welds were inspected by qualified personnel in accordance with the applicable drawing requirements. The team noted that inspection and test results were documented in applicable WOs in accordance with quality procedures and that test results and inspection reports were traceable to the applicable inner CV unit serial number.

The team also observed machining of inner CV components and noted it was performed using the applicable drawing information to program the machine to meet the component dimensional requirements. The team noted that the machine operator was well versed in its operation and knowledgeable of the process to ensure a quality product. Lastly, the team observed helium mass spectrometer leak testing was performed in accordance with the approved procedure using the approved test setup with appropriately trained personnel or trainees under direct supervision by trained personnel.

The team assessed that OEL established controls with M&TE in accordance with their quality standard procedure requirements, industry standards and regulatory requirements.

No findings of significance were identified.

#### 1.4.3 Conclusions

The team determined, for the items selected for observation and review that the Croft and OEL performed fabrication, maintenance, and testing in accordance with the approved SARP, written procedures, and specifications, as applicable.

### 1.5 **Procurement**

#### 1.5.1 Inspection Scope

The team reviewed processes and procedures that addressed procurement, including receipt inspection, traceability of material, and CGD, as applicable. The team reviewed selected drawings and records and interviewed personnel to verify that procurement specifications for materials, fabrication, and inspection met design commitments and requirements contained in the SARP and CoC. The team reviewed Croft implementing procedures, receipt inspection records, POs, and sampled CGD packages.

- CAP 05-18, "Commercial-Grade Dedication," issue F
- CAP 06-01, "Purchasing," issue Q
- OEL CP10, "Purchasing Procedure," issue 1
- OEL CP104, "Management of Contractors"

The procedures were reviewed to verify if they were being properly implemented. The team also reviewed Croft's current Approved Suppliers List (ASL), to determine if materials and services were being procured from qualified suppliers and the suppliers were being acceptably qualified.

The team selected a sample of ITS category A materials for review. Croft does not procure materials from any suppliers designated as ITS category A so for those materials required to be ITS category A, CGD is performed. Therefore, the team

selected a sample of inner and outer O-rings to review the adequacy of the CGD package and conformance to the requirements of CAP 05-18, and interviewed key personnel involved in dedication activities.

### 1.5.2 Observation and Findings

The team reviewed the documentation associated with inner and outer O-rings, dedicated and supplied to OEL as ITS category A items, part number IC-6050-G items 7 and 8, to verify compliance with the program requirements adequate implementation of design requirements. The team focused on the adequacy of the critical characteristics identified and the traceability of the O-rings and sample buttons through the procurement, receipt inspection, manufacturing, testing and inspection process. The team reviewed QF 315, "Critical Characteristics Identification for CGD," for the O-rings, prepared by engineering and approved by the Quality Assurance Manager. This form lists different critical characteristics with acceptance criteria to be verified using source documents and reason for criticality defined.

1. Croft had procured O-rings from Southern Rubber Co. Inc. (Southern Rubber), a commercial distributor of Parker Hannifin, an original equipment manufacturer. The PO placed on Southern Rubber invoked technical and quality requirements including batch number traceability of parts and sample buttons. During receipt inspection, Croft failed to 1) verify and document the O-rings batch number and 2) verify the five test button samples received were marked with identification and batch number on goods receipt checklist no. 3289, revision 1.

Further, Croft placed PO 13148id, and Advice Note No. AN4426 to Ceetak Sealing Solutions (Ceetak) to perform 100 percent visual and dimensional inspection of the O-rings but did not invoke the part numbers and the traceability batch number as critical characteristics but relied on Ceetak's certificate of compliance and inspection reports as a means of acceptance of the results. Further, Croft placed PO 13147id to Rubber Consultants along with critical characteristics identification for CGD to verify critical characteristics that included but was not limited to material verification test, compression set test, heat-resistant test, minimum tensile test, low temperature property test, and material hardness test, but did not invoke the O-rings traceability batch number nor any traceability of the five test button samples. Croft did not verify Rubber Consultants technical report RC30438 referenced the O-rings part numbers or batch number but accepted the test report as an acceptable process.

The team identified this issue as more than minor safety significance because Croft could not re-establish material traceability.

2. Croft's procedure CAP 05-18 addresses the process of supplier commercial-grade assessment. A survey form QF 317, "Supplier Survey-CGD," is prepared prior to the assessment to identify the critical and supplier program controls to be verified during the surveillance. This form identifies the specific dimensions or the critical characteristics to be verified.

The team reviewed QF 316, "Supplier Surveillance Report," that documents Croft approved Southern Rubber and Ceetak based on International Organization for Standardization (ISO) 9001:2015 certificate and listed them as ITS category B

suppliers on the ASL. Rubber Consultants was approved based on ISO 9001:2015 certification and United Kingdom Accreditation Service schedule of accreditation to ISO/IEC 17025:2005 and listed them on the ASL as an ITS category B supplier.

Upon review of the CGD record, the team noted that Croft had neither performed a commercial-grade survey, nor source surveillance to assess Southern Rubber controls over quality assurance activities to verify critical characteristics such as material identification, traceability, handling and proper storage conditions were adequately implemented and maintained. Croft relied on Southern Rubber's ISO 9001:2015 certificate as an approval process and did not verify the certificate of conformance/compliance specified the O-rings traceability batch number as a critical characteristic.

Further, Croft had not performed commercial-grade survey or source surveillance of Ceetak to assess quality assurance activities to verify critical characteristics such as material identification and traceability, handling and storage, M&TE calibration, control of commercial calibration service provider and personnel training are adequate and effectively maintained during visual and dimensional inspection of the O-rings. Croft relied on Ceetak's ISO 9001:2015 certification as a basis of approval and acceptance of the certificate of compliance and visual and dimensional inspection report using M&TE calibrated by a commercial calibration service provider.

In addition, Croft accepted test results from Rubber Consultants, an approved ISO/IEC 17025 accredited calibration and testing laboratory for material verification and testing without establishing and documenting in Croft's QAP and procedures a methodology for the use of accreditation by an International Laboratory Accreditation Cooperation/Mutual Recognition Arrangement signatory. Croft's PO to Rubber Consultants did not invoke the requirements for ISO/IEC 17025:2015.

This team identified this issue as more than minor safety significance because no dedication has been performed to ensure critical characteristics were identified and verified to ensure the ITS category A items will perform their safety function.

3. The team performed walkdown of OEL's manufacturing process and selected a sample of M&TE used during inspection and testing activities on ITS category A items to assess OEL's control of approved suppliers under its QAP. Specifically, the team reviewed calibration records of a CMM calibrated by Hexagon Metrology, digital light meter calibrated by RS Components and MP Calibration Services for mechanical M&TE and requested OEL for the supplier audit records. The team noted that OEL approved and placed all the calibration services providers on its ASL, through third-part certification with ISO 9001 certification and did not invoke technical and quality requirements on these suppliers but placed blanket POs.

The team determined that Croft failed to ensure OEL performed CGD of its commercial-grade calibration service providers as part of acceptance of calibration services for use of M&TE in inspection and testing of ITS category A items. In addition, Croft failed to ensure OEL has established adequate technical and quality requirements to include on its PO to flow down to commercial calibration service suppliers as part of CGD.

This team identified this issue as more than minor safety significance because no dedication has been performed to ensure critical characteristics were identified and verified to ensure the ITS category A services include the necessary quality for the ITS category A items to perform their safety function.

The team assessed these three examples constituted a violation of NRC requirements. The team determined that a violation of 10 CFR 71.107, "Package Design Control," and 10 CFR 71.115, "Control of Purchased Material, Equipment, and Services," occurred in that Croft failed to: (1) re-establish traceability of ITS category A item as part of dedication; (2) perform commercial-grade dedication to ensure critical characteristics were identified and verified to ensure the ITS category A item will perform its safety function; and (3) ensure OEL, an ITS category A contractor, established and invoked technical and quality assurance requirements in its POs and performed CGD to ensure critical characteristics of ITS category A services were being identified and verified such that the applicable ITS category A items will perform their safety function.

As required by 10 CFR 71.107 it states, in part that "Measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions for the structures, systems and components."

As required by 10 CFR 71.115 it states, in part that "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery."

Contrary to the above, as of May 3, 2024,

1. Croft failed to ensure that: a) the traceability of the five test coupons received with O-rings procured from distributor Southern Rubber, was traceable to the same batch and lot number as the associated O-rings; b) the POs invoked the O-ring part number and batch number to Ceetak, a visual and dimensional inspection service supplier, as well as to Rubber Consultants, a commercial testing service provider; and c) the certificate of conformance from the subcontractors adequately reflected the O-rings part number and batch number traceability. Croft documented this issue as CAR 239.
2. Croft failed to verify the validity of the certificates of compliance provided by a commercial distributor, subcontractor, and commercial test service provider by performing a commercial-grade survey, source surveillance, or other acceptable methods, as necessary for ensuring the critical characteristics of O-rings used for performing the sealing function for the Safkeg-LS and supplied to Croft for either part of original Safkeg-LS fabrication or sold as replacement parts. Croft documented this issue as CAR 240.
3. Croft failed to ensure OEL established and invoked applicable technical and quality requirements in their POs to commercial calibration service suppliers which include

RS Component Ltd., Hexagon Metrology, and MP Calibration Services that performed calibration of M&TE that were used for inspection and testing of ITS category A components. Specifically, Croft did not ensure OEL performed CGD of its applicable commercial calibration services. Croft documented this issue as CAR 246.

The team dispositioned the violation using the traditional enforcement process in section 2.3 of the NRC Enforcement Policy (ADAMS Accession No. ML23333A447). The team determined that the violation was of more than minor safety significance in accordance with Inspection Manual Chapter (IMC) 0617, "Vendor and Quality Assurance Implementation Inspection Reports," appendix E, "Minor Examples of Vendor and QA Implementation Findings." The team utilized example 9.a as the traceability could not be established and example 19.b as no dedication has been performed to ensure critical characteristics were identified and verified to ensure the ITS category A item will perform its safety function. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, section 6.8. Croft entered these issues in its CAP under CARs 239, 240 and 246. Because this violation was of low safety significance, was entered into Croft's CAP, and the issue was not repetitive or willful, this violation was treated as a non-cited violation (NCV), consistent with Section 2.3.2.a of the NRC Enforcement Policy. **(71-0939/2024-201-01)**

### 1.5.3 Conclusions

The team concluded that overall, Croft had adequate procurement controls. However, the team identified Croft's CGD as an area of improvement as evidenced by the three examples where Croft failed to establish traceability and perform adequate CGD, including critical characteristic identification, to ensure the ITS category A item will perform its safety function. The team identified three examples of inadequate CGD as a violation of 10 CFR 71.107 and 10 CFR 71.115 requirements.

## 1.6 **Nonconformance and Corrective Actions**

### 1.6.1 Inspection Scope

The team reviewed selected records and interviewed selected personnel to verify that Croft and OEL implemented their nonconformance and corrective action programs for identified deficiencies in materials, parts, and components that did not conform to requirements, and that for those deficiencies, Croft and OEL resolved and completed disposition of those items in a technically sound and timely manner. The team reviewed the following implementing procedures for Croft and OEL nonconformance and corrective action programs:

- CAP 05-06, "Product Non-conformance Control," issue Q
- CAP 05-17, "Conditions Adverse to Quality - NRC," issue E
- CAP 12-03, "QMS Corrective Action," issue O
- PM/02, "Control of Nonconforming Items," issue 18
- PM/11, "Review of Supplier Nonconformances," issue 5
- CP/34, "Control of Fabrication of Nonconforming Items," issue 3
- CP/35, "Corrective Action," issue 7
- C/P 114, "Preventive Action Procedure," issue 2



The team reviewed Croft and OEL nonconformance programs to assess the effectiveness of controls established for the processing of nonconforming materials, parts, and components. The team reviewed a sample of five nonconformance reports (NCRs) for the Safkeg-LS packages since fabrication began. The review focused on NCRs that were dispositioned as "Use-As-Is" and "Repair," to determine if Croft and OEL had justified their dispositions of the NCRs adequately. However, with the limited number of NCRs identified and completed for the fabrication activities, the team reviewed all the NCRs generated for the project.

The team also reviewed all the CARs and a sample of corrective action notes generated since the start of the fabrication activities at OEL, including previous CARs from the last inspection at OEL.

#### 1.6.2 Observation and Findings

Overall, the team assessed that Croft and OEL had adequate nonconformance and corrective action controls in place to identify, track, and resolve ITS related deficiencies and deviations. The team noted from the nonconformances, and corrective actions reviewed that overall, Croft and OEL appropriately dispositioned and resolved these deficiencies and deviations in a timely manner and in accordance with their implementing procedures.

No findings of significance were identified.

#### 1.6.3 Conclusions

The team determined that Croft and OEL effectively implemented their nonconformance program and CAP and has adequate procedures in place to ensure compliance with the applicable regulations and QA requirements.

### 1.7 **Personnel Training and Quality Assurance Oversight**

#### 1.7.1 Inspection Scope

The team reviewed selected records and procedures, and interviewed selected personnel to verify that individuals performing activities affecting quality are properly trained and qualified, and to verify that management and QA staff are cognizant and provide appropriate oversight.

Specifically, the team reviewed training and qualification records for selected OEL employees that have performed NDT and welding activities to verify the personnel qualifications were adequate and current. The review also included lead auditors' certifications and qualifications.

#### 1.7.2 Observation and Findings

The team noted NDT personnel performing visual weld and PT examinations were qualified in accordance with OEL's quality procedures. In addition, the team noted that

welding personnel were qualified per American Society of Mechanical Engineers (ASME), Boiler and Pressure Vessel Code, Section IX, as required by the SARP.

Upon review of Croft's QA manager lead auditor qualification records, the team was provided with only a copy of his ASME Nuclear Quality Assurance (NQA)-1 lead auditor training certification. Croft did not furnish form QF 367 as objective evidence of approved certification as a competent, trained, and qualified lead auditor per section 3.2, "Certification," of Croft's CAP 13-09, "NQA-1 Lead Auditor Qualification," issue A. The team identified that the QA manager had not completed all requisite audits to be qualified as a lead auditor under CAP 13-09. The team determined this issue was a violation of NRC requirements and is documented in detail in section 1.8 of this report.

### 1.7.3 Conclusions

The team determined that Croft and OEL had trained and qualified individuals performing activities affecting quality and that Croft management provided appropriate oversight of quality related activities, as applicable. However, Croft failed to ensure a lead auditor that performed audit of OEL, an ITS category A supplier was qualified in accordance with Croft procedure CAP 13-09. See section 1.8 of this report for details of the violation.

## 1.8 **Audit Program**

### 1.8.1 Inspection Scope

The team reviewed the audit programs to verify that Croft and OEL scheduled, planned, and performed audits in accordance with their QAPs and associated implementing procedures. The team reviewed the audit results to determine if Croft and OEL identified deficiencies and addressed these deficiencies within their CAP.

The team selected a sample of internal and external audits and interviewed personnel to verify that Croft and OEL effectively implemented their audit program from 2022 to the present. The team reviewed a sample of internal and lead auditors' certifications and qualifications to conduct audits in accordance with approved procedures. In addition, the team reviewed the last two management reviews of Croft's QAP to determine whether Croft management performed the reviews as required and if the reviews were an effective tool to use for the overall health of the program. The team also reviewed external audits for suppliers of ITS materials, equipment, and services.

- QAR 144, Section 71.137, "Audits," issue E
- CAP 06-08, "Approved Supplier – NRC," issue G
- CAP 12-01, "Audit Procedure," issue X
- CAP 13-09, "NQA-1 Lead Auditor Qualification," issue A
- CAP 06-08, "Approved Supplier – NRC," issue G
- QAG009, "Categorization for Quality Categories," issue J
- QAG007, "US Quality Source Surveillance"
- QAF317, "Supplier Survey – NRC"

### 1.8.2 Observation and Findings

Overall, the team assessed that for the audits sampled of Croft and OEL generally conducted audits with qualified and certified personnel, scheduled and evaluated applicable elements of their QAPs. The team noted that Croft and OEL identified observations and findings as applicable within the audits and documented issues identified in accordance with the approved quality procedures. Additionally, the team noted that Croft and OEL addressed the observations and findings identified within their CAP.

The team reviewed Croft's QA manager's lead auditor qualifications records, however, only a copy of the QA manager's ASME NQA-1 lead auditor training certification was provided. Croft did not furnish form QF 367 as objective evidence of approved certification record documenting the QA manager to be competent, trained and qualified lead auditor per Section 3.2, "Certification," of Croft's CAP 13-09, "NQA-1 Lead Auditor Qualification," issue A. The team identified that the QA manager had not completed all requisite audits to be qualified as a lead auditor under CAP 13-09. Specifically, a nuclear QA audit had not been performed within the last 12 months. Subsequently, the QA manager performed an external audit of OEL as the lead auditor in April 2024.

Croft procedure CAP 12-01, "Audit Procedure," Issue X, Section 2, "Responsibilities," states that auditor competency shall be determined by completion of a recognized lead auditor training course and recent evidence of carrying out auditing activities, within the previous 12 months for supplier approval audits. Further, Croft procedure CAP 13-09, "NQA-1 Lead Auditor Qualification," Issue A, Section 2, "Purpose," states, in part that any person required to carry out internal and supplier audits in accordance with the requirements of 10 CFR 71 Subpart H, are required to be carried out by an experienced competent and qualified lead auditor.

The team determined that a violation of 10 CFR 71.137, "Audits," occurred in that Croft did not ensure that a triennial audit of an ITS category A supplier be performed by a trained and qualified lead auditor, the result of which is an audit of indeterminate quality. 10 CFR 71.137 states, in part that licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow up action, including reaudit of deficient areas, must be taken where indicated.

Contrary to the above, as of May 3, 2024, Croft failed to ensure triennial audit of an ITS category A supplier be performed by a trained and qualified lead auditor, the result of the audit affecting the qualification of the supplier is of indeterminate quality.

The team dispositioned the violation using traditional enforcement process in section 2.3 of the NRC Enforcement Policy. The team determined that the violation was of more than minor safety significance as the lead auditor had not completed all required qualification requirements at the time of the audit and the audit quality is indeterminate. The team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, section 6.5. Croft entered the issue into its CAP under CAR 241. Because this violation was of low safety significance, was entered into Croft's

CAP, and the issue was not repetitive or willful, this violation was treated as an NCV, consistent with section 2.3.2.a of the NRC Enforcement Policy. (71-0939/2024-201-02)

### 1.8.3 Conclusions

The team concluded overall that for the items selected for review that Croft and OEL were performing oversight and audits in accordance with their QAP. However, the team identified Croft's audit program as an area for improvement as evidenced by the identification of one violation of NRC requirements for inadequate implementation of its audit procedure for performing external audits by an unqualified lead auditor.

## 2.0 **Entrance and Exit Meeting**

On April 29, 2024, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Croft and OEL staff. On May 3, 2024, the NRC inspection team discussed the results of the inspection during an exit meeting with Croft and OEL staff. Section 1 of the attachment to this report shows the attendance for the entrance and exit meetings.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES AND INDIVIDUALS INTERVIEWED

Name	Title	Affiliation	Entrance	Exit
Jeremy Tapp	Inspection Team Leader	NRC	X	X
Marlone Davis	Inspector	NRC	X	X
Raju Patel	Inspector	NRC	X	X
Trevor Tait	Operations Director	Croft	X	X
Robert Petre	QA Manager	Croft	X	X
Ian Dingwall	Manufacturing Manager	Croft	X	X
Mark Cracknell	Project Engineer	Croft	X	
Anna Bazylakova	Project Engineer	Croft	X	
Karim Sekkat	Chairman	OEL	X	X
Lesley Hindmarch	Operations Director	OEL	X	X
Mark Vallis	Quality Manager	OEL	X	X
James Langdon	Quality Specialist	OEL	X	X

2. INSPECTION PROCEDURES USED

IP 86001	Design, Fabrication, Testing, and Maintenance of Transportation Packagings
NUREG/CR-6407	Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety
NUREG/CR-6314	Quality Assurance Inspections for Shipping and Storage Containers

3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
71-0939/2024-201-01	Opened & Closed	NCV	Failure to establish traceability and perform adequate CGD
71-0939/2024-201-02	Opened & Closed	NCV	Failure to perform audit with qualified lead auditor

4. LIST OF ACRONYMS USED

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
ASL	Approved Suppliers List
ASME	American Society of Mechanical Engineers
CAP	Corrective Action Program
CAR	Corrective Action Report
Ceetak	Ceetak Sealing Solutions
CGD	Commercial-Grade Dedication
CMM	Coordinate Measuring Machine
CoC	Certificate of Compliance
Croft	Croft Associates Limited

CV	Containment Vessel
GTAW	Gas Tungsten Arc Welding
IMC	Inspection Manual Chapter
IP	Inspection Procedure
ISO	International Organization for Standardization
ITS	Important to Safety
M&TE	Measuring and Test Equipment
NCR	Nonconformance Report
NCV	Non-cited violation
NDT	Nondestructive Testing
NQA	Nuclear Quality Assurance
NRC	U.S. Nuclear Regulatory Commission
OEL	Oxford Engineering Limited
PDR	Public Document Room
PO	Purchase Order
PT	Dye Penetrant Testing
QA	Quality Assurance
QAG	Quality Assurance Guidelines
QAP	Quality Assurance Program
QMS	Quality Management System
QAR	Quality Assurance Report
SARP	Safety Analysis Report for Packaging
Southern Rubber	Southern Rubber Co. Inc.
VT	Visual Testing
WO	Works Order
WPQ	Welder Performance Qualification
WPS	Welding Procedure Specification

## 5. DOCUMENTS REVIEWED

Certificate holder documents reviewed during the inspection were specifically identified in the Report Details above.

## 6. CORRECTIVE ACTION REPORTS OPENED AS A RESULT OF THE INSPECTION

- CAR 239, "Coupons traceability issue," dated May 7, 2024
- CAR 240, "CGD control on sub-suppliers," dated May 7, 2024
- CAR 241, "Unqualified Lead Auditor," dated May 7, 2024
- CAR 242, "Supplier audit beyond 3-year period," dated May 7, 2024
- CAR 243, "Cat "A" Annual Supplier assessments," dated May 8, 2024
- CAR 244, "Suppliers Audit period specification," dated May 8, 2024
- CAR 245, "NQA Requirements not captured in Audit Procedure," dated May 8, 2024
- CAR 246, "Requirements for external providers," dated May 8, 2024