



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

November 9, 2022

Stephen Ralls  
Quality Manager  
Croft Associates Limited  
Building F4, Culham Science Center  
Culham, Abingdon  
Oxfordshire, OX14 3DB, England, UK

SUBJECT: CROFT ASSOCIATES LIMITED - NRC INSPECTION REPORT  
NO. 71-0939/2022-201 AND NOTICE OF VIOLATION

Dear Stephen Ralls:

This letter refers to the inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on July 18 to 21, 2022, at the Croft Associates Limited (Croft) facility in Oxfordshire, England in the United Kingdom. The inspection team continued the inspection activities with an in-office review and held an exit meeting on September 26, 2022, with you and other members of your staff.

The purpose of the inspection was to verify and assess the adequacy of Croft's activities associated with the transportation of radioactive material and determine if they were performed in accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," and Croft's NRC approved Certificate of Compliance (CoC) and Quality Assurance Program (QAP). The inspection scope included management, design, fabrication interaction, and maintenance controls. The enclosed report presents the results of this inspection.

The inspection examined activities conducted under your NRC approved QAP as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of the applicable CoCs. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.


Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Website at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). One of the violations is non-cited while the second violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding both violations are described in detail in the subject inspection report. The one violation is being cited in the Notice because the violation was repetitive as a result of inadequate corrective action and was identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

Sincerely,

**Aida E. Rivera-  
Varona**

 Digitally signed by Aida E.  
Rivera-Varona  
Date: 2022.11.09 10:09:47 -05'00'

Aida E Rivera-Varona, Chief  
Inspection and Oversight Branch  
Division of Fuel Management  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 71-0939

Enclosure: 1. Inspection Report No. 71-0939/2022-201  
2. Notice of Violation

Subject: CROFT ASSOCIATES LIMITED - NRC INSPECTION REPORT  
NO. 71-0939/2022-201 AND NOTICE OF VIOLATION

DOCUMENT DATE: November 9, 2022

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| <b>DATE:</b> | 10/31/2022      | 11/1/2022       | 11/9/2022       |

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

**Inspection Report**

Docket No.: 71-0939

Report No.: 71-0939/2022-201

Certificate Holder: Croft Associates Limited  
Building F4, Culham Science Center  
Culham, Abingdon  
Oxfordshire, OX14 3DB, England, UK

Inspection Dates: July 18 – September 26, 2022

Inspectors: Jon Woodfield, Transportation and Storage Safety Inspector, Team  
Leader  
Jeremy Tapp, Transportation and Storage Safety Inspector  
Matthew Learn, Transportation and Storage Safety Inspector

Approved by: Aida E. Rivera-Varona, Chief  
Inspection and Oversight Branch  
Division of Fuel Management  
Office of Nuclear Material Safety  
and Safeguards

## EXECUTIVE SUMMARY

### **Croft Associates Limited NRC Inspection Report 71-0939/2022-201**

This routine inspection from July 18 to September 26, 2022, evaluated the on-going activities at Croft Associates Limited's (Croft) corporate facility in Oxfordshire, England, UK related to the design of transportation packages for radioactive material. The purpose of the inspection was to verify and assess the adequacy of Croft's activities associated with the transportation of radioactive material to determine if they were performed in accordance with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," and Croft's NRC approved Certificate of Compliance (CoC) and Quality Assurance Program (QAP). The inspection scope included management, design, fabrication interface, and maintenance controls. The results of the inspection are as follows:

#### Management Controls

The team determined that the QA controls at Croft were generally adequate. Regarding the overall QA policy, the team concluded that Croft conducts its activities associated with QA organization independence and QA responsibilities in accordance with their NRC approved QAP. (Section 1.1)

The team concluded that Croft has an adequate nonconformance control program in place to ensure compliance with the applicable regulations and quality assurance program requirements. (Section 1.2)

The team identified Croft's corrective action program (CAP) as an area for improvement as evidenced by the issue identified and described in this report. The team identified one Severity Level IV violation of 10 CFR 71.133, "Corrective action" for Croft's failure to take adequate corrective actions for three issues identified during two previous NRC inspections. Also, a fourth issue was identified during the current inspection supporting the violation in that Croft failed to document internal audit nonconformances on corrective action reports per Croft procedures to officially correct the nonconformances. This was an additional example of Croft's failure to take adequate corrective action. (Section 1.2)

The team concluded that Croft was effectively implementing its document and records control program and had adequate procedures in place to ensure compliance with the applicable regulations and QAP requirements. (Section 1.3)

The team found that for the audits reviewed, Croft conducted the audits with qualified personnel independent of the areas being audited and adequately evaluated the applicable functional areas of the QAP. (Section 1.4)

#### Design Controls

The team identified Croft's design control program as an area for improvement as evidenced by the issue identified and described in this report. The team identified one Severity Level IV non-cited violation of 10 CFR 71.111, "Instructions, procedures, and drawings" for Croft having three active procedures that did not correctly prescribe activities affecting quality. Specifically, CAP-02-02, Project Quality Plan; CAP-02-04, Project Specifications; and CAP-02-05, Project Plan; are no longer current with what Croft is actually doing to fill out Croft form QF376, Project Quality Plan. (Section 2.)

### Fabrication Interface

The team determined that the procurement controls were adequate, and Croft was generally effective in implementing their procurement program to support their transportation packaging fabricator. (Section 3.1)

Croft's implementation of fabrication controls for fabrication and assembly was assessed to be adequate based on a sample review of fabrication final documentation packages for Croft's transportation packages. (Section 3.2)

The team assessed that Croft had adequate controls for testing and inspection of its fabricated transportation packages as they were being inspected per approved QA procedures and fabrication specifications by qualified personnel. The team based its assessment on a sample review of fabrication final documentation packages. (Section 3.3)

### Maintenance Controls

The team reviewed maintenance procedures and maintenance records associated with packaging maintenance controls for activities affecting quality and interviewed Croft personnel involved with maintenance. The team determined that Croft's implementation in this area was adequate. (Section 4.1)

The team assessed that overall, the measuring and test equipment (M&TE) quality procedures being implemented at Croft provided adequate guidance for M&TE calibration and use, and Croft adequately implemented M&TE calibration, tracking, and use requirements. (Section 4.2)

## REPORT DETAILS

### 1. Management Controls

#### 1.1 Quality Assurance Policy

##### 1.1.1 Scope

The NRC inspection team reviewed Croft's Quality Management System (QMS) and associated implementing procedures to verify how Croft conducts activities in accordance with the NRC issued CoCs for the two Safkeg radioactive material packages, and NRC-approved QAP. The team reviewed Croft's Quality Assurance Requirements (QAR) 144, "Quality Assurance Program Description Manual (QAPDM) for 10 CFR Part 71, Subpart H," Issue E, implementing procedures, work instructions (WI), and quality assurance guidelines (QAG) developed to comply with specific NRC requirements and guidance. The team reviewed Croft Associates Procedure (CAP) 05-14, "Graded Approach to Quality," Issue F, to verify that Croft used a graded approach for identifying Important-to-Safety (ITS) components and applied this graded quality level to applicable documents and processes. The team also reviewed a sample of personnel qualifications and indoctrination training records in accordance with implementing procedure CAP 13-01, "Training and Competence Records," Issue I.

##### 1.1.2 Observations and Findings

The team assessed that Croft's overall program for quality had an adequate QMS and quality implementing procedures (i.e., CAPs, WIs and QAGs) in place to ensure their quality activities were conducted in accordance with their CoCs, NRC-approved QAP, and Part 71 requirements. The team also verified that Croft clearly defined and documented the quality program authorities and responsibilities and that the quality assurance organization functioned as an independent group as described in Croft's QAPDM.

##### 1.1.3 Conclusions

The team determined that the QA controls at Croft were generally adequate. The team concluded that Croft conducts its activities associated with QA organization independence, QA responsibilities, and the graded approach in accordance with QAR-144.

#### 1.2 Nonconformance and Corrective Action Controls

##### 1.2.1 Scope

The team reviewed a sample of Croft's nonconformance reports (NCRs) and interviewed selected personnel to verify that Croft effectively implemented a nonconformance control program. The review included an evaluation of how Croft's nonconformance control and corrective action programs addressed identified quality deficiencies and materials, parts, and components that do not conform to requirements. The team also reviewed provisions for reporting defects that could cause a substantial safety hazard. The team reviewed the following Croft quality procedures and guidelines:

- CAP 05-06, "Product Nonconformance Control," Issue Q
- CAP 05-17, "Conditions Adverse to Quality - NRC," Issue E
- CAP 12-03, "QMS Corrective Action," Issue O
- QAG 006, "Reporting to US Nuclear Regulatory Commission," Issue D

The team reviewed nonconformances and corrective actions from the previous five years. The team also reviewed several corrective action notes (CAN) initiated from NCRs. The team discussed the nonconformances and corrective actions with the Croft staff to understand the process. The team focused the review on use-as-is and repair type dispositions to evaluate how Croft technically justified the NCRs reviewed. In particular, the team reviewed each technical justification provided for the use-as-is and repair NCRs. In addition, the team requested a list of Part 21 evaluations and notifications associated with the Croft transportation packagings and interviewed Croft personnel to verify their familiarity and knowledge of QAG 006 and CAP 05-17. The team also reviewed postings within the Croft office to determine if Croft complied with the 10 CFR 21.6, "Posting requirements."

### 1.2.2 Observations and Findings

Overall, the team assessed that Croft completed NCRs in a technically sound manner. The team also verified that Croft completed corrective actions for identified deficiencies and nonconformances in a timely manner for those items identified as needing a CAN or Corrective Action Report (CAR). The team noted that Croft could initiate a CAN or CAR for an NCR that needed corrective actions. The team noted that Croft used both to identify corrective actions needed to resolve issues but mostly used CANs to defer long-term corrective actions. The long-term corrective actions were for potential CoC and Safety Analysis Report (SAR) changes. The team noted that Croft would assess the CAN to determine if the Quality Manager needed to assign a condition adverse to quality (CAQ) number.

The team assessed and evaluated the implementing procedures for CAQ and corrective actions, CAP 05-17, and CAP 12-03, respectively.

The team reviewed corrective actions generated as a result of previous inspections at Croft in 2017 (ML17248A478) and Oxford Engineering Limited, a category A supplier to Croft, in 2019 (ML19060A092).

The team identified that during the 2017 inspection of Croft, the previous inspection team identified that CAP 12-01, Issue S, failed to require a periodicity for internal audits as required by 10 CFR 71.137, "Audits," to ensure all applicable quality assurance criteria are audited on a periodic basis. The team determined this to be a violation of 10 CFR 71.111, "Instructions, Procedures, and Drawings." Croft entered this issue into their corrective action program as CAR 136, dated May 25, 2017; however, the team determined the actions of the CAR did not directly align with the violation and the violation was not corrected. Specifically, the team determined that procedure CAP 12-01, Issue V did not specify a required periodicity for internal audits and that only 14 of 18 quality assurance criteria be audited. Croft subsequently documented this issue again in CARs 175 and 176 during the 2022 inspection.



The team identified that during the 2017 inspection of Croft, the previous inspection team had identified that CAP 05-17, Issue E and CAP 12-03, Issue M, did not provide guidance to determine the cause of Significant Conditions Adverse to Quality (SCAQ), and the corrective action necessary to preclude repetition. The procedures lacked specific guidance that described a systematic methodology that Croft personnel could use to 1) identify the causes of SCAQs and how to address the extent of condition and extent of cause; 2) determine corrective actions taken to address the issue; and 3) preclude repetition by ensuring that there is a corrective action for each root and contributing cause. The team determined this to be a violation of 10 CFR 71.133, "Corrective Action." Specifically, the team determined that while the NCR database and form had been revised to require a causal evaluation, CAP 12-03, Issue M, did not require a causal evaluation to be performed for SCAQs not associated with a non-conformance report. Croft entered this issue into their corrective action program as CAR 137; however, the team determined the actions of the CAR did not directly align with the violation and the violation was not corrected. Croft subsequently documented this issue again in CAR 174 during the 2022 inspection.

The team identified that during the 2019 inspection of Oxford Engineering Limited (OEL), the previous inspection team identified that CAP 06-08, Step 2.2.1 stated, in part, that a Quality Category A supplier shall have a current assessment and approval to an appropriate quality system standard. Contrary to this, Croft assessed OEL to qualify them to encompass the additional requirements of 10 CFR Part 71, but OEL's internal auditor did not meet those requirements nor did OEL have a quality procedure or process in place for qualifying internal auditors. The team determined that this issue was a violation of 10 CFR 71.111, "Instructions, procedures, and drawings." Croft entered this issue into their corrective action program as CAR 147; however, the team determined the actions of the CAR did not directly align with the violation and the violation was not corrected. Specifically, the team determined that no action was taken to ensure that OEL's internal auditor's met the requirements of 10 CFR Part 71 and OEL did not have a quality procedure or process in place for qualifying internal auditors to ensure compliance with 10 CFR Part 71, Croft subsequently documented this issue again in CAR 173 during the 2022 inspection.

Additionally, the team sampled a number of internal audits performed by Croft since the previous inspection (See Section 1.4 of this Inspection Report), and of the audits sampled, the team noticed that no CARs had been generated as a result of the audits, even when findings or observations had been identified. Specifically, as an example, during quality audit 448, Croft identified that no calibration certifications for equipment items CC0216 and CC0215 existed which was contrary to the requirements of CAP 07-01, "Calibration." CAP 12-01 Section 2.3 identifies that, "when carrying out an internal audit, nonconformances must be recorded in the CAR database." However, the inspection staff identified that no CAR had been generated for the audit finding. Croft documented this issue in CAR 180.

The team assessed that these four examples were a violation of NRC requirements. The team determined a violation of 10 CFR 71.133, "Corrective action" occurred in that Croft took inadequate corrective actions during the 2017 and 2019 NRC inspections after writing CARs to address NRC findings. In addition, Croft failed to document nonconformances from internal audits on CARs per its procedure so corrective action could be taken to address the nonconformances.

10 CFR 71.133, "Corrective action," states, in part, that the licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined, and corrective action taken to preclude repetition.

Contrary to this, Croft took inadequate corrective action from the 2017 and 2019 inspections as documented in CARs 136, 137, 147 to preclude repetition of the NRC findings identified. In addition, Croft has not documented internal audit nonconformances on CARs so that adequate corrective action could be taken to preclude repetition.

The team dispositioned the violation using the traditional enforcement process in Section 2.3 of the NRC Enforcement Policy. The team determined the violation was 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 16a in its decision to make the violation more than minor since the adverse conditions were not corrected in the first three examples and recurred and not documented in the fourth example.

Therefore, the team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, Section 6.8. The violation is being cited since Croft took inadequate corrective action when the first three examples were put into the Croft corrective action program and must now be readdressed. This violation is being cited in the enclosed Notice of Violation (Notice) (71-0939/2022-201-01).

### 1.2.3 Conclusions

The team identified Croft's CAP as an area for improvement as evidenced by the four examples of corrective action issues identified and described above. The team identified one violation of NRC requirements concerning the failure by Croft to take adequate corrective actions from findings identified during the two previous NRC inspections and the current NRC inspection.

## 1.3 Documentation Controls

### 1.3.1 Scope

The team reviewed Croft's documentation and quality records control program and associated quality procedures to assess the effectiveness of controls established for the development, review, approval, issuance, use, and revision of quality documents. The team also reviewed the tracking, verification, and storage of quality records. The team reviewed the following QAPDM sections and quality procedure documents associated with document control and records to verify they are being properly implemented:

- QAR 144, Section 71.109, "Procurement document control," Issue E
- QAR 144, Section 71.113, "Document control," Issue E
- QAR 144, Section 71.135, "Quality assurance records," Issue E

- CAP 01-11, "Control of Records," Issue D
- CAP 01-13, "Staff Roles, Document Compilation, Checking and Approval Authorities," Issue H
- WI 01-01, "Document Numbering System," Issue L
- WI 01-02, "Drafting Documents," Issue K
- WI 01-03, "Change Control of Documents," Issue J
- WI 01-04, "Forms," Issue H
- WI 01-05, "Document Review," Issue K
- WI 01-06, "Issuing Documents," Issue I
- WI 01-09, "Reference Document Control," Issue J
- WI 01-10, "EMS, CAPs and WIs," Issue K
- WI 04-01, "Issue of Drawing/Product Numbers Related," Issue G
- WI 04-02, "Preparation of Drawings/Related Documents," Issue M
- WI 04-03, "Master Drawing Control," Issue K
- WI 04-04, "Modification of Drawings, Issue L
- WI 04-06, "Design Job Control," Issue K
- WI 04-07, "Illustrations and Sketches," Issue E
- WI 14-06, "Creating Project Numbers," Issue J

The team also interviewed Croft personnel regarding documentation and record controls.

### 1.3.2 Observations and Findings

The team assessed that Croft had adequate and effective controls established by their implementing procedures for the approval, issuance, use, storage, and revision of quality documents and records. No issues of significance were identified.

### 1.3.3 Conclusions

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

## 1.4 Audit Program

### 1.4.1 Scope

The team reviewed Croft's audit program to determine if Croft scheduled, planned, and performed internal and external audits in accordance with their approved implementing CAPs and as described in the Croft QAPDM. The team selected a sample of internal and external audits since the last Croft corporate inspection in 2017. The team reviewed the audit results to determine if Croft identified deficiencies and whether Croft addressed these deficiencies within their corrective action program, as required. The team reviewed the following QAPDM section and CAPs:

- QAR 144, Section 71.137, "Audits," Issue E
- CAP 06-08, "Approved Supplier – NRC," Issue G
- CAP 12-01, "Audit Procedure," Issue V
- CAP 13-01, "Training and Competence Records," Issue I

- CAP 13-09, “NQA-1 Lead Auditor Qualification,” Issue A
- WI 12-08, “Supplier Audit,” Issue E

Additionally, the team selected a random sample of audit personnel records, including lead auditor, to determine if they met the applicable requirements, including those stated in CAP 13-01 and 13-09.

#### 1.4.2 Observations and Findings

Overall, the team assessed that for the audits sampled Croft generally conducted them with qualified and certified personnel and identified observations and findings in most of the audit reports reviewed. The team noted that external audits were performed on the required 3-year periodicity for ITS Category A suppliers. In addition, the team noted that some findings identified within the internal audit reports reviewed that were conditions adverse to quality were not documented as a CAR, as required. The team also noted that CAP 12-01 did not define an internal audit periodicity. These issues are discussed in more detail in Section 1.2 above.

#### 1.4.3 Conclusions

The team concluded that Croft had an adequate audit program in place to schedule, develop an audit plan, evaluate applicable elements of their QAP, and document the results. The team determined that Croft appropriately identified issues but, in some cases, did not document conditions adverse to quality in a CAR, as required, when auditors identified findings or observations during audits. (Reference Section 1.2)

## 2. Design Controls

### 2.1 Design Development

#### 2.1.1 Scope

The team reviewed the design control section of the QAPDM and applicable implementing quality procedures to verify that Croft was properly implementing their design control program. The team reviewed the following QAPDM section and quality procedure documents associated with design control to verify they are being properly implemented:

- QAR 144, Section 71.107, “Package design control,” Issue E
- CAP 02-02, “Project Quality Plan,” Issue L
- 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
- CAP 10-01, “Competent Authority Licensing,” Issue J
- CAP 10-02, “Review of Certificates and Validations,” Issue J
- CAP 10-10, “Update of Foreign Competent Authority Approvals,” Issue D
- WI 03-04, “Design Calculations,” Issue B

### 2.1.2 Observations and Findings

The team assessed that Croft overall had adequate and effective controls established by their implementing procedures for project planning, development of project quality requirements, implementing project controls, developing design specifications, design development and design controls, performing and reviewing design calculations, performing overall design reviews, and performing competent authority design licensing.

The team reviewed quality form QF 376, Project Quality Plan, for Croft's latest Part 71 model 3977B (Safkeg-HS) packaging which had been recently submitted to the NRC in an application for NRC review and certification. The form QF 376 had been revised, but procedures CAP 02-02, Project Quality Plan; CAP 02-04, Project Specifications; and CAP 02-05, Project Plan; in which procedural guidance was to be provided on how to fill out QF 376 were no longer current with what Croft was actually doing to fill out form QF 376.

The team assessed that these three examples of inadequate procedures were a violation of NRC requirements. The team determined a violation of 10 CFR 71.111, "Instructions, procedures, and drawings" occurred in that during the NRC inspection Croft had three active procedures that did not correctly prescribe activities affecting quality.

10 CFR 71.111, "Instructions, procedures, and drawings," states, in part, that the certificate holder for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed.

Contrary to the above, as of July 21, 2022, CAP 02-02, Project Quality Plan; CAP 02-04, Project Specifications; and CAP 02-05, Project Plan; are no longer current with what Croft is actually doing to fill out Croft form QF376. So, during the inspection Croft had three active procedures that did not correctly prescribe activities affecting quality.

The team dispositioned the violation using the traditional enforcement process in Section 2.3 of the NRC Enforcement Policy. The team determined the violation was more-than-minor safety significance in accordance with Inspection Manual Chapter 0617, "Vendor and Quality Assurance Implementation Inspection Reports," Appendix E, "Minor Examples of Vendor and QA Implementation Findings." The team utilized examples 6a and 6b in its decision to make the violation more than minor since three procedures were not current instead of just one.

Therefore, the team characterized the violation as a Severity Level IV violation in accordance with the NRC's Enforcement Policy, Section 6.8. In accordance with the policy, the violation is non-cited since Croft put the issue in its corrective action program as CAR 177 (71-0939/2022-201-02).

### 2.1.3 Conclusions

The team concluded that Croft had in place an adequate design control program to meet the requirements of the transportation regulations. However, the team identified Croft's

design control program as an area for improvement as evidenced by the three examples of design control procedures not being current with Croft's actual practice for filling out form QF 376 as identified and described above. The team identified the three examples of inadequate procedures as a violation of 10 CFR 71.111, "Instructions, procedures, and drawings" requirements.

### **3. Fabrication Interface Controls**

#### **3.1 Material Procurement**

##### **3.1.1 Scope**

The team reviewed Croft's procurement of ITS materials, which included the review of procurement documents, drawings and procedures, and receipt inspection records. The team reviewed the following sections of the QAPDM, and CAPs associated with procurement:

- QAR 144, Section 71.109, "Procurement document control," Issue E
- QAR 144, Section 71.115, "Control of purchased material, equipment and services," Issue E
- CAP 05-18, "Commercial Grade Dedication," Issue F
- CAP 06-01, "Purchasing," Issue Q

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, commercial grade dedication is performed. Therefore, the team selected a sample of stainless steel round bar to review the adequacy of the commercial grade dedication package and conformance to the requirements in CAP 05-18. The team focused on the adequacy of the critical characteristics identified and the traceability of the stainless steel through the manufacturing, testing, and inspection process.

##### **3.1.2 Observations and Findings**

No issues of significance were identified.

##### **3.1.3 Conclusions**

The team determined that the procurement controls were adequate, and Croft was generally effective in implementing their procurement program.

#### **3.2 Fabrication and Assembly**

##### **3.2.1 Scope**

The team reviewed records associated with fabrication and fit-up of SAFKEG-HS packagings, specifically keg assemblies and a containment vessel for domestic use in the United States, to verify the fabrication and assembly processes sampled were properly controlled and implemented. Since Croft contracted the fabrication of the SAFKEG-HS to the OEL fabrication facility, Croft's responsibility for fabrication and assembly controls resided in part, in the review and acceptance of the final document package for the completed SAFKEG-HS packagings. Therefore, the team reviewed records that were part of the final document package accepted by Croft from OEL. The records reviewed included routing sheets (shop travelers) and QA Reports to verify that fabrication and assembly activities were accomplished and appropriately documented according to the controlled drawings, routing sheets, and manufacturing specification, MSP 157, "Manufacturing Specification HS Safkeg Packaging Assembly Design No 3977A," Issue H.

### 3.2.2 Observations and Findings

The team noted that for the routing sheets reviewed, Croft signed off on each of the customer hold points and none had been waived by Croft oversight personnel. No issues of significance were identified.

### 3.2.3 Conclusions

Croft's review and acceptance of the final document package records related to fabrication and assembly, as a part of their implementation of fabrication controls, was assessed, overall, to be adequate and effective.

## 3.3 Test and Inspection

### 3.3.1 Scope

The team reviewed records associated with the test and inspection of the SAFKEG-HS packaging, specifically a containment vessel for domestic use in the United States, to verify that the test and inspection processes sampled were properly controlled and implemented. Like section 3.2 above, the team reviewed records that were part of the final document package accepted by Croft from OEL. The records reviewed included QA reports that included weight and dimensional measurements, and a helium leak test report, to verify that test and inspection activities were accomplished and appropriately documented according to the controlled drawings, routing sheets, and manufacturing specification, MSP 157, Issue H.

### 3.3.2 Observations and Findings

No issues of significance were identified.

### 3.3.3 Conclusions

Croft's review and acceptance of the final document package records related to inspection and test, as a part of their implementation of fabrication controls was assessed, overall, to be adequate.

## **4. Maintenance Controls**

### **4.1 Maintenance Activities**

#### **4.1.1 Scope**

Since the last NRC inspection in 2017, Croft has started performing maintenance activities at their facility in Abingdon, Oxfordshire, England. Both the SAFKEG-LS and HS models require periodic or annual maintenance to be performed. The team reviewed Croft's maintenance program to determine if the quality procedures were adequate to ensure the requirements of the applicable package safety analysis report would be met. The team reviewed the following quality documents associated with maintenance:

- MIS 049, "Periodic Maintenance and Inspection Schedule Packaging Design No. 3977A, HS Safkeg," Issue B
- WI 08-01, "Control of Packages at Maintenance," Issue I

The team reviewed a sample of maintenance records for maintenance performed at Croft's facility for a package user in the United States. In addition, a damage assessment and repair plan was reviewed regarding four containment vessel's and two tungsten inserts that were returned to Croft from a United States package user to determine if the proposed repair activities met the requirements of the applicable licensing drawings and package safety analysis report.

#### **4.1.2 Observations and Findings**

No findings of significance were identified

#### **4.1.3 Conclusions**

The team determined that, overall, Croft had an adequate maintenance program in place to ensure proper implementation of the required maintenance activities.

## **4.2 Tools and Equipment**

#### **4.2.1 Scope**

The team reviewed selected measuring and test equipment (M&TE) and reviewed records and procedures to assure that equipment used in activities affecting quality were properly controlled and calibrated. The team reviewed the following Section of the QAPDM and CAP:

- QAR 144, Section 71.125, "Control of Measuring and Test Equipment," Issue E
- CAP 07-01, "Calibration," Issue L

#### **4.2.2 Observations and Findings**

No issues of significance were identified.



#### 4.2.3 Conclusions

The team concluded that the M&TE quality procedure being implemented at Croft provided adequate guidance for M&TE calibration and use, and Croft adequately implemented M&TE calibration, tracking, and use requirements.

#### 5. **Entrance and Exit Meeting**

On July 18, 2022, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Croft Quality Manager Steve Ralls, Managing & Technical Director Mark Johnson, and other members of the Croft staff. On July 21, 2022, the NRC inspection team presented the inspection results and observations during an onsite preliminary exit meeting. On September 26, 2022, the NRC inspection team leader conducted a final telephone conference exit with Steve Ralls, Mark Johnson, and other members of the Croft 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 |
|---------------|--------------------------------|-------------|----------|------|
| Jon Woodfield | Inspection Team Leader         | NRC/DFM     | X        | X    |
| Jeremy Tapp   | Inspector                      | NRC/DFM     | X        |      |
| Matthew Learn | Inspector                      | NRC/DFM     | X        |      |
| Mark Johnson  | Managing & Technical Director  | Croft       | X        | X    |
| Steve Ralls   | Quality Manager                | Croft       | X        | X    |
| Alex Ferguson | Licensing Director             | Croft       | X        | X    |
| Ian Dingwall  | Head of Manufacture            | Croft       | X        | X    |
| Trevor Tait   | Head of Projects & Engineering | Croft       |          |      |
| Greg Tilling  | Design                         | Croft       |          |      |

### 2. INSPECTION PROCEDURES AND OTHER NRC DOCUMENTS 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 ACRONYMS USED

|       |   |
|-------|---|
| ADAMS | Agencywide Documents Access and Management System       |
| ASL   | Approved Suppliers List                                 |
| CAN   | Corrective Action Notes                                 |
| CAP   | Corrective Action Program or Croft Associates Procedure |
| CAQ   | Condition Adverse to Quality                            |
| CAR   | Corrective Action Report                                |
| CFR   | Code of Federal Regulations                             |
| CoC   | Certificate of Compliance                               |
| DFM   | Division of Fuel Management                             |
| IMC   | Inspection Manual Chapter                               |
| IP    | Inspection Procedure                                    |
| ITS   | Important-to-Safety                                     |
| M&TE  | Measuring and Test Equipment                            |
| NCR   | Nonconformance Report                                   |
| NRC   | Nuclear Regulatory Commission                           |
| OEL   | Qxford Engineering Limited                              |
| QA    | Quality Assurance                                       |
| QAG   | Quality Assurance Guidelines                            |
| QAP   | Quality Assurance Program                               |
| QAPDM | Quality Assurance Program Description Manual            |
| QAR   | Quality Assurance Requirements                          |
| QMS   | Quality Management System                               |

|      |  |
|------|--|
| SAR  | Safety Analysis Report                   |
| SCAQ | Significant Condition Adverse to Quality |
| SER  | Safety Evaluation Report                 |
| WI   | Work Instruction                         |

#### 4. DOCUMENTS REVIEWED

Certificate holder documents reviewed during the inspection were specifically identified in the report details above.

#### 5. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

| <u>Item Number</u>  | <u>Status</u>   | <u>Type</u> | <u>Description</u>   |
|---------------------|-----------------|-------------|--|
| 71-0939/2022-201-01 | Opened          | NOV         | Inadequate corrective action to address findings from 2017 and 2019 NRC inspections and write CARs for internal audit nonconformance findings. |
| 71-0939/2022-201-02 | Opened & Closed | NCV         | Croft had three active procedures that were not current with how to fill out form QF376.   |

#### THE FOLLOWING CARs WERE OPENED BY CROFT DURING THE INSPECTION DUE TO DISCUSSIONS WITH THE INSPECTION TEAM

| <u>Item Number</u> | <u>Status</u> | <u>Description</u>  |
|--------------------|---------------|---|
| CAR 170            | Opened        | Possible typographical error in field 36 of MIS049 issue B. Reference to Section 8.2.3.4.3 of the SARP CTR2008/11 should read 8.2.3.6.3.  |
| CAR 171            | Opened        | Field 7 of MIS 049 issue B omitted some references to the drawings that are made in the SARP. The MIS is a record of maintenance work carried out in accordance with the SARP and must make the same statements as the sections referenced.                     |
| CAR 172            | Opened        | Internal audit reports do not show a review of the previous audit findings as required by CAP 12-01 paragraph 2.4. Additionally, paragraph 2.2 should contain an instruction to review the previous audit as part of preparation.                               |
| CAR 173            | Opened        | CAR 147 raised during a previous NRC audit had not been adequately closed off in that the Oxford Engineering Limited procedure, CP03, had not been revised to clarify auditor training and qualification requirements or to clarify the auditor's independence. |

|         |        |  |
|---------|--------|--|
| CAR 174 | Opened | CAR 137 raised during a previous NRC audit had not been adequately closed off due to a misunderstanding of the required corrective action. The NCR database and form had been revised to require an assessment of whether a CAQ had occurred. This requirement had not been applied to the CAR system.   |
| CAR 175 | Opened | The first four clauses of 10CFR71 subpart H were omitted from the internal audit schedule as they were considered more to be policy requirements than processes.   |
| CAR 176 | Opened | CAR 136 raised during a previous NRC audit required the internal audit program to specifically address the clauses of 10CFR71 subpart H. The corrective action added fourteen of the clauses to the audit schedule which was considered inadequate by the NRC team – see CAR 175. Additionally, the revised procedure did not state a specific period for internal audits. |
| CAR 177 | Opened | During inspection of the 3977B documentation it was noted that some forms referenced in Croft procedures were not being used. CAP 02-02 (Quality Plan), CAP 02-04 (Project Specifications) and CAP 02-055 (Project Plan) and related forms are no longer used due to the introduction of form QF376 which incorporated all three activities.                               |
| CAR 178 | Opened | WI 01-06 Controlled Documents requires revision to reflect current practice which has undergone some minor changes due to the move to electronic documentation. e.g., negating the need to rubber stamp paper documents.   |
| CAR 179 | Opened | The 3977B HS package was manufactured ahead of the design approval and issue of a certificate by the NRC. The Project Quality Plan has a field in the project closure section to address manufacture at risk but this needs to be fully documented as to what was reviewed and confirming that the 'as manufactured' package complies with the certificates as issued.     |
| CAR 180 | Opened | Internal audit findings as detailed on form QF327 do not always result in a CAR being raised as required by CAP 12-01 and WI 13-05.  |
| CAR 181 | Opened | A document package submitted by Oxford Engineering for the 3977A had been approved and signed off by Croft but a number of pages were missing the sign-off by Oxford Engineering.  |
| CAR 182 | Opened | 10CFR21.6 Posting Requirements state that Section 206 of the Energy Reorganization Act 1974 and 10CFR71.9 Employee protection state that NRC form 3 shall be posted  |

in a conspicuous position for all staff to see. The documents had not been posted.

CAR 183

Opened

The SARP CTR2008/11 calls out Hydrostatic testing in section 8.2.3.1 but this is not called out in MIS049 field 7 which simply states: Pressure Test. The MIS is a record of maintenance work carried out in accordance with the SARP and must make the same statements as the sections referenced.

## NOTICE OF VIOLATION

Croft Associates Limited  
Oxfordshire, England, UK

Docket No. 07100939

During an NRC inspection conducted July 18 to September 26, 2022, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (10 CFR), Section 71.133, "Corrective action" requires, in part, that the certificate holder shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition.

Contrary to the above, Croft took inadequate corrective action from the NRC 2017 inspection of Croft and the NRC 2019 inspection of Croft fabricator Oxford Engineering Limited.

Specifically, in 2017, Croft wrote Corrective Action Report (CAR) 136 to address that Croft Associates Procedure (CAP) 12-01, Issue S, Audit Procedure, failed to require a periodicity for internal audits as required by 10 CFR, Section 71.137, "Audits" to ensure all applicable quality assurance criteria are audited on a periodic basis. However, the actions taken by the CAR did not directly align with the issue and the issue was not corrected.

In 2017, Croft wrote CAR 137 to address that CAP 05-17, Issue E, Conditions Adverse to Quality, and CAP 12-03, Issue M, QMS Corrective Action, did not provide guidance to determine the cause of Significant Conditions Adverse to Quality and the corrective action necessary to preclude repetition. However, the actions taken by the CAR did not directly align with the issue and the issue was not corrected.

In 2019, Croft wrote CAR 147 to address that CAP 06-08, Approved Supplier, Step 2.2.1 required that a Quality Category A supplier shall have a current assessment and approval to an appropriate quality system standard. Croft assessed Oxford Engineering Limited to qualify them to encompass the additional requirements of 10 CFR Part 71, but Oxford Engineering's internal auditor did not meet those requirements, nor did Oxford Engineering have a quality procedure or process in place for qualifying internal auditors. However, the actions taken by the CAR did not directly align with the issue and the issue was not corrected.

In addition, during the 2022 inspection, several Croft internal audits were sampled, and it was determined that no CARs had been written when findings had been identified as a result of the audits. CAP 12-01, Audit Procedure, Section 2.3 states that when carrying out an internal audit, nonconformances must be recorded on the CAR database.

Enclosure 2

This is a Severity Level IV violation (Section 6.8).

Pursuant to the provisions of 10 CFR 2.201, Croft Associates Limited, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to Aida Rivera-Varona, Chief, Inspection and Oversight Branch, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 9th day of November 2022.