July 7, 2008

Mr. Robert Vaughan
Croft, Inc. (UK) Ltd.
F4 Culham Science Center
Abingdon
Oxfordshire, England, OX14 3DB

SUBJECT: U. S. NUCLEAR REGULATORY COMMISSION (NRC) INSPECTION REPORT NO. 71-0939/2008-201

Dear Mr. Vaughan:

This letter refers to the team inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on May 14-20, 2008, at the Croft Inc. Ltd. (Croft) facility at the Culham Science Center, Abingdon, Oxfordshire, England. The purpose of the inspection was to assess the status of Croft's NRC-approved Quality Assurance (QA) program in the areas of QA program management, packaging design, fabrication, and maintenance, in preparation for Croft's intention to become an NRC 10 CFR Part 71 Certificate of Compliance (CoC) holder and for subsequent fabrication of packagings to be used domestically within the United States. The enclosed report (Enclosure 1) presents the results of this inspection.

With respect to the inspection results, the NRC inspection team assessed that, overall, as presently developed and implemented, Croft's QA program and procedures do not acceptably meet the QA requirements of 10 CFR Part 71. The team identified multiple examples where Croft personnel were not following QA procedures, where QA procedures did not contain sufficient details with regard to quality activities, and where the QA procedures did not support requirements in 10 CFR Part 71, Subpart H, or in the QA Program Description submitted to the NRC that formed the basis of the NRC's approval of the Croft QA program. The term "observation" as used in this report means a non-conforming condition or activity that had it concerned packagings with an NRC CoC, the observation would have been a violation of the applicable requirement in 10 CFR Part 71.

At present, the inspection findings have no adverse safety impacts as Croft has yet to submit their packaging design to the NRC for certification. However, the issues identified in the enclosed report will need to be addressed by Croft management prior to the issuance of an NRC CoC or the start of packaging fabrication. At the inspection exit meeting, the team requested that Croft inform the NRC once the inspection findings have been addressed, and prior to any packaging fabrication, so that a re-inspection of Croft's QA program implementation can be scheduled.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

/RA/
David W. Pstrak, Chief
Rules, Inspections, and Operations Branch
Licensing and Inspection Directorate
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-00939

Enclosure: NRC Inspection Report No. 71-00939/2008-201

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U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Spent Fuel Storage and Transportation

Inspection Report

Docket:	71-00939
Report:	71-00939/2008-201
Certificate Holder:	Croft, Inc. (UK) Ltd. F4 Culham Science Center Abingdon Oxfordshire, England, OX14 3DB
Date:	May 14-20, 2008
Inspection Team:	Jim Pearson, Team Leader, SFST Robert Temps, Senior Inspector, SFST Earl Love, Inspector-In-Training, SFST
Approved by:	David W. Pstrak, Branch Chief Rules, Inspections, and Operations Branch Licensing and Inspection Directorate Division of Spent Fuel Storage and Transportation Office of Nuclear Material Safety and Safeguards

Enclosure

EXECUTIVE SUMMARY

On May 14-20, 2008, the U.S. Nuclear Regulatory Commission (NRC) performed an announced team inspection of Croft, Inc. (Croft), at its facility at the Culham Science Center. The purpose of the inspection was to determine if Croft's activities associated with the transportation of radioactive material were being performed in accordance with the requirements of 10 CFR Parts 21 and 71, applicable certificates of compliance, related Safety Analysis Reports (SARs), and the NRC - approved quality assurance (QA) program. The team inspected Croft's management, design, fabrication, and maintenance activities. The enclosed report presents the results of this inspection.

During the inspection, a number of weaknesses were identified with regard to Croft's implementation of their NRC-approved program. Overall, the NRC is concerned that these weaknesses represent a programmatic breakdown in Croft's QA program implementation.

With respect to the inspection results, the NRC inspection team assessed that, overall, as presently developed and implemented, Croft's QA program and procedures do not acceptably meet the QA requirements of 10 CFR Part 71. The team identified multiple examples where Croft personnel were not following QA procedures, where QA procedures did not contain sufficient details with regard to quality activities, and where the QA procedures did not support requirements in 10 CFR Part 71, Subpart H, or in the QA Program Description submitted to the NRC that formed the basis of the NRC's approval of the Croft QA program. The term "observation" as used in this report means a non-conforming condition or activity that had it concerned packagings with an NRC CoC, the observation would have been a violation of the applicable requirement in 10 CFR Part 71.

At present, the inspection findings have no adverse safety impacts as Croft has yet to submit their packaging design to the NRC for certification. However, the issues identified in this enclosed report will need to be addressed by Croft management prior to the issuance of an NRC CoC or the start of packaging fabrication. At the inspection exit meeting, the team requested that Croft inform the NRC once the inspection findings have been addressed, and prior to any packaging fabrication, so that a re-inspection of Croft's QA program implementation can be scheduled.

REPORT DETAILS

1.0 Inspection Scope and Background

Earlier this year Croft was granted an NRC 10 CFR Part 71 Quality Assurance (QA) Program Approval as a prerequisite to its submittal of a Type B radioactive material packaging design for which it is seeking an NRC Certificate of Compliance. The inspection will focus on how Croft is implementing its NRC-approved QA program with respect to packaging design, fabrication, and maintenance. Croft is designing two packages to replace the U. S. Department of Transportation (DOT) specification containers (6M & 20WC-1) which will become obsolete and will not be authorized for use after October 1, 2008. The SAFEKEG models will be used for transportation of medical and industrial isotopes from the University of Missouri research reactor (MURR).

As noted on the cover page, the term "observation" as used in this report means a non-conforming condition or activity that had it concerned packagings with an NRC CoC, the observation would have been a violation of the applicable requirement in 10 CFR Part 71. Observations have been listed in these inspector notes so that Croft can take appropriate actions for these non-conformances consistent with their QA program requirements.

1.1 Inspection Procedures/Guidance Documents Used

IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings," NUREG/CR 6314, "Quality Assurance Inspections for Shipping and Storage Container," Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material."

1.2 List of Acronyms Used

ASL	Approved Suppliers List
CAN	Corrective Action Notice
CAP	Croft Associates Procedure
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
DOT	U. S. Department of Transportation
IT	Information Technology
M&TE	Measuring and Test Equipment
MURR	Missouri University Research Reactor
NCR	Nonconformance Report
NRC	U.S. Nuclear Regulatory Commission
OOC	Out Of Calibration
PO	Purchase Order
PQP	Project Quality Plan
QA	Quality Assurance
QAM	Quality Assurance Manager
QAPDM	Quality Assurance Program Description Manual for 10 CFR Part 71
QMS	Quality Management System
SAR	Safety Analysis Report
SCAQ	Significant Condition Adverse to Quality
SFST	Spent Fuel Storage & Transportation

1.3 Persons Contacted

The team held an entrance meeting with Croft on May 14, 2008, to present the scope and objectives of the NRC inspection. On May 20, 2008, the NRC held an exit meeting with Croft to present the final inspection results. The individuals present at the entrance, de-briefing meetings and exit meeting are listed in Table 2.

Table 2
Entrance and Exit Meetings Attendance

NAME	AFFILIATION	ENTRANCE	EXIT
Jim Pearson	NRC	X	X
Robert Temps	NRC	X	X
Earl Love	NRC	X	X
Ian Barlow	DfT (UK)	X	X
Rob Vaughan	CROFT	X	X
Rodney Clayton	CROFT	X	X
Norman Jorgenson	CROFT	X	X
Ron Hows	CROFT	X	
Alex Ferguson	CROFT	X	
Ian DIngwall	CROFT	X	

2.0 Management Controls

2.1 Quality Assurance Policy

2.1.1 Scope

The team interviewed personnel, reviewed organizational responsibilities (as well as delegation of responsibilities), objectives and practices, personnel responsibilities, QA organizational independence, management involvement, and staffing levels to determine the effectiveness of plans and procedures that implement its program.

2.1.2 Observations and Findings

The team reviewed the statement of policy and authority in the Croft Quality Assurance Program Description Manual for 10 CFR Part 71 (QAPDM), Subpart H and noted Croft's reference to the Quality Management System (QMS) and the expected alignment of the QAPDM and the QMS. The team also reviewed CAP 16-03, Issue L, "Responsibilities" and noted that detailed responsibilities are developed for the General Manager, Quality Manager, Project Manager(s), and Project Engineers (Design, Manufacturing, Licensing, and Maintenance). In addition the team noted that delegations of responsibilities were also addressed. The team interviewed the Quality Assurance Manager and other Croft personnel who were responsible for performing quality activities. The team determined from the interview and from assigned (formally and informally) responsibilities noted in Croft documents, that the Quality Assurance Manager (QAM) is currently performing a variety of daily tasks that include him in the Croft processes to such an extent that independence is not always obvious. In addition the team noted that Croft is a relatively small organization and the QAM is physically located essentially in the middle of their office space surrounded by a variety of staff members. While this location may be

acceptable under most conditions, it may be a disadvantage for the QAM in maintaining the Croft QA oversight and independence from the ongoing work functions.

The team reviewed Croft procedure CAP 2-03, "Project Control," that describes the way in which projects are controlled. The team noted the existence of specific guidance with respect to the generation of controlling documents such as Contract Review, Project Quality Plans (PQPs), Project Specification, Design Reviews, Raising of Project Numbers, Design Review Report, and a Project Closing Checklist. The team reviewed various finalized and preliminary PQPs used to describe the Quality Assurance aspects to be implemented during the MURR project. It was noted as a part of a review of the Project Management PQP that other (i.e., Testing, Prototype Manufacture, and Production Units Manufacture) project specific PQPs are required to be generated. During the review the team noted a key element in the project planning phase specific to the overall managing of the Quality Assurance/Control segment of the MURR project was missing. Specifically, methods have not been established for planning, performing and reporting Quality inspection/surveillance activities both within Croft, as well as, at supplier, manufacturing or testing facilities, and verification of supplier activities associated with critical activities for compliance to 10 CFR Part 71 requirements.

2.1.3 Conclusions

The team determined that the current procedures were prepared intending to satisfy ISO 9001:2000 and the intent described in the Croft NRC approved QAPDM for 10 CFR Part 71, Subpart H is to satisfy the application to Part 71. However as noted elsewhere in this report, many of the Croft procedures do not adequately support implementation of Part 71. Therefore the review of the current procedures in regard to application to Part 71 should be accomplished and any necessary corrective actions completed to ensure the proper and full implementation of the QAPDM. In addition, the team noted that based on the QAM interview, some of the activities involving the QAM include those that are essentially part of the overall operation of Croft. Because of the involvement of the QAM, an acceptable level of QA independence is not evident at Croft. The team assessed that some of the activities currently performed by the QAM would not provide the independence required to meet the requirements of 10 CFR Part 71 in regard to quality assurance independence.

The observations in the project control area represent a non-conformance with regard to the requirements of 10 CFR 71.103 in that CAP 2-03 does not adequately address the quality assurance function to assure that an appropriate quality assurance program is established and effectively executed and that activities affecting the safety related functions have been correctly performed. Overall, the team assessed that Croft's project controls specific to quality organization were not adequate in addressing the applicable requirements of 10 CFR Part 71, Subpart H.

2.2 Nonconformance Controls

2.2.1 Scope

The team reviewed selected records and interviewed selected personnel to verify effective implementation of the nonconformance control program, and that corrective actions for identified deficiencies were technically sound and completed in a timely manner.

2.2.2 Observations and Findings

The team reviewed CAP 5-06, "Non-Conformance Control" and 12-03, "Corrective Actions," as well as associated forms F237, "Corrective Action Report" and F78, "Non Conformance Reporting," used in conjunction with the CAPs. These procedures and forms represent the relevant portions of Croft's problem identification and corrective action program of interest to the NRC with regard to activities under 10 CFR Parts 21 and 71.

Discussions were held with QA personnel, and the team also reviewed selected documents such as Non Conformance Reports (NCRs) and Corrective Action Notices (CANs). The team identified a number of significant concerns and observations with regard to the manner in which Croft was implementing their problem identification and corrective action program processes. As noted in the cover letter, the term "observation" as used in this report means a non-conforming condition or activity that had it concerned packagings with an NRC CoC, the observation would have been a violation of the applicable requirement in 10 CFR Part 71. Observations have been listed in this inspection report so that Croft can take appropriate actions for these non-conformances consistent with their QA Program requirements.

The team identified an observation related to CAP 12-03 in that the procedure, as presently written, fails to address the issue of significant conditions adverse to quality (SCAQs). 10 CFR 71.133, "Corrective action" specifically states, in part, that "In the case of a SCAQ, the measures must assure that the cause of the condition is determined and corrective actions taken to preclude repetition. The identification of the SCAQ, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management." The team also noted that Croft failed to implement a statement from their Quality Assurance Program Manual Description (QAPDM) submittal to the NRC (used as the basis for NRC's approval of the QAPDM for meeting Part 71 QA requirements). Specifically, in Section 71.133, "Corrective action," Croft stated, in part, that "procedures have been established to identify significant conditions adverse to quality." However, as noted above, CAP 12-03 does not use the term SCAQ, does not address 10 CFR 71.133 requirements, and does not reflect statements made in Croft's QAPDM submittal to the NRC.

An observation was identified with respect to NCR 290 that involved rejected parts that were subsequently released for use with conditions. The team determined that the NCR procedure, CAP 5-06, does not address the release of non-conforming items with conditions. The team also identified that the parts in question had not been quarantined, as required by CAP 5-06, pending NCR resolution, and that they had not been released to stores, also as required by CAP 5-06, once the NCR was resolved. The team also identified that the supplier of the parts was not listed in Croft's Approved Supplier List (ASL). Lastly, the team identified that the block on Form F78 (used to document NCRs) that states "Action required to prevent reoccurrence" was circled as "Yes," yet a CAN was not issued even though form F78 indicates that a CAN shall be issued if "Yes" is circled. The team identified several additional NCRs where CANs were not generated even though "Yes" was circled. The failure of Croft personnel to follow procedure CAP 5-06, as well as the procedure governing procurement of items through the ASL, is considered a non-compliance with 10 CFR 71.111, "Instructions, procedures, and drawings," that states, in part, that "the CoC holder or applicant for a CoC shall prescribe activities affecting quality by documented procedures and shall require that these procedures be followed."

An observation was noted with regard to Croft's failure to implement a statement from their QAPD Manual submittal to the NRC. Specifically, in Section 71.131, "Non-conforming material,

parts or components," Croft stated, in part, that "Non-conforming items are identified as use-as is, reject, repair, or rework" and that "the disposition of items as use-as-is or repair includes technical justification." Contrary to these statements, the team identified that the term "rework" is not defined nor addressed in CAP 5-06 and that the term "concess" is used in lieu of "use-as-is." The team also identified that many of the NCRs that were dispositioned as "concess" (equivalent to "use-as-is") did not have any technical justification listed on the associated form F78.

Other issues identified by the team, during the NCR review, requiring resolution by Croft included:

- Two different versions of NCR 285; the issue in both versions was the same, but the proposed corrective action sections were different, yet both versions were signed by Design, Licensing, Productions, and Quality Assurance personnel apparently without questioning the duplication. The team identified this as a concern with regard to the control of quality records.

- NCRs 276 and 280 were marked as cancelled, yet nothing in CAP 5-06 describes a process for cancelling NCRs.

- NCR 278 stated "Yes" for both the "concess" and "repair" blocks and was also missing a required signature.

- While most NCRs were numbered sequentially, several instances were noted where NCRs were numbered otherwise, such as NCRs 284/1 and 284/2 and 271/1, 271/2 and 271/3. Each NCR was different and were not revisions of the base NCR number. CAP 5-06 does not address the numbering method to be used for NCRs.

- Open NCRs 284/1 and 272/3 referred to CAN 364 yet the CAN was closed and did not deal with the issue identified in the NCRs.

- The team noted that neither the CAN form nor the NCR form have provisions for the evaluation of documented problems for regulatory reporting requirements such as those of 10 CFR Part 21.

2.2.3 Conclusions

Overall, the team assessed that Croft's controls on non-conformance controls and corrective actions were not adequate in addressing the applicable requirements of 10 CFR Part 71, Subpart H.

2.3 Documentation Controls/Records

2.3.1 Scope

The team reviewed applicable instructions, procedures, and drawings to determine if controlled documents, including changes, were reviewed for adequacy, approved for release, and distributed and used at the location where the prescribed activity is performed.

2.3.2 Observations and Findings

The team reviewed Croft procedures CAP 1-08, "Archiving" as well as CAP 5-03, "Manufacturing Records," and determined that procedural guidance was lacking for determinations regarding the generation of quality related records and their retention periods. More specifically, the procedures do not contain enough detail to assure compliance to the requirements set forth in 10 CFR Part 71 quality record retention program and the requirement as stated in the NRC's Quality Assurance Program Approval for Radioactive Material packages No. 0939, Revision 0, dated January 31, 2008. In addition, the team noted that Croft procedures relating to Information Technology (IT) and electronic databases, that contain quality information (i.e., ASL, Corrective Action Notification, Measuring and Test Equipment, Procurement Controls, etc.) are non existent.

Documents Reviewed:

- Croft Proposal No. C032907, 4/2007, Proposal for LS & HS SAFEKEG Packages for MURR
- Containment Vessel Drawing Nos. 1C-6050(LS) and 1C-5950(HS) - Draft
- MURR Purchase Order No. C0000045160, dated 9/28/2007, "Shipping Containers for Radioisotopes According to Croft Proposal No. C032907"
- Project Quality Plan No. PQP060810-PM-ADDM1, "Project Management"
- Project Quality Plan No. PQP060810-LIC, "Licensing"
- Manufacturing Specification Plan, MSP No. 083, Revision B, "Flask Design No. 2993"
- CTR 2004/07, Issue A, "Design review of SAFEKEG Packages 2816C and 2816E"
- CAP 1-04, "Forms"
- CAP 1-08, "Archiving"
- CAP 2-01, "Contract Review"
- CAP 2-03, "Project Control"
- CAP 2-04, "Project Specifications"
- CAP 3-02, "Design Reviews"
- CAP 3-03, "Design Control"
- CAP 4-04, "Modification to Drawings"
- CAP 5-03, "Manufacturing Records"
- CAP 5-14, "Graded Approach to Quality"
- CAP 10-01, "Competent Authority Applications"
- CAP 10-04, "Modification to Certification for Croft Associates Approved Packages"
- CAP 10-05, "Approval of Croft Package Design"
- CAP 10-07, "Modifications to Competent Authority Applications"

2.3.3 Conclusions

The observations represented a non-conformance with regard to the requirements of 10 CFR 71.135 in that CAP 2-03 and CAP 5-03 do not adequately address control of records pertaining to the use of the package for shipment of radioactive material consistent with the regulation.

Overall, the team assessed that Croft's project controls specific to quality organization was not adequate in addressing the applicable requirements of 10 CFR Part 71, Subpart H.

2.4 Audit Program

2.4.1 Scope

The team reviewed Croft's audit program to determine whether plans, procedures, and records were available. The team determined whether Croft scheduled and performed internal QA audits and vendor audits in accordance with approved procedures or checklists; whether qualified, independent, personnel performed the audits; whether Croft management reviewed audit results; and whether Croft took appropriate follow up actions in those areas found to be deficient.

2.4.2 Observations and Findings

The team reviewed CAP 12-01, Issue K, "Audit Procedure" and noted the requirements for the audit of the Croft Quality Management System at least once a year. In addition, the team noted the requirement of the Quality Manager to ensure that audit results are included in the management review required by CAP 12-02, Issue F, "Management Review." The team reviewed QAR 140, Issue A, "Supplier Auditing Guidelines" in regard to completed supplier assessment for Lead Shield Engineering Ltd., performed by a Croft engineer on 11/28/07. The team also reviewed both certifications for an internal lead auditor and a contracted lead auditor and found both to be adequate. The team interviewed the QAM and noted that there was no process for determining proficiency or recertification of lead auditors. The team also noted that the current internal audit schedule was not updated to include the most current status and approval. The team also noted the requirement for development of an external audit schedule and to ensure auditor independence is maintained from the auditor's work. The team determined that no external audit schedule was available for review during the inspection. The team noted that little if any formal audit planning is prescribed in Croft procedures to ensure the proper audit scope would be performed based on the appropriate technical and quality references.

2.4.3 Conclusions

Overall the team assessed that Croft's control of the external audit program and both internal and external audit planning were not adequate in addressing the Croft procedure requirements (CAP 12-01) and applicable requirements of 10 CFR Part 71, Subpart H.

3.0 Design Controls

3.1 Design and Modifications

3.1.1 Scope

The team interviewed selected personnel and reviewed selected design documentation to determine if adequate design controls were implemented. The team reviewed selected drawings, procedures, and records, and observed selected activities to determine if fabrication, test, and maintenance activities met design specifications identified in the SAR and CoC.

3.1.2 Observations and Findings

The team reviewed Croft procedure CAP 5-14, "Graded Approach to Quality," that provides an objective approach in determining applicable QA requirements for supplies of product in connection with Croft's activities in design, licensing and manufacture of packaging that is used for the transport of radioactive material. The team noted that the procedure was developed according to the guidelines set forth in NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," as well as Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material." Further, it was noted that the procedure requires the QA program user to analyze all structures, systems, and components that appear on the packaging drawings, to determine whether their functions or physical characteristics are essential to safety and to document the results of this analysis on a 'Q' list.

The team reviewed selected draft design drawings and procedures to determine the adequacy of Croft's Graded Approach. The team noted a weakness in that Croft has not performed a detailed evaluation and documented a basis for classifying items that are considered important to safety. Instead, the basis for items important to their safety and their classification is that strictly derived from the guidance set forth in NUREG/CR-6407 and RG 7.10 with no other technical documentation for support. Further, procedures lack activities specific to how Croft suppliers are approved for quality class A and B items or services specifically commercial grade items that are dedicated for the intended service.

The team reviewed Croft procedure CAP 3-03, "Design Control," that requires a design specification that states function, performance, environment, material restrictions, cost limits, and standards and regulations to be applied and that the extent of the design specification depends on the complexity and the function of the items to be designed. Further, Croft's procedure requires the Project Manager to ensure that design requirements are properly specified in the design specification. The team reviewed Croft proposal (C032907, dated 4/2007) for the "light shielding" SAFEKEG-LS and "heavy shielding" SAFEKEG-HS designed for use for shipping medical and industrial isotopes from the MURR. The team noted that Croft intends to utilize the proposal as that of a project specification. It was noted during the inspection that Croft has yet to implement certain aspects of its Design Control program such as the generation of a Design Specification, the performance of design reviews and design verification by independent personnel, generation of a Safety Analysis Report for Packagings (SARP), as well as a baseline configuration controlled design and manufacturing drawings. In addition, the team noted procedural weakness prescribing activities that must take place specific to modifications that do not meet NRC approved design, such that, changes in conditions specified in a CoC would require prior NRC approval. The inspection team noted that licensing procedures (Index, Section 10) as written lack sufficient detail for compliance to 10 CFR Part 71 and are based primarily on DOT/UK and DOT (according to 49 CFR) licensing activities. It was noted by the team that as part of the procedures, 10 CFR Part 71 was annotated as a reference statement only and that activities to assure compliance to the regulation were non existent.

3.1.3 Conclusions

The observations represented a non-conformance with regard to the requirements of 10 CFR 71.107 in that implementation of CAP 3-03 has not occurred relative to several design control measures including the generation of a specification, safety analysis report, design reviews, design verification, and design changes. Further, CAP 5-14 does not adequately consider the

complexity and proposed use of the package and its components including a product acceptance program specific to products procured for use in safety-related systems as well as commercial grade products as having been evaluated for suitability for use as safety related.

Overall, the team assessed that Croft's controls on graded approach to quality, including commercial grade dedication, along with several design control measures were not adequate in addressing the applicable requirements of 10 CFR 71, Subpart H.

4.0 Fabrication Controls

4.1 Material procurement

4.1.1 Scope

The team reviewed procedures, selected drawings and records, and interviewed selected personnel, to verify that the procurement specifications for materials, equipment, and services met the design requirements.

4.1.2 Observations and Findings

The team reviewed CAP 6-01, Issue H, "Purchasing," Croft purchase order (PO) 5425id, for the purchase and fabrication of Dummy CV Lead (285.72mm X 241.18mm, issued to Lead Shield Engineering Ltd. The team noted a PO requirement to indicate the measuring and test equipment used on the receiving inspection report. Upon review of a sample of receiving inspection reports by the team, two (2) out of three (3) reports did not have the equipment listed as required. The team discussed the missing data with the QAM and found that there was no consequence to the supplier for not meeting the PO requirements. The team also noted that there was no indication of any corrective action or that the requirement was not met in the PO documentation. The team noted that the documented material analysis required for the lead batch was provided by the supplier. The team also reviewed PO 5307 to AS Scientific for the purchase of a single SAFEKEG HS mockup to be manufactured to drawing DL-OC-5817, Issue P3. Both PO reviews indicated that the POs were developed in different formats from the controlled form, F77, Revision 5, as required in CAP 01-04, Issue F, Section 7.

The team reviewed QAR 140, issue A, "Supplier Auditing Guidelines" and interviewed the QAM and a Croft engineer in regard to the purchase of materials as noted earlier under Section 2.3. The QAM indicated that there was no access control to the Approved Suppliers Listing (ASL), an Access database used to determine acceptable suppliers to be used for procurement of quality materials. No access control on the ASL allows for inadvertent changes as well as intentional changes to be made without necessary review and approval. The team reviewed the approved supplier listing and the approved supplier Access database as well as CAP 05-14, Issue A, "Graded Approach to Quality." The team noted from the review that final categorization needed to occur for the SAFEKEG models as well as final consideration as to the qualification of supplier evaluation categorizations and evaluations. The team discussed both areas at length with both the Croft Managing Director and the QAM.

4.1.3 Conclusions

The team determined that there was no process for determining proficiency/recertification for lead auditors. Also noted were only minimum requirements for assessment of

vendors/suppliers and insufficient supplier grading on ASL. The team also noted that no specific procedural guidance was in place on the use of alternate forms and no corrective action initiated for missing equipment on purchase orders.

4.2 Fabrication & Assembly

4.2.1 Scope

The team interviewed personnel and reviewed documentation of fabrication activities affecting safety aspects of the packaging to verify if they were performed in accordance with approved methods, procedures, and specifications.

4.2.2 Observation and Findings

Since no fabrication was occurring during the inspection the team reviewed the Croft CAPs that place controls on fabrication activities. These included:

- CAP 5-01, “Manufacturing Control”
- CAP 5-03, “Manufacturing Records”
- CAP 5-04, “Process Control”
- CAP 5-07, “Sub-contractor Control”

4.2.3 Conclusions

From a procedural standpoint, the team assessed that the CAPs provide adequate control for packaging fabrication activities. However, as actual fabrication processes were not observed during the inspection, the efficacy of the implementation of these CAPs could not be assessed. Such an assessment will be made at such time as the NRC performs an inspection of future Croft 10 CFR Part 71 packaging fabrication activities.

4.3 Tools & Equipment

4.3.1 Scope

The team reviewed selected measuring and test equipment including records and procedures to assure that equipment used in activities affecting quality were properly controlled and calibrated.

4.3.2 Observations and Findings

The team reviewed CAP 7-01, “Calibration” that provides controls over the use of measuring and test equipment (M&TE) and related calibration records for various tools and equipment used at Croft’s facility and at remote locations. The team also interviewed the QAM who provided documentation related to equipment calibration.

The team reviewed the calibration record book as well as the hard-copy index contained in the book as well as an electronic data base of equipment maintained by the QAM. The team confirmed that the hard-copy index in the calibration book was the official index of calibrated equipment. The team noted multiple inconsistencies between the calibrated equipment index and the actual calibration records as well as inconsistencies between these records and the index maintained by the QAM. These issues were discussed with the QAM for corrective action. The team also noted that the QAM’s data base was being used to track equipment not

subject to calibration and it was suggested these items be removed from the index and tracked separately.

The team noted the following observations with regard to improper control of M&TE and inadequacies in the M&TE procedure:

- Appendix 2 of CAP 7-01 indicates that calibrated equipment will be placed in an identified storage location; however, the official calibration index has no provision for formally assigning a storage location. The electronic index maintained by the QAM does record the last known location of equipment based upon periodic surveillance by the QAM, but this is not an official record.

- CAP 7-01 states that equipment that is out of calibration (OOC) shall be quarantined and be affixed with an OOC sticker; however, device Seaward PAT500H that had been OOC since 23 May 2004, was not maintained in quarantine and did not have an OOC sticker affixed to it.

- CAP 7-01, step 7.6, states that calibrated equipment may be withdrawn by completing the Removed Equipment Record; however, the team questioned how this step was being consistently implemented given, as previously noted, that the calibrated equipment index has no provision for recording the official location of equipment. Further, the team identified that a torque wrench that was last noted as being on shelf 1 in the equipment cupboard was not in that location and the nearby Removed Equipment Record sheets had no record of the torque wrench having been removed from the cupboard.

- This led to a larger concern with regard to Croft's ability to maintain a record of calibrated equipment usage so that if equipment is later found to be out of calibration, a record of its usage can be retrieved and reviewed for any potential adverse impact as a result of the out of calibration condition. The team noted that Croft's QAP Description Manual, Section 71.125, paragraph 5, states that "If M&TE is found to be out of calibration, an evaluation is performed and documented regarding validity of inspections or test performed and the acceptability of items inspected or tested since the previous acceptable calibration." The team determined that CAP 7-01 as presently written does not provide a means for implementing this statement. Further, the team identified one instance where a calibrated tool had been used, and later found to be OOC when sent for calibration, where Croft did not document the issue in an NCR or CAN and did not evaluate the situation. This is discussed further in the Maintenance section of the inspection report.

4.3.3 Conclusions

Collectively, the observations represented a non-conformance with regard to the requirements of 10 CFR 71.111 in that CAP 7-01 does not adequately prescribe activities affecting quality in appropriate procedures and where Croft personnel did not follow instructions in CAP 7-01.

Overall, the team assessed that Croft's controls on tools and equipment was not adequate in addressing the applicable requirements of 10 CFR Part 71, Subpart H.

5.0 Maintenance Controls

5.1 Maintenance Activities

5.1.1 Scope

The team interviewed personnel and reviewed documentation of fabrication activities affecting safety aspects of the packaging to verify if they were performed in accordance with approved methods, procedures, and specifications.

5.1.2 Observation and Findings

The team interviewed the QAM and the Croft Project Engineer (currently performing Package maintenance). The team verified required training had been completed by the project engineer for the 2950 model package. The team reviewed the Croft procedures that place controls on maintenance activities. These included:

- CAP 08-01, Issue F, “Control of Transport Packaging Received for Maintenance”
- MIS 014, Issue B, “Periodic Maintenance and Inspection Schedule”
- CSP-046, Issue D, “Serviceability Checks for Packaging Design No: 2950

During interviews the team noted that the Croft Project Manager identified the use of the torque wrench RS.4959. The team reviewed both the certificates of calibration for both the before calibration check and the after torque wrench calibration by R.S. Calibration (Croft’s Calibration and Repair Service). The team noted that R.S. Calibration was identified on the Croft ASL, though not specifically for calibration services. The inspector also noted that the before calibration checks indicated that the torque wrench was out of tolerance as returned for calibration. When the QAM was questioned regarding what corrective action was initiated, the response was no corrective action was initiated. The team noted that no action had been taken to return to jobs/tasks that the torque wrench had been used on to determine the need for re-torquing.

5.1.3 Conclusions

Overall, the maintenance activities performed and reviewed by the team were acceptable. The observation by the team that the control of measuring and test equipment did not meet Part 71 requirements is addressed elsewhere in the report.

6. Meetings

On May 14, 2008, the team conducted a entrance meeting with Croft personnel. On May 20, 2008, an exit meeting was held where the inspection findings were presented to Croft management.

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FROM: David Pstrak

SUBJECT: INSPECTION REPORT 71-00939/2008201

REMARKS: This report is the result of an May/08 inspection of Croft Associates Ltd..

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