January 7, 2009

Dr. Robert Vaughan
Croft Associates, (UK) Limited
F4 Culham Science Center
Abingdon
Oxfordshire, England, OX14 3DB

SUBJECT: U. S. NUCLEAR REGULATORY COMMISSION (NRC) INSPECTION REPORT NO. 71-0939/2009-201 AND NOTICE OF VIOLATION

Dear Dr. Vaughan:

This letter refers to the team inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on December 7-10, 2009, at the Croft Associates, (UK) Ltd. (Croft) facility at the Culham Science Center, Abingdon, Oxfordshire, England. The purpose of the inspection was to assess Croft's progress in addressing concerns identified in the May 2008 NRC inspection of Croft's NRC-approved Quality Assurance (QA) program in that the 2008 inspection identified that Croft's QA program, as implemented at that time, did not meet the NRC's 10 CFR Part 71 QA program requirements. Croft is currently seeking an NRC Certificate of Compliance (CoC) approval for two packaging designs and plans to commence fabrication in early 2010. The enclosed report (Enclosure 1) presents the results of this inspection.

With respect to the inspection results, the NRC inspection team assessed that, overall, Croft adequately addressed the concerns identified in the 2008 inspection and that Croft's NRC-approved QA program, as presently developed and implemented, adequately meets the QA requirements of 10 CFR Part 71; however, the team determined that two issues identified in the 2008 inspection were not properly addressed. The team also determined that Croft's plans for packaging fabrication need further development and strengthening, particularly with regard to Croft's QA oversight plans and the commercial grade dedication process.

Based on the results of this inspection, the NRC has determined that one (1) Severity Level IV violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) (Enclosure 2) and the circumstances surrounding it are described in detail in the subject Inspection Report. The violation is being cited in the Notice because it 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. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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. 71-0939

Enclosure: 1) NRC Inspection Report No. 71-0939/2009-201
2) Notice of Violation (Notice)

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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:	71-0939
Report:	71-0939/2009-201
Certificate Holder:	Croft, Inc. (UK) Ltd. F4 Culham Science Center Abingdon Oxfordshire, England, OX14 3DB
Date:	December 7-10, 2009
Inspection Team:	Jim Pearson, Team Leader, SFST Rob Temps, Senior Inspector, SFST Earl Love, Safety Inspector, 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

EXECUTIVE SUMMARY

On December 7-10, 2009, the U. S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Croft Associates, (UK) Ltd. (Croft) facility at the Culham Science Center, Abingdon, Oxfordshire, England. The purpose of the inspection was to assess Croft's progress in addressing concerns identified in the May 2008 NRC inspection of Croft's NRC-approved Quality Assurance (QA) program in that the 2008 inspection identified that Croft's QA program, as implemented at that time, did not meet the NRC's 10 CFR Part 71 QA program requirements. Croft is currently seeking an NRC Certificate of Compliance (CoC) approval for two packaging designs and plans to commence fabrication in early 2010.

With respect to the inspection results, the NRC inspection team assessed that, overall, Croft adequately addressed the concerns identified in the 2008 inspection and that Croft's NRC-approved QA program, as presently developed and implemented, adequately meets the QA requirements of 10 CFR Part 71; however, the team determined that two issues identified in the 2008 inspection were not properly addressed. The team also determined that Croft's plans for packaging fabrication need further development and strengthening, particularly with regard to Croft's QA oversight plans and the commercial grade dedication process.

Based on the results of this inspection, the NRC determined that one (1) Severity Level IV violation of NRC requirements occurred.

REPORT DETAILS

1.0 Inspection Scope and Background

In early 2008, Croft was granted an NRC 10 CFR Part 71 QA Program Approval as a prerequisite to its submittal of a Type B radioactive material packaging design (identified as SAFKEG-LS and SAFKEG-HS) for which it is seeking an NRC Certificate of Compliance. The two SAFKEG packages are expected to replace the U. S. Department of Transportation (DOT) specification containers (6M & 20WC-1) which will become obsolete. The SAFKEG models will be used for transportation of medical and industrial isotopes from the University of Missouri Research Reactor (MURR).

An initial inspection of Croft's QA program implementation was conducted by the NRC in May 2008. With respect to those inspection results, the NRC assessed that, overall, as developed and implemented at that time, Croft's QA program and procedures did not meet the QA requirements of 10 CFR Part 71. The team identified multiple examples where Croft personnel were not following QA procedures. In other instances, QA procedures did not contain sufficient details with regard to quality activities, and QA procedures did not support requirements in 10 CFR Part 71, Subpart H. Some of these examples also did not meet the criteria of the QA Program Description submitted to the NRC that formed the basis of the NRC's approval of the Croft QA program.

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
CAP	Croft Associates Procedure
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
CP	Controlled Procedure
CV	Containment Vessel
DOT	U. S. Department of Transportation
IT	Information Technology
ITS	Important to Safety
MSP	Manufacturing Specification Plan
M&TE	Measuring and Test Equipment
MURR	Missouri University Research Reactor
NRC	U.S. Nuclear Regulatory Commission
OOC	Out Of Calibration
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 December 7, 2009, to present the scope and objectives of the NRC inspection. On December 10, 2009, the NRC held an exit meeting with Croft to present the final inspection results. The individuals present at the entrance and exit meetings are listed below in Table 1.

Table 1
Entrance and Exit Meetings Attendance

NAME	AFFILIATION	ENTRANCE	EXIT
Jim Pearson	NRC	X	X
Robert Temps	NRC	X	X
Earl Love	NRC	X	X
Rob Vaughan	CROFT	X	X
Rodney Clayton	CROFT	X	X
Norman Jorgenson	CROFT	X	X
Don Olson	Columbiana Hi-Tech		X

2.0 Management Controls

2.1 Nonconformance Controls

2.1.1 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 from the 2008 NRC inspection were proper and completed in a timely manner.

2.1.2 Observations and Findings

The team reviewed CAP 5-06, "Product Non-Conformance Control," and 12-03, "Corrective Actions," as well as associated forms QF237, "Corrective Action Note," QF176, "Product Deviation Request," and QF078, "Non-Conformance Report," used in conjunction with the CAPs. The team noted that changes were made in these procedures to address issues identified during the 2008 inspection. The team also reviewed various completed Non-Conformance Reports, Product Deviation Requests, and Corrective Action Notices, and noted that they were all properly filled out and contained required signatures and technical justifications where required. The team did not identify any repeat issues from the 2008 inspection with regard to the manner in which these documents were processed.

The team also reviewed two new procedures developed by Croft; procedures QAG006, "Reporting of Conditions Adverse to Quality to US NRC," and CAP 05-17, "Conditions Adverse to Quality." The first procedure adequately addresses reporting of issues to the NRC under the provisions of 10 CFR Part 21. The second procedure addresses the determination of what issues should be considered as a condition adverse to quality (CAQ) and any associated reporting requirements to various regulatory bodies depending upon to which level the CAQ is classified.

During the 2008 inspection, the NRC identified a finding related to CAP 12-03 in that the procedure failed 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." During the current inspection, the team identified that Croft's corrective action procedures still do not address the term SCAQ and therefore do not meet 10 CFR 71.133 requirements nor statements made in Croft's Quality Assurance Program Description Manual (QAPDM) submitted to the NRC. Croft's failure to properly address this issue after its identification in the May 2008 NRC inspection represents a violation of 10 CFR 71.133, "Corrective action," that states, in part, that an applicant for a Certificate of Compliance (CoC) shall establish measures to assure that conditions adverse to quality are promptly identified and corrected. This example is one of two cited in the attached Notice.

2.1.3 Conclusions

The team assessed that Croft's response to issues identified in the 2008 NRC inspection were adequate, and that overall, Croft's controls for non-conformances and corrective actions are now adequate in addressing the applicable requirements of 10 CFR Part 71, Subpart H. One exception, which is cited in the attached Notice, is Croft's failure to procedurally address how

significant conditions adverse to quality are defined and processed in the corrective action program.

2.2 Documentation Controls/Records

2.2.1 Scope

The team reviewed applicable instructions, procedures, and drawings to assess the adequacy of Croft's corrective actions to issues identified from the NRC inspection in 2008.

2.2.2 Observations and Findings

The team reviewed a sample of Croft's procedures and determined that procedural guidance was adequate for determinations regarding the generation and control of quality related procedures and records and their retention periods in regard to the requirements set forth in 10 CFR Part 71, Subpart H. The observations identified during the 2008 inspection have been corrected in that the requirements of 10 CFR 71.135, "Quality Assurance Records," contained in CAP 2-03, "Project Control," and CAP 5-03, "Manufacturing Records," now adequately address control of records pertaining to the use of packages for shipment of radioactive material consistent with NRC regulations. In addition, Croft addressed the 2008 concerns regarding QA database management. The team determined that requirements for database control are now adequately addressed in QAG 005, "Electronic Backup," WI 05-15, "CAN Database User Instructions," WI 06-07, "Approved Supplier Database User Instructions," and WI 12-05, "CAR Database User Instructions."

2.2.3 Conclusions

Overall, the team assessed that Croft's corrective actions to the issues identified in the 2008 inspection were proper and that document and record controls specific to the quality organization now adequately address the applicable requirements of 10 CFR Part 71, Subpart H.

2.3 Audit Program

2.3.1 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.

2.3.2 Observations and Findings

The team reviewed CAP 12-01, "Audit Procedure," and noted the requirement 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, "Management Review." The team also reviewed the qualification for an internal lead auditor and a contracted lead auditor and found both to be

adequate. The team also noted that the current internal and external audit schedules, on Croft form QF303, were updated to include the most current status and approval. The team noted that audit planning and preparation is now prescribed in Croft procedures to ensure the proper audit scope is performed based on appropriate technical and quality references. The team reviewed Croft procedure QAG 007, "US Quality Source Surveillance," which was (recently) specifically developed for use during source surveillance of suppliers in the United States, including Croft's potential fabricator of the SAFKEG transportation packagings. The team also reviewed a recent internal audit of Croft Associates and a recent desktop audit of Columbiana Hi-Tech as a possible fabricator to be used by Croft.

2.3.2 Conclusions

Overall, the team assessed that Croft's control of the audit process has improved, since the last NRC inspection, due to recent procedure enhancements. The team noted both internal and external audit planning and scheduling were adequate in addressing both 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 Safety Analysis Report (SAR) and CoC.

3.1.2 Observations and Findings

The team reviewed Safety Analysis Report (SAR), CTR 2008/10, Revision 0, dated July 2009, along with selected design drawings relating to the SAFKEG-LS Design, No. 3979A (NRC Docket No. 71-9337) and preliminary SAFKEG-HS design drawings . The team noted that the SAFKEG-LS design drawings adequately detailed the package including nominal dimensions and the major design features including classification of components according to importance to safety.

The team reviewed various manufacturing specifications, along with design review reports and verification reports for regulatory compliance and determined that design, quality, and technical requirements for materials, fabrication, welding, inspection, examination, and testing for the fabrication of the package were adequate.

The team reviewed Croft's design change control process and verified adequate procedural controls concerning design changes using design control measures equal to those of the original design. In addition, the team noted that Croft now has procedural controls and sufficiently detailed procedures to ensure that any packaging design changes, or change in conditions specified as part of the CoC, requiring NRC approval are identified as such.

The team noted, with regard to the design of energy absorbing features (cork) and containment sealing (O-rings), that Croft's procedures describing the commercial grade dedication process

are inadequate. Croft has classified outer, top and inner cork, along with inner containment seals as Important to Safety (ITS) Category A components. By definition, ITS Category 'A' items require the highest level of assurance of their quality and Croft plans to purchase these items as commercial grade and then upgrade them to ITS Category 'A' through commercial grade dedication. The team noted that Croft's written procedures are not prescriptive in ensuring adequate design control measures and the need for verification of quality when using commercial grade dedication.

The team noted that Croft's commercial grade dedication process was determined to be deficient in the 2008 inspection and that Croft's corrective actions to this issue since then were inadequate. Croft's failure to properly address this issue after its identification in the May 2008 NRC inspection represents a violation of 10 CFR 71.133, "Corrective action," that states, in part, that an applicant for a Certificate of Compliance (CoC) shall establish measures to assure that conditions adverse to quality are promptly identified and corrected. This example is one of two cited in the attached Notice.

The team reviewed Croft's change control process involving modifications to drawings resulting from a previously 'as-built' package as part of the overall transition from design to production. Specifically, the team reviewed tested/as-built drawings, production drawings and licensing drawings, as well as modification reports, corrective action notices, project review forms, project deviation requests, and change control records, as part of Croft's controls specific to incorporating changes to the base line design as a result of production enhancements applicable to the SAFKEG-LS Package. The team noted Croft's compliance to detailed work instructions and documents for initiating, approving, and completing modifications to drawings. No concerns were identified.

3.1.3 Conclusions

With the exception of procedures for the commercial grade dedication process, the team determined that, overall, Croft has adequate procedures and controls in place governing the implementation of their QA program for 10 CFR Part 71, Subpart H, design control and modification activities.

4.0 Fabrication Controls

4.1 Material procurement / Fabrication & Assembly

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

Since no fabrication or procurement was occurring during the inspection the team reviewed Manufacturing Specification Plans (MSPs) as well as a Controlled Procedure (CP) to verify specifications for materials, equipment, and services were adequate to complete fabrication, welding, testing, and inspection in accordance with established design requirements. These included:

- MSP-154, Issue C, Containment Vessel (CV)
- MSP-155, Issue B, SAFKEG-LS Packaging
- MSP-156, Issue B, Keg Assembly
- MSP-169, Issue A, Insert Assembly
- CP-373, Issue C, Helium Leak Testing During Manufacturing of CV

The team assessed that the MSPs provide adequate quality control and technical requirements to be met when manufacturing and testing activities occur. The team noted controls were appropriately applied for records to be generated as well as the requirements necessary to complete fabrication, welding, and inspection in accordance with SAR requirements and the American Society of Mechanical Engineers Boiler and Pressure Vessel Code, as applicable.

4.1.3 Conclusions

The efficacy of these documents will be determined at such time as the NRC performs an inspection of fabrication activities for the SAFEKEG packagings.

4.2 Tools & Equipment

4.2.1 Scope

The team reviewed selected measuring and test equipment including records and procedures to determine if concerns from the May 2008 NRC inspection were adequately addressed.

4.2.2 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 noted that CAP 7-01 had been revised and significantly simplified since the 2008 inspection. However, in doing so, guidance on the handling of out of calibration equipment was removed. Also, the procedure does not specifically require that calibration stickers placed on equipment contain the next calibration due date as described in Section 71.125 of the Croft QAPDM. Croft stated these observations would be addressed through their corrective action program. The team determined that the revised CAP 7-01 addressed a concern from the May 2008 NRC inspection in that it now provides sufficient controls for recording 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.

4.2.3 Conclusions

Overall, the team assessed that Croft's actions in responding to the May 2008 inspection M&TE issues were adequate and that Croft now complies with the applicable requirements of 10 CFR Part 71, Subpart H.

5. Meetings

On December 7, 2009, the team conducted an entrance meeting with Croft personnel. On December 10, 2009, an exit meeting was held where the inspection findings were presented to

Croft management. The team confirmed with Croft management that no proprietary information was discussed at these meetings.

NOTICE OF VIOLATION

Croft Associates, (UK) Ltd. Docket 71-0939
Abingdon, Oxfordshire, England

A. 10 CFR 71.133, "Corrective action," states, in part, that an applicant for a Certificate of Compliance (CoC) shall establish measures to assure that conditions adverse to quality are promptly identified and corrected. Contrary to this requirement, during an inspection conducted December 7 – 10, 2009, the NRC identified the following instances in which Croft, an applicant for a CoC, did not implement appropriate measures to correct conditions adverse to quality identified during an NRC inspection conducted in May 2008. Specifically:

1. Croft did not implement adequate corrective action to define what significant conditions adverse to quality are and how they are to be processed, and

2. Croft did not implement adequate corrective action to provide proper procedural guidance for controlling the commercial grade dedication process.

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, Croft Associates, (UK) Ltd., is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to David W. Pstrak, Chief, Rules, Inspections, and Operations Branch, Division of Spent Fuel Storage and Transportation, 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 to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. 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 from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), http://www.nrc.gov/NRC/ADAMS/index.html to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, (the Public Electronic Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted 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 2.790(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.

Dated this 7th day of January 2010.