



SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER: Croft Associates Limited (Croft) Building F4, Culham Science Centre Culham, Abingdon Oxfordshire, OX14 3BD, United Kingdom		2. NRC/REGIONAL OFFICE Headquarters U. S. Nuclear Regulatory Commission Mail Stop 3WFN 14C-28 Washington, DC 20555-0001	
REPORT NUMBER(S) 71-0939/2019-201			
3. CERTIFICATE/QAP DOCKET NUMBER(S) 71-0939, 71-9337, and 71-9338	4. INSPECTION LOCATION Oxford Engineering Limited Abingdon, Oxfordshire, UK	5. DATE(S) OF INSPECTION January 14 - 18, 2019	

CERTIFICATE/QUALITY ASSURANCE PROGRAM HOLDER:

The inspection was an examination of the activities conducted under your QAP as they relate to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your QAP Approval and/or Certificate(s) of Compliance. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- ☐ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☒ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.



One Non-cited violation(s) was/were discussed involving the following requirement(s) and Corrective Actions(s):
Title 10 of the Code of Regulations (10 CFR), Part 71.111, "Instructions, procedures, and drawings," requires, in part, that the certificate holder shall prescribe activities affecting quality by documented procedures of a type appropriate to the circumstance and shall require that these procedures be followed. Contrary to, as of January 17, 2019, Croft did not follow procedure CAP 06-08, Step 2.2.1. Specifically, Step 2.2.1 of CAP 06-08, states, in part that a Quality A supplier shall have a current assessment and approval to an appropriate quality system standard, which meets the requirements of 10 CFR Part 71, Subpart H. In this case, Oxford Engineering (Croft's Quality A Supplier) did not have an adequate internal audit qualification program in place for qualifying internal auditors. Croft entered this violation into their corrective action program for resolution.
- ☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
CERTIFICATE/QAP REPRESENTATIVE	Steve Ralls / Quality Manager		2/2/19
NRC INSPECTOR	Marlone Davis / Team Lead		2/22/19
BRANCH CHIEF	Christian Araguas		3/1/19

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder	Croft Associates Limited (Croft) Building F4, Culham Science Centre Culham, Abingdon Oxfordshire, OX14 3BD, United Kingdom
Licensee/Certificate Holder contact	Mr. Stephen Ralls, Quality Manager
Docket Nos.	71-0939, 71-9337, and 71-9338
Inspection Report No.	71-0939/2019-201
Inspection Date(s)	January 14 - 18, 2019
Inspection Location(s)	Oxford Engineering Limited (OEL) Abingdon, Oxfordshire OX14 1AU United Kingdom
Inspectors	Marlone Davis, Team Leader, Senior Inspector Jon Woodfield, Safety Inspector Jeremy Tapp, Safety Inspector
Summary of Findings and Actions	During the week of January 14 through 18, 2019, the U.S. Nuclear Regulatory Commission (NRC) conducted a team inspection of the implementation of Croft's NRC-approved Quality Assurance Program for the fabrication of the SAFKEG-Heavy Shielded (HS) transportation packaging. The team identify one violation of NRC requirements in management control. The team dispositioned the violation as a Severity Level IV non-cited violation (NCV), which was consistent with Section 2.3.2 of the NRC Enforcement Policy. Croft and OEL acknowledged the information presented and documented the violation in a corrective action program for resolution.
Lead Inspector Signature/Date	Marlone Davis  For M. Davis
Inspector Notes Approval Branch Chief Signature/Date	Christian Araguas 

Inspector Notes

On January 14 through 18, 2019, a team of NRC inspectors conducted inspection activities at Oxford Engineering Limited (OEL) to verify and assess Croft Associates Limited (Croft)'s compliance with Title 10 of the *Code of Regulations* (10 CFR) Part 71 requirements for the design, modification, fabrication, assembly, testing, and procurement of the SAFKEG-Heavy Shielded (HS) transportation packaging. Oxford Engineering is under contract with Croft to fabricate important to safety (ITS) components and subcomponents of eighteen SAFKEG-HS. Croft is also the designer of the SAFKEG-Light Shielded (LS) transportation packaging. The certificate of compliance (CoC) associated with both are as follows:

Model #	Docket#	Package Identification#	Revision
3979A (SAFKEG - LS)	71-9337	USA/9337/B(U)-96	3
3977A (SAFKEG – HS)	71-9338	USA/9338/B(U)-96	2

Previously, on May 22-26, 2017, an NRC inspection team performed the most recent inspection of Croft at its main office at the Culham Science Center near Abingdon, England (ML17248A478). Overall, the team assessed focused on whether Croft had implemented their quality assurance program in the areas of Management, Design, Fabrication, and Maintenance Controls. However, the team identified two non-cited severity level IV violations. The two violations were as follows: Croft failed to maintain traceability of commercial grade materials, which were dedicated and used to fabricate Important-to-Safety Category A components; and Croft Associates Procedures 05-17 and 12-03 did not provide sufficient guidance as to how to identify the cause of a Significant Condition Adverse to Quality and the corrective action necessary to preclude repetition. The NRC will follow-up on those violations during the next corporate inspection. On November 8-10, 2016, an NRC inspection team performed the last fabrication inspection of Croft at Columbiana HI Tech (CHT) in Kernersville, NC. CHT was under contract to Croft for the fabrication of ten SAFKEG - HS packaging. The inspection team assessed that Croft's oversight of fabrication activities using their NRC approved QA program was adequate. The team did not identify any violations during the inspection.

The purpose of this inspection activity is to assess Croft's compliance with 10 CFR Parts 21 and 71, and to verify that Croft provides adequate oversight of fabrication activities occurring at OEL. The NRC inspection team verified the adequacy of planned activities relate to fabrication, assembly, testing, procurement, repair, and maintenance of the SAFKEG-HS transportation packaging. Specifically, the team verified that activities conducted under both Quality Assurance Programs (QAP) were in accordance with commitments and requirements specified in the SAFKEG-HS's CoC, Safety Analysis Report for Packaging's (SARP), NRC-approved QAP for transportation of radioactive material packages, and more importantly 10 CFR Part 71 requirements. The team conducted the inspection activity requirements in accordance with NRC Inspection Procedure 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packaging". The team observed fabrication activities and reviewed selected procedures and records and interviewed personnel. The team discussed the results of this inspection in a final exiting meeting on January 18, 2019 at the completion of the inspection week. The team identify one violation of NRC requirements, 10 CFR 71.111, in management control. The team described the violation in Section 2.09 of the inspector notes for this report.

The team dispositioned the violation as a Severity Level IV non-cited violation (NCV). The team decided to treat this Severity Level IV violation as a NCV, which is consistent with Section 2.3.2

of the NRC Enforcement Policy. Croft and OEL acknowledged the information presented and documented the violation in a corrective action program for resolution.

INSPECTOR NOTES: AS DESCRIBED BELOW, THE TEAM PERFORMED AND DOCUMENTED APPLICABLE PORTIONS OF 02.02 THROUGH 02.10 OF INSPECTION PROCEDURE (IP) 86001 USED FOR THIS INSPECTION

02.02 Verify that the CoC holder's activities related to transportation packagings are being conducted in accordance with the Certificate of Compliance, as well as the NRC approved QAP (reference Regulatory Guide 7.1 0), and that implementing procedures are in place and effective.

The NRC inspection team reviewed Croft Associates' Limited (Croft) quality management system (QMS) and associated implementing procedures to verify how Croft implemented its program in accordance with the NRC Certificate of Compliance (CoC) for radioactive material packages, and NRC-approved Quality Assurance Program (QAP) at Oxford Engineering Limited (OEL). The team reviewed Croft's 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. Croft, the holder of the CoC and designer of the SAFKEG, contracted with OEL to fabricate the SAFEKEG HS 3977A transportation packaging. The team also reviewed OEL quality manual CM/01 and related implementing procedures to develop an understanding of how OEL performed quality activities for fabricated components.

In addition, the team reviewed OEL's documentation control program to assess the effectiveness of controls established for the approval, issuance, revision and use of quality documents. The team reviewed CP/01, "Document and Data Control Procedure," Issue 1. The team interviewed personnel responsible for the program to ensure they were knowledgeable of the program requirements and were implementing the program as required. The team verified for one works order reviewed that no changes were made to it after it had received customer approval, as required. The team also reviewed CP/02, "Control of Records Procedure," Issue G2. The team discussed with document control and quality assurance personnel how the applicable regulatory and procedural requirements for quality record control were being implemented by OEL to ensure they were being performed as required. Specifically, the team discussed document retention and record storage requirements with document control and responsible personnel.

The team assessed that Croft and OEL quality assurance programs and implementing procedures provided adequate guidance for conducting fabrication activities and processing quality document approvals to manufacture as necessary. For the work orders reviewed, the team assessed that the quality documents were approved per procedure by appropriate personnel and the most current version was available for use on the shop floor. The team determined the document control and QA record procedures were adequate and being followed by OEL personnel. The team also noted that OEL only keeps electronic records as quality records except for radiography film. The electronics records are backed up on virtual servers and then to the cloud every night. Radiography film is stored in fire rated cabinets. The team noted there is only one original paper copy of a works order available on the shop floor and all other quality documents are electronic and uncontrolled if printed. The team did not identify any major concerns in the documentation control and records management areas.

02.03 Verify that provisions are in place for reporting defects which could cause a substantial safety hazard, as required by 10 CFR Part 21.

The team reviewed OEL procedure CP/116, "Reporting of Defects and Noncompliance in Accordance with 10 CFR Part 21," Issue 1. The team requested a list of 10 CFR Part 21 (or Part 21) evaluations and notifications associated with the fabrication of the SAFKEG-HS and interviewed personnel to verify if they were familiar with the implementing procedure CP/116. The team also reviewed OEL's posting of Part 21 requirements in accordance with the 10 CFR 21.6, "Posting requirements."

The team verified that the OEL procedure met the requirements of the Part 21 regulations and takes responsibility for the reporting requirements, as necessary. The team noted that OEL posted the current Part 21 regulations and CP/116 but were not required to because OEL is not physically located within the United States. There were no closed or open Part 21 reports related to the Croft SAFKEG work. The team did not identify concerns regarding Part 21 program controls or implementation at OEL.

02.04 Interview selected personnel and review selected design documentation to determine that adequate design controls are implemented.

The team reviewed Section 71.107, "Design Control," of the Croft Quality Assurance Program Description Manual, QAR 144 Issue E. In addition, the team specifically reviewed the following Croft and Oxford Engineering procedures associated with design control to verify that they were being properly implemented, as applicable:

- CAP 02-02, Quality Plan, Issue J
- CAP 02-03, Project Control, Issue M
- CAP 02-04, Project Specifications, Issue E
- CAP 02-05, Project Plan, Issue D
- CAP 03-03, Design Control, Issue I
- CAP 05-07, Sub-contractor Control, Issue H
- SP 02-02, Design – Modification to Existing Design, Issue A
- SP 02-03, Design Validation – Hardware Inspection, Issue A
- WI 10-08, Packaging Serial Numbers, Issue I
- CP/01, Document and Data Control Procedure, Issue 1
- CP/11, Customer Supplied Material Procedure, Issue C, Revision 5
- CP/25, Compilation and Control of OE Drawings, Issue 6
- PM/28, Company Documentation Dissemination Process, Issue 3

Croft is responsible for the SAFKEG-HS transportation packaging design development and therefore OEL does not have any design authority or design change authority. Croft developed the SAFKEG-HS design/fabrication drawings. Therefore, the team addressed design control by reviewing the design control process between the SAFKEG HS transportation packaging designer Croft and fabricator OEL. The team reviewed Croft's purchase order (PO) PO11549, revision 3 to OEL for the manufacture of SAFKEG-HS components. The PO included references to packaging design/fabrication drawings, specifications, and materials/parts to be supplied by Croft. The HS design/fabrication drawings and specifications were made part of the PO by reference to drawing lists DL-0C-7520 issue C and DL-1C-5950 issue K, which are controlled by revision. If a revision to the drawings and specifications is needed, it will be done through a PO change order to OE. The team reviewed the Croft Project Plan (PP18-02-12-

3977A) titled "Manufacture of 18 HS 3977A Packagings," for compliance with procedure CAP 02-05. The team reviewed Croft's "Review Report Form" dated June 18, 2018 associated with the project and developed in accordance with CAP 02-03. The team reviewed the HS fabrication project Quality Plan QP18-02-12-3977A issue A for compliance with procedure CAP 02-02. The team also reviewed MSP 157, "Manufacturing Specification HS SAFKEG Packaging Assembly Design No. 3977A," Issue G for compliance with CAP 02-04.

Based on this review, the team assessed that both Croft and OEL followed their design procedures, as applicable, to ensure that design/fabrication drawings and any associated specifications and travelers were consistent with the Croft design/fabrication drawings, NRC approved licensing drawings, design requirements, and commitments as documented in the CoC for the SAFKEG-HS. The team did not identify any concerns with the transmittal and design control of Croft design/fabrication drawings to OEL. The team verified that the design and fabrication drawings developed by Croft had received the proper Croft initiator and checker/approver signatures at each revision. The team also verified that OEL had the current drawings and specifications listed on the drawing lists referenced in the PO.

02.05 Review selected drawings, procedures and records, and observe selected activities being performed to determine that design and maintenance activities meet SARP design requirements documented in the CoC

The team evaluated OEL control of the fabrication process through observations, examinations, and personnel interviews in the areas of fabrication and assembly, test and inspection, and familiarity with tools and equipment to determine that design activities met the SARP design requirements documented in the CoC. The team observed the following activities:

- Machining of some of the containment vessel components, and
- Insertion of the depleted uranium and welding of the casing body

The team observed the setup configuration, required programming of the machining equipment, and measurements following the machining evolution. The team also observed welding of the enclosed depleted uranium in the casing body of the SAFKEG-HS.

The team assessed for activities observed that the components met SARP design requirements documented in the CoC following examinations conducted during these inspection activities. However, the team was unable to observe the welding non-destructive testing (NDT) and pressure and helium leakage test because of scheduling delays in the production of the SAFKEG-HS.

02.06: Observe activities affecting safety aspects of the packaging (such as fabrication, assembly, and testing) to verify that they are performed in accordance with approved methods, procedures, and specifications.

The team observed activities affecting the safety aspects of the SAFKEG fabrication, assembly, and testing to verify OEL performed these activities in accordance with approved methods, procedures, and specifications. The team reviewed a representative sampling of work order, drawings, and testing procedures. The team also reviewed purchase order PO 11895id issued to LTS to perform the HS helium leak testing.

Test Control

The team reviewed Section 71.123, "Test control," of the Croft Quality Assurance Program Description Manual, QAR 144 Issue E. The team also reviewed the following Croft procedures associated with testing and inspection to verify that they were being properly implemented, as applicable:

- CAP 09-02, Control of Testing, Issue G
- CP 378, Procedure for Internal Pressure Testing During Manufacture of HS Containment Vessel 3978, Issue E
- CP 372, Procedure for Helium Leakage Testing During Manufacture of HS Containment Vessel 3978, Issue G
- SP 02-04, Design Validation – Hardware Testing, Issue A
- SP 08-01, Testing (new procedure), Issue A
- SP 08-02, Testing (existing procedure), Issue A

OEL will not perform the helium leakage testing of the HS components for Croft. At the time of the inspection, OEL was only responsible for performing the internal pressure testing on the HS containment vessel (CV). Croft contracted with Leak Test Specialists (LTS) from the United States to perform all component leak testing for the SAFKEG-HS units being fabricated by OEL. The team verified that Leak Test Specialists was on the Croft Approved Supplier List as a Category B supplier of services.

Croft plans to have all CVs pressure tested and HS components leak tested after OEL fabricates all the units under contract. Therefore, the team did not witness any pressure or leak testing during the inspection. The team reviewed photos of all the Croft equipment that will be supplied to LTS for its use after its personnel travel to Croft to perform the testing. The team could not check calibration on the equipment since it was located at the Croft facility and not at OEL. The team requested and reviewed the certificate of conformity for the helium gas that will be used to perform the testing.

The team reviewed in detail the Croft testing procedures CP 378 (CV Pressure Testing) and CP 372 (Helium Leakage Testing). The team also reviewed active Croft procedure CP 552, Helium Mass Spectrometer Leak Test Procedure for 3978 and 3980 CVs – Helium Reservoir Technique, issue B. The team found an incorrect issue letter for a reference in the procedure. Croft initialed CAR 148 to address the issue.

Although unable to observe actual testing and review all final testing procedures, the team determined that there was reasonable assurance that all the pressure and leak testing would be adequately performed by knowledgeable and qualified inspectors. The Croft contractor LTS has performed helium leak testing on HS units in the past which also provides increased reasonable assurance that the testing will be performed adequately based on their experience.

Measuring and Test Equipment (M&TE)

The team reviewed selected measuring and test equipment (M&TE) including records and procedures to assure that equipment used in activities affecting quality were properly controlled and calibrated. The team reviewed OEL's quality procedure PM/06, "Calibration Procedure," Issue 6, which prescribes activities and requirements concerning control and use of M&TE; that calibration occurs to national standards; and actions to take when any piece of equipment is

found out of calibration. The team also interviewed personnel involved in the control of M&TE for use on the shop floor, control of out of calibration equipment, and equipment needing periodic recalibration. The team compared a sampling of M&TE used for recent fabrication and testing activities to the applicable requirements of PM/06. The M&TE selected consisted of a micrometer and weld machine, among others.

The team assessed that PM/06 provided adequate guidance for M&TE calibration and use, and OEL had adequately implemented M&TE calibration, tracking, and determined overall compliance to the requirements. Each equipment selected had current calibration certificates, and were in calibration, as applicable. In addition, the team verified that if the M&TE had been sent offsite for calibration that the calibration service providers were current on OEL's approved supplier list.

02.07 Review selected drawings and records, and interview selected personnel, to verify that the procurement specifications for materials, equipment, and services received by the QA Program holder meet the design requirements

The team reviewed selected drawings and records and interviewed selected personnel to verify that the procurement specifications for materials, fabrication, inspection, and services performed at OEL met design requirements of the SAFKEG-HS. The team also reviewed Croft's processes that addressed procurement, including traceability and receipt inspection, to verify it was being properly implemented at Croft and transmitted to OEL in accordance with implementing procedures. The team reviewed the procurement documents specific to SAFKEG-HS and the following quality procedures:

- CAP 05-01, "Manufacturing Control," Issue M
- CAP 05-18, "Commercial Grade Dedication," Issue E
- CAP 06-08, "Approved Supplier – NRC," Issue F
- CP/12, "Identification and Traceability Procedure"
- CP/23, "Welding Control Procedure"

The team assessed that Croft procured material, equipment, services that met the design requirements for the SAFKEG-HS. The team verified that procurement specifications and receipt documentation including certified material reports met the design specifications, applicable quality procedure requirements, and was traceable throughout the procurement process.

02.08: Review selected records and interview selected personnel to verify that a nonconformance control program is effectively implemented, and that corrective actions for identified deficiencies are technically sound and completed in a timely manner.

The team reviewed Croft's and OEL's non-conformance programs to assess the effectiveness of measures established to control materials, parts, components, and services that have been identified by Croft and OEL as not conforming to specified requirements. The team also reviewed OEL's corrective action program (CAP) to assess the effectiveness of the measures established to identify and correct issues, and if required, prevent recurrence. The team reviewed the following Croft and OEL quality procedures:

- CAP 05-06, "Product Non-conformance Control," Issue P
- PM/11, "NCR Disposition," Issue 5

- PM/02, "Corrective and Preventative Action Process Map," Issue 17

The team assessed that the quality procedures provided adequate guidance for the processing of nonconforming items and corrective actions. The team reviewed a selection of non-conformance reports (NCRs) issued by Croft regarding the SAFKEG project and all NCRs issued by OEL since the start of the SAFKEG work. The review consisted of NCRs with different dispositions such as "use as is", "scrap", and "re-make." The team also toured the facility to verify that OEL controlled the current non-conforming items, as necessary.

The team assessed that the quality procedures being implemented at Croft and OEL provided adequate guidance for the processing of nonconforming items and corrective actions. The team found that no corrective actions had been written by OEL for the SAFKEG project, so none could be reviewed by the team. The team assessed that for the 11 NCRs reviewed, Croft and OEL appropriately evaluated and dispositioned the items. There were three components on the shop floor that had open NCRs and the team verified that OEL had proper controls in place for each. The controls consisted of NCR tags on the components themselves or adequate documentation in the traveler, depending on the status of the NCR for each component.

02.09 Review selected records and procedures, interview selected personnel, and observe selected activities affecting the safety aspects of the packaging to verify that individuals performing activities affecting quality are properly trained and qualified, and to verify that management and quality assurance (QA) staff are cognizant and provide appropriate oversight

The team reviewed selected records and procedures, interviewed personnel for the ongoing fabrication activities of the SAFKEG-HS. The team reviewed applicable procedures and records to assess whether individuals performing quality-related activities were properly trained and qualified. This review also included an assessment of Croft's oversight of OEL management and QA staff. The team sampled training and qualification records for three technicians. The team also reviewed the certification and qualification records for a welder that perform welding on the SAFKEG-HS. The team reviewed the following Quality Procedures based on the fabrication activities observed:

- CP/105, "Shop Floor Programming of Puma and Hicell Lathes"

In addition, the team performed a sample review of certification records for several Quality Control inspectors and test personnel for nondestructive examinations according to the American Society of Nondestructive Testing (ASNT) in the NDE methods of Visual Examinations (VT) and Magnetic Particle (MT) Examinations.

The team assessed that OEL had trained and qualified personnel and used the proper forms to document the qualification records in accordance with implementing procedures. The team also assessed that personnel performed fabrication activities through the observation and review of individual fabrication records. The team determined that personnel were appropriately qualified according to applicable standard requirements.

02.10 Verify that audits of the QAP and activities affecting the safety aspects of the packaging are scheduled, have been performed as scheduled, and that identified deficiencies have been satisfactorily resolved in a timely manner.

The team reviewed OEL's internal audit program and Croft's external audit of OEL as defined in CP/03, "Quality & Environmental System Audit Procedure," Issue I and CAP 06-08, "Approved Supplier - NRC," Issue F, respectively. This review was done to verify that the programs were comprehensive and that OEL and Croft scheduled and conducted audits periodically in accordance with approved procedures. Additionally, the team evaluated whether OEL and Croft performed audits by trained and qualified audit personnel who documented the audit results and assessed deficient areas as a part of the corrective action program. The team reviewed a selection of internal audits performed in 2017 and 2018 as well as the 2017 to 2018 internal audit schedule to verify that they were conducted in accordance with the program as previously defined. The team also reviewed Croft's supplier audit of OEL that qualified them as a supplier ITS Category A components to determine if it met the requirements of CAP 06-08.

The team assessed that OEL performed annual internal audits that covered all applicable quality criteria areas over three years, and one individual performed these audits. The team also assessed that for the internal audits reviewed, they covered a representative sample of OEL's activities in the area being audited, the audit reports were written in a timely manner, and OEL assessed audit findings as a part of the corrective action program as necessary. However, the team noted that in a 2017 internal audit of the audit program, an auditor performed an assessment of 1) their own qualifications and 2) an audit they performed in 2016. The team discussed the apparent lack of objectivity of the auditor with Croft and OEL representatives. The team decided to document this this report as an observation because the audit occurred before Croft approved OEL as a qualified supplier of ITS Category A components.

During the review of Croft's supplier audit report of OEL, QAR number 420, dated August 17, 2018, the team identified that the audit covered all applicable quality criteria, required OEL compliance with 10 CFR Part 71 and ASME NQA-1 where applicable, and utilized a comprehensive checklist to perform the audit. However, during review of the checklist documentation in the area of internal auditor qualifications, the team identified that Croft accepted the international standard used by OEL to qualify the individual, which does not meet the requirements of 10 CFR Part 71 and ASME NQA-1 for a lead auditor or auditor. In addition, the team noted that the supplier audit did not reference a quality procedure or process at OEL for the qualification of internal lead auditors or auditors, and the team found that OEL did not have one in place.

CAP 06-08, Step 2.2.1 states, in part, that a Quality Category A supplier shall have a current assessment and approval to an appropriate quality system standard, for example ISO-9001 or NQA-1. Contrary to the above, Croft assessed OEL to qualify them to encompass the additional requirements of 10 CFR Part 71 and ASME NQA-1, 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", for failure to follow procedures. The team determined this violation to be more than minor because OEL's quality assurance program did not meet all applicable requirements of 10 CFR Part 71, Subpart H or ASME NQA-1. The team evaluated the violation in accordance with Section 2.3 of the NRC Enforcement Policy and characterized it as a non-cited Severity Level IV violation. Croft entered this issue into their corrective action program as CAR Number 147, dated January 16, 2019. The team noted that OEL had not yet performed any internal audits since Croft had qualified them as an ITS Category A supplier.

Overall, the team assessed that the internal audit program was adequately implemented by performing audits with trained and qualified personnel of all applicable aspects of the Quality Assurance Program every 3 years. In addition, the external audit reviewed was adequately performed except in the area of internal auditor qualifications. One Severity Level IV non-cited violation was identified for failure to follow procedure to qualify a supplier to 10 CFR Part 71 and ASME NQA-1 standards for internal auditor qualifications.