

US NRC
Attn: Document Control Desk
Washington
DC 20555-0001
USA

25th November 2022

Reply to Notice of Violation 71-0939 US NRC 9th November 2022

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

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

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

Item 1

Specifically, in 2017, Croft wrote Corrective Action Report (CAR) 136 to address that Croft Associates Procedure (CAP) 12-01, Issue S, Audit Procedure, failed to require a periodicity for internal audits as required by 10 CFR, Section 71.137, "Audits" to ensure all applicable quality assurance criteria are audited on a periodic basis.

However, the actions taken by the CAR did not directly align with the issue and the issue was not corrected.

Response

The initial observation advised to Croft by the NRC team was that the internal audit schedule related to internal procedures and processes and not the specific clauses of 10CFR71 Subpart H. This was always the case since before Croft gained 10CFR71 certification. 14 of the 18 clauses were added to the audit schedule accordingly in 2017 at the request of the Inspection Team. With respect to the periodicity of audits, 10CFR71 does not specify what that period should be. Croft has audited these 14 clauses on an annual basis since then. The procedure, CAP 12-01 revision W, did not specifically state the periodicity of audits since our QMS is dual certified and neither standard (10CFR71 or ISO 9001) specify a 12 month period. The NRC team initially stated that a 12 month periodicity was a mandatory requirement under other NRC guidelines but later conceded that this could not be enforced. Croft acknowledged that some periodicity should be defined and CAP 12-01 has been revised to state: *"Audits shall normally be conducted annually but the audit period may be extended up to a maximum of two years in areas where there is evidence of consistent compliance and conversely may be reduced in areas where there is evidence of repeated non compliance."* This was accepted by the NRC team at the time of the inspection in

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2022. CAR 176 refers to this and is now closed with the action completed.

Item 2

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

Response

CAR 137 was raised to address if a Condition Adverse to Quality had occurred when closing out an NCR. CAR's were not discussed at the 2017 inspection. The corrective action was to include an assessment and to decide if a CAQ had occurred and if it was reportable under 10CFR21 requirements. The guidance for this is provided in procedure QAG006 and not in CAP 05-17 or CAP 12-03. QAG006 has been reviewed by the NRC in the past and found to be acceptable. At the time of the 2017 inspection no reference was made to CAR's by the Inspection Team. It should be noted that both the NCR and CAR processes also address actions that do not result from a failure of any kind but also planned deviations such as concessions or document review and updates. In such cases Croft would not approve anything which would cause a CAQ. The CAR database has been revised to include a root cause analysis requirement to determine if a CAQ has occurred and if it is reportable when a CAR is closed out and CAP12-03 and WI12-05 have both been revised and the database user instructions have been amended. QAG006 issue D remains valid. CAR 174 refers to this and is now closed with the actions completed.

Item 3

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

Response

When Croft performed the Supplier Approval audit against the requirements of NQA-1, records for the previous two years were sampled with respect to internal audits with no adverse findings. The NRC Inspection Team took this back a further year and discovered one instance where the auditor in question, A Lakhani, had, amongst a number of samples, sampled one audit he had himself carried out.

It was acknowledged that the OEL procedure lacked clarity and this was discussed with OEL's Quality Manager. He reviewed 10CFR71 requirements which do not appear to specifically address supplier approval requirements.

Clauses 71.109 Procurement Document Control and 71.115 Control of Purchased Material, Equipment and Services do not state that the suppliers Quality Management System must meet all of the requirements of 10CFR71 and 71.109 ambiguously states "to the extent necessary". OEL initially declined to amend their audit procedure but following intervention at Director level their procedures were reviewed and revised. OEL had disagreed with the NRC findings and initially declined to make the changes to their QMS as requested by CAR 147. There was also the question of how far back do you go when auditing.

After intervention at Director level OEL have provided evidence of training and certification by a recognised body for their two auditors and have revised the procedure CP03 to add the following:

4.1 Formally trained staff, with an appropriate certificate issued by a recognised certification body, who are objective and impartial will carry out audits.

4.2 To ensure independence and impartiality the Auditors shall not sample any previous activities or records for which they are (or were) responsible.

Procedure CP03 was released at issue K on the 2nd August 2022.

CAR 173 refers to this and is now closed with the actions completed.

Item 4

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

Response

CAP12-01 has been revised to reflect that CAR's arising from internal audits will be raised by the Croft Quality Manager as part of the Management Review of audit reports. It was previously the responsibility of the individual auditor and this was not always being done.

CAR 180 refers to this and is now closed with the actions completed.

Conclusion

Croft have now addressed the requirements of the notice of violation. All corrective actions have been implemented and verified and the corresponding CAR's closed.



S P Ralls CQP MCQI
Quality Manager

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

Appendix

CAR's raised by Croft during the inspection:

CAR No	Details	Cause / Actions	Status
170	Possible typographical error in field 36 of MIS049 issue B. Reference to Section 8.2.3.4.3 of the SARP CTR2008/11 should read 8.2.3.6.3.	This was found to be a typographical error when compiling the original document. MIS049 has been revised to correct the error and released at issue C on 3 rd August 2022.	Closed
171	Field 7 of MIS 049 issue B omitted some references to the drawings that are made in the SARP. The MIS is a record of maintenance work carried out in accordance with the SARP and must make the same statements as the sections referenced.	Drawing references were omitted for brevity of the MIS as the drawings were referenced three times in the same section. Drawing references have been reinstated at the request of the NRC inspectors. MIS049 has been revised and released at issue C. The MIS now reads the same as the SARP wrt the cited drawing references.	Closed
172	Internal audit reports do not show a review of the previous audit findings as required by CAP 12-01 para 2.4. Additionally, para 2.2 should contain an instruction to review the previous audit as part of the preparation.	Caused by a Slow deviation in applying the requirements of the procedures. All auditors have been reminded of the requirements and the procedure CAP12-01 has been revised and released at issue W with more explicit instructions on documenting the review.	Closed
173	CAR 147 raised during a previous NRC audit had not been adequately closed off in that the Oxford Engineering procedure, CP03, had not been revised to clarify auditor training and qualification requirements or to clarify the auditor's independence.	OEL disagreed with the NRC findings and initially declined to make the changes to their QMS as requested by CAR 147. After consultation at Director level OEL have revised the procedure CP03 to add the following: 4.1 Formally trained staff, with an appropriate certificate issued by a recognised	Closed

		<p>certification body, who are objective and impartial will carry out audits.</p> <p>4.2 To ensure independence and impartiality the Auditors shall not sample any previous activities or records for which they are (or were) responsible.</p>	
174	<p>CAR 137 raised during a previous NRC audit had not been adequately closed off due to a misunderstanding. The NCR database and form had been revised to require an assessment of whether or not a CAQ had occurred. This requirement had not been applied to the CAR system.</p>	<p>The CAR system did not have a cause analysis as it was intended to be for management systems. However, it was not fully realised that significant breakdowns in the management systems could be a SCAQ in itself.</p> <p>The CAR database has been revised to include a root cause analysis requirement and CAP12-03 and W112-05 have both been revised and the database user instructions have been amended. QAG006 issue D remains valid.</p>	Closed
175	<p>The first four clauses of 10CFR71 subpart H were omitted from the internal audit schedule as they were considered more to be policy requirements than processes. The first four clauses of 10CFR71 subpart H were omitted from the internal audit schedule as they were considered more to be policy requirements than processes.</p>	<p>The original audit schedules had been based on ISO9001 and internal procedures for many years and this had been accepted by NRC inspectors. In 2017 it was requested that we add clauses of 10CFR71 to the audit schedule. The clauses 71.101, 71.103, 71.105 & 71.106 were not included in the schedule for the reasons already stated. These four clauses have now been added to the audit schedule such that all eighteen clauses are audited annually.</p>	Closed
176	<p>CAR 136 raised during a previous NRC audit required the internal audit program to specifically address the clauses of 10CFR71 subpart H. The corrective action added fourteen of the clauses to the audit schedule</p>	<p>10CFR71 does not state a specific period, NRC guidelines state audits 'should' be carried out annually but this is guidance only.</p> <p>Clause 2 of the procedure,</p>	

	which was considered inadequate by the NRC team – see CAR 175. Additionally, the revised procedure did not state a specific period for internal audits.	CAP12-01, has been amended to state that : “Audits shall normally be conducted annually but the audit period may be extended up to a maximum of two years in areas where there is evidence of consistent compliance and conversely may be reduced in areas where there is evidence of repeated non compliance.”	Closed
177	During inspection of the 3977B documentation it was noted that some forms referenced in Croft procedures were not being used. CAP02-02 (quality plan) , 02-04 (project specifications) & 02-05 (project plan) and related forms are no longer used due to the introduction of form QF376 which incorporates all three activities.	The form QF376 has been developed to include project specifications and project plans, it was not realised that the forms from the other two procedures were no longer used. CAP02-02,CAP 02-04 & CAP02-05 have been revised to reflect current practice and use of forms. Obsolete forms have been withdrawn.	Closed
178	WI01-06 Controlled Documents requires revision to reflect current practice which has undergone some minor changes due to the move to electronic documentation e.g. negating the need to ‘rubber stamp’ paper documents.	WI01-06 revised and issued as issue J. This refers to electronic stamping etc as opposed to ‘rubber stamps’ and ‘red ink’.	Closed
179	The 3977B HS package was manufactured ahead of the design approval and issue of a certificate by the NRC. The Project Quality Plan has a field in the project closure section to address manufacture at risk but this needs to be fully documented as to what was reviewed and confirming that the ‘as manufactured’ package complies with the certificate as issued.	This is already covered in the Project Quality Plan form QF376. Section 5 (Project Closure) states:- If manufacture at risk has taken place (e.g. manufacture to drawings ahead of approval by regulatory bodies NRC/ONR) verify that the as built product complies with the approved drawings/licence requirements. A full review of the as built package against the licence requirements will take place and be documented. With the exception of the label, the package is the same as the	Closed

		<p>3977A, only the inserts (internal hardware) are different due to different customer requirements.</p> <p>As previously explained, this is already addressed in the Project Quality Plan. The change to the package is only the label on the keg. The reason for the design number change is to cover different internal hardware at the customer's request. Therefore, the as built package will be to the approved design requirements.</p>	
180	Internal audit finding do not always result in a CAR being raised as required by CAP12-01 and WI13-05.	Deviation from procedure, Corrective actions were carried out but not documented as CAR's. Awareness of the requirements of the procedure was raised with the Croft QM to have responsibility to raise CAR's when the audit report is reviewed.	Closed
181	A document package submitted by Oxford Engineering for the 3977A had been approved and signed off by Croft but a number of pages were missing the signoff by Oxford Engineering.	Pressure of work led to errors when reviewing the documents specifically for accuracy of content and final signature requirements had been missed. A review of OEL route cards related to the HS / LS documentation was carried out, and signed by OEL where required and resubmitted to Croft. The route cards have now all been signed. Documents were reviewed by I Dingwall ref: PRF 714	Closed
182	10CR21 – 21.6 Posting Requirements states that Section 206 of the Energy Reorganisation Act 1974 and NCR form 3 shall be posted in a conspicuous position for all staff to see. The documents had not been	Croft had previously only addressed the reporting requirements of the 10CFR21 regulation. Croft were unaware of the requirement to post these documents and this was addressed at the time of the	Closed

	posted.	inspection. Both documents are now displayed in a prominent position adjacent to the main office noticeboard and attention raised to all staff via email.	
183	The SARP CTR2008/11 calls up Hydrostatic testing in section 8.2.3.1 but this is not called up in MIS049 field 7 which simply states 'Pressure Test'. The MIS is a record of maintenance work carried out in accordance with the SARP and must make the same statements as the sections referenced.	The SARP calls up Hydrostatic testing when there has been pitting corrosion which has been dressed out. However, for initial manufacture Section 8.1.3 simply states 'Pressure test' referencing ASME NB-6000[8.2]. MIS049 field 7 has been revised to correlate with SARP CTR2008/11 section 7.	Closed