

US NRC
ATTN: Document Control Desk
Washington
DC 20555
USA

Reply to Notice Of Violation 71-0939 US NRC 21st October 2013

Violation:

During an inspection conducted September 9-12, 2013 at Croft Associates Limited, an NRC Certificate Holder, a violation of NRC requirements was identified. In accordance with the "NRC Enforcement Policy" dated July 09, 2013, the violation is listed below.

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

Contrary to the above, the following instance was identified by the NRC where a procedure for an activity affecting quality was not followed:

Croft quality procedure CAP12-01, "Audit Procedure" issue Q, section 2 "Actions", states that auditor competency shall be determined by confirmation of attendance and successful completion of a recognised Lead Auditor training course and recent evidence of carrying out auditing activities, both internally and externally.

The NRC identified that 1) Croft allowed an individual (no longer at Croft) who ultimately was unable to produce evidence of successful completion of a recognised Lead Auditor training course to perform audits and 2) a different auditor had evidence of successful completion of a Lead Auditor course in their qualification file but recent evidence of carrying out auditing activities was not documented in the file.

1) Reason for Violation

- i) The person concerned was a new starter with the company and had listed numerous training courses and qualification on their CV, on their training records sheet when employment commenced and this was supported by a letter of reference. These made reference to Lead Auditor training and qualification. The person was unable to produce documentary evidence in the form of certificates as they had recently moved house and all the documentation was still in storage. It was agreed prior to commencement of employment that the certification would be provided within the probationary period. This person left by mutual agreement within the probationary period and had not yet provided copies of certification relating to auditor qualifications.

- ii) Croft Associates has one qualified lead auditor, the Quality Manager. As a consequence the activities performed by or those being the direct responsibility of the Quality Manager cannot be self audited. An external auditor was contracted to conduct internal audits on those areas of the Quality Management System. The auditor was selected on the basis of documented qualifications and IRCA¹ registration, was assessed as a supplier and registered on the Croft supplier list. Although evidence of their qualifications and IRCA registration was obtained and since it is a requirement of IRCA registration that an audit log is maintained to ensure auditors are current, no records of evidence of recent auditing other than the previous audits carried out at Croft over the last six years (since 2008) were kept by Croft.

2) Corrective steps and results achieved

- i) Review of internal and external audits carried out by this person between May 1st and July 30th 2012 to assess validity of audits. Internal audits are repeated 12 monthly and all of these will have been re-audited by the end of 2013, one supplier audit was carried out and this will be repeated in December 2013 to re-assess the supplier.

Audit area	Date	Audit report No.	Date re-audited	Re-audit report No.
Licensing	25 th May 2012	QAR 237	Scheduled for November 2013	n/a
Maintenance and preservation of product	4 th July 2012	QAR 243	15 th March 2013	QAR 263
			20 th June 2013	QAR 269
Purchasing & GI	29 th May 2013	QAR 238	20 th June 2013	QAR 270
Manufacturing – planning & product realisation	12 th June 2012	QAR 239	Scheduled for November 2013	n/a
Records – Control, retention & storage	21 st June 2012	QAR 240	21 st August 2013	QAR 285
Supplier approval / control / monitoring of manufacturing	25 th July 2012	QAR 244	24 th June 2013	QAR 268

Table 1. Internal audits carried out by person i) and re-audits conducted in 2013.

Audit area	Date	Audit report No.	Date re-audited	Re-audit report No.
Supplier audit	25 th July 2012	QAR 247	Scheduled for December 2013	n/a

Table 2. Supplier audits carried out by person i) and planned re-audit date.

- ii) This contract auditor has now retired and as a consequence evidence of recent auditing outside of Croft is not available. The IRCA registration in conjunction with records of audits performed at Croft in 2010 (QAR 184), 2011 (QAR 204), 2012 (QAR 254) and 2013 (QAR 268) is considered sufficient evidence.

3) Corrective steps taken to avoid further violations

- i) This person is no longer employed by Croft. Any persons recruited in the future will be required to produce documented evidence of qualifications and if evidence of recent audit activity cannot be produced then auditing will be supervised by the Quality Manager until that person is deemed competent and the Company skills matrix annotated accordingly. These requirements will be added to Croft procedure CAP 13-01 Training and Competence Records under CAR 088.
- ii) Contract auditors will in future be asked to submit a copy of their audit log for the previous 12 months as part of their supplier approval. This requirement will be added to Croft procedures CAP 06-06 “Approved Supplier” and CAP 06-08 “Approved Supplier – NRC” under CAR 089 and CAP 12-01 will be clarified with respect to how recent the audit activity must be under CAR 090.

4) Date when full compliance will be achieved

- i) The procedure CAP 13-01 will be revised and issued by 1st December 2013.
- ii) The procedures CAP 06-06 and 06-08 will be revised and issued by 1st December 2013.
- iii) CAP 12-01 “Audit Procedure” will be revised and issued by 1st December 2013.
- iv) Re auditing with respect to tables 1 and 2 will be completed by the End of December 2013.

We expect to be fully compliant by 1st January 2014.



S P Ralls
Quality Manager