



U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D.C. 2055

February 4, 2010

Subject: Reply to a Notice of Violation
Inspection Report No. 71-0939/2009-201

References: Letter from Mr David W Pstrak (NRC) to Dr Robert Vaughan (Croft) dated
January 7, 2010

Dear Sir or Madam

The reference letter transmitted the results of the NRC Inspection conducted on December 7-10, 2009 at Croft Associates Ltd premises in Culham, UK in Inspection Report 71-0939/2009-201. The referenced report also transmitted a Notice of Violation.

Croft Report QAR 160, Issue A (enclosed with this letter) provides the required response to the Notice of Violation.

If you have any questions, please contact me or our Quality Manager Mr R. Clayton.

Sincerely

Dr R.A. Vaughan

Enclosure: QAR 160, Issue A, Response to NRC NoV dated January 7, 2010

cc: D.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
US Nuclear Regulatory Commission
Washington, D.C. 2055 - 0001

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Response to NRC Notice of Violation dated January 7, 2010

1 Scope

The Notice of Violation enclosed with Mr David W Pstrak's letter dated January 7 2010, states in part:

10 CFR 71.133, "Corrective action," states, in part, that an applicant for a Certificate of Conformity (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)

This report (QAR 160) provides the required response to the Notice of Violation regarding these two items.

2 Background

The NRC carried out an inspection in May 2008 (ref NRC Inspection Report No. 71-0939/2008-20) which recommended a number of improvements that Croft should make to its QMS in order to meet the requirements of 10 CFR 71.

Following this inspection, Croft carried out a thorough review of its QMS – this included making changes in response to the NRC recommendations.

The NRC inspection carried out in Dec 2009 (ref NRC Inspection Report No. 71-0939/2009-201) showed that, “overall, Croft adequately addressed the concerns identified in the May 2008 inspection and that Croft’s NRC approved QA program, as presently developed and implemented, adequately meets the QA requirements of 10 CFR 71”. However, the two issues indicated below were identified as not being properly covered.

Significant Conditions Adverse to Quality (SCAQ)

Commercial Grade Dedication (CGD)

That these items are not currently fully compliant does not present a safety issue as they apply to activities that are not planned to be carried out until mid 2010, by which time Croft’s QMS will be modified to fully meet the requirements of 10 CFR 71 including all aspects of the issues identified in the Notice of Violation.

3 Reason for the violation

The reasons for the individual violations are addressed separately for each item in the following sections.

3.1 SCAQ

Croft’s QAPDM had been developed from an existing certified ISO 9001:2000 Quality Management System (QMS). The requirements regarding “significant conditions adverse to quality” (SCAQ) had been added to the QMS, but, as is evident from the Notice of Violation, Croft had not fully understood how to address these requirements.

3.2 CGD

The issues arising from the difficulty of procuring Quality Grade A materials and services had been addressed in Croft’s QMS by delegating compliance to the (US) supplier who would be required to fully meet the requirements of 10 CFR 71 (eg following the Commercial Grade Dedication (CGD) methodology) and therefore were not fully addressed in the QMS.

4 Corrective actions taken and results achieved

The corrective actions taken and results achieved are addressed separately for each item in the following sections.

4.1 SCAQ

A number of corrective actions have been identified to address the issues raised in the Notice of Violation re SCAQ. These require revision of procedures, work instructions, quality forms, databases, QA guidelines and flowcharts that augment procedures.

All corrective actions have been identified and revisions to all the affected documents have been drafted.

4.2 CGD

A number of corrective actions have been identified to address the issues raised in the Notice of Violation re CGD. These require revision of procedures, work instructions, quality forms, databases, QA guidelines and flowcharts that augment procedures.

All corrective actions have been identified and revisions to all the affected documents have been drafted.

5 Corrective actions that will be taken

The corrective actions that will be taken are addressed separately for each item in the following sections.

5.1 SCAQ

The revisions to all the documents that have been edited in order to address the issues raised in the Notice of Violation re SCAQ will be reviewed, finalised, issued and implemented.

Following issue of the revised procedures, etc, training will be given to all employees regarding SCAQ identification; the measures that have to be taken to assure that the cause of the condition is determined and corrective actions measures required to preclude repetition.



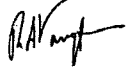
5.2 CGD

The revisions to all the documents that have been edited in order to address the issues raised in the Notice of Violation re CGD will be reviewed, finalised, issued and implemented.

Following issue of the revised procedures, etc, training will be given to all employees regarding procuring Quality Category A materials and services and the procedures to be followed to apply CGD where appropriate.

6 Date when full compliance will be achieved

Full compliance is planned to be achieved for both the CAQ and CGD items by end February 2010.

Title Response to NRC Notice of Violation dated January 7, 2010	Number QAR 160 Issue Issue A File Reference [QAR160A-v3.1-Response to NRC NoV of Jan2010-sig]
Compiled  R Clayton	Checked  N Jorgensen
Approved  RA Vaughan	Date 4 February 2010
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