CROFT

9th July 2018

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

Submission of QAPDM for approval of changes

Docket No. 71-0939

Please find enclosed Croft Associates QAPDM issue E submitted for approval in accordance with 10 CFR 71.106

Changes are:

Issue B to C

i) Pg 4 – change "Managing Director" to "CEO"
ii) Pg 7 - NRC approval of changes (71.106) and reference to NSAN and NEF added
iii) Pg 24 - change "CAN" to "CAR"
iv) Pg 28 – add "CAR" to the list of abbreviations
v) Pg 29 – updated org chart
vi) Pg 30 – remove reference to AF047

Issue C to D

i) Pg 2 – add 71.106 to contents list
ii) Pg 3 – change of scope to include CALT units, change ISO 9001:2008 to ISO 9001:2015
iii) Pg 4 – change "CEO" to "MD"
iv) Pg 8 – add section for 71.106
v) Pg 24 – add reference to corrective action note (CAN)
vi) P 29 – Appendix 1 – insert current organisation chart with names removed
vii) Pg 30 – Appendix 2 – insert reference to 71.106

Issue D to E

i) 71.115 – Change of title – Control of purchased material, equipment and services.
ii) Appendix II – addition of new procedures for He leak test and NQA-1 lead auditor qualification, 71.121 and 71.137 respectively
iii) Add reference to IAEA SSR-6

S P Ralls
Quality Manager

Q004
NMSS01
NMSS

Croft Associates Ltd
F4 Culham Science Centre
Culham, Abingdon,
Oxon, United Kingdom
OX14 3DB

T: +44 (0)1865 407740
F: +44 (0)1865 407449
E: info@croftltd.com
W: www.croftltd.com

The National Skills Academy NUCLEAR Manufacturing

NEF ASSURED NUCLEAR

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Quality Assurance Program Description Manual for 10 CFR Part 71, Subpart H

Controlled Copy Number

Title	Quality Assurance Program Description Manual for 10 CFR Part 71, Subpart H	**Number** **Issue** **File Ref**	QAR 144 E QAR144-E.doc
Compiled	S Ralls	**Checked**	G Hostford
Approved	M Johnson	**Date**	9th July 2018

Croft Associates Ltd, F4 Culham Science Centre, Abingdon, Oxfordshire, OX14 3DB. +44 1865 407740

Contents

Introduction

Croft Associates Ltd, hereafter referred to as Croft, operates a Quality Management System (QMS) that complies with the requirements of ISO 9001:2015, the scope of which is:
Project management, consultancy, design studies, supervision of manufacture, inspection and testing, licensing and maintenance of containers for the transport, storage and disposal of radioactive materials to national and international standards and to statutory and customer requirements.
Design, manufacture, maintenance and calibration of the CALT leak test equipment and delivery of certified CALT operator training.

Croft's Quality Assurance Program Description Manual (QAPDM) for 10 CFR Part 71, Subpart H, has been developed to describe the procedures used by Croft to control activities governing the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair, and maintenance of storage and transport systems for radioactive materials.

This QAPDM is used by Croft and it is also applicable to activities specifically identified in Nuclear Regulatory Commission (NRC) Certificate(s) of Compliance issued to Croft or referenced documents. This QAPDM is a means of identifying alignment between 10 CFR Part 71, Subpart H and the components of Croft's existing Quality Management System (QMS).

Croft is currently located at:

Croft Associates Ltd
F4 Culham Science Centre
Abingdon
Oxfordshire
United Kingdom
OX14 3DB

Croft is responsible for the implementation of this QAPDM, however, the ultimate overall responsibility is retained by the MD of Croft. Croft's QMS is comprised of this QAPDM; Croft's Quality Manual (QM) and Croft Associates' Procedures and Work Instructions (CAP's and WI's). The CAP's and WI's are designed and administered to meet the requirements of BS EN ISO 9001:2015 and 10 CFR Part 71, Subpart H. Croft has operated a British Standard (BS) certified quality system since the original inception of the company in 1981, its first system meeting the prerequisites of BS 5750 and as such many of the historical values of a mature quality assurance system have been retained and enhanced where appropriate.

Croft maintains Certificates of Authorisation for the design, fabrication, supply and delivery of products in accordance with the requirements of the Competent Authority for the United Kingdom (Office of Nuclear Regulation (RMTT)), under regulations which implement the International Atomic Energy Authority (IAEA) Regulations For The Safe Transportation of Radioactive Material, TS-R-1 (2009) and SSR-6 (2012).

Statement of Policy and Authority

Croft is engaged in the business of design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair, and maintenance of storage and transport systems for radioactive materials. This business carries with it the responsibility of protecting the health and safety of the public and workers from the deleterious effects of radiation. Therefore, it is the Policy of Croft that all products and services are required to be delivered with the highest levels of quality, consistent with the expectations of our customers, shareholders and the government agencies which regulate Croft's activities.

In order to carry out this Policy, Croft has established a Quality Assurance Program that includes this Quality Assurance Program Description Manual (QAPDM) and is in compliance with 10 CFR Part 71, Subpart H. This QAPDM was prepared for review and approval by the U.S. Nuclear Regulatory Commission. Compliance with Croft's QMS is mandatory for all Croft personnel performing quality related activities on projects subject to the requirements of this QAPDM.

While the ultimate responsibility for implementation of the Croft QMS rests with the MD, each and every Croft employee is expected to assume personal responsibility for performing their assigned work activities in accordance with the applicable requirements of the QMS and implementing the procedures that are in effect. The requisites of Croft's QMS are required to be invoked to the extent applicable upon suppliers to which Croft subcontracts quality related work. The Quality Assurance Manager has delegated responsibility to establish and maintain the QMS consistent with this Policy.

71.103 – Quality Assurance organisation

Responsibility for compliance with Croft's QMS resides ultimately with the MD of Croft. QMS activities include actions necessary to comply with the applicable criteria of 10 CFR Part 71, Subpart H. When suppliers are used for performance of quality related activities, Croft qualifies those organisations to ensure compliance with applicable criteria; however Croft retains the overall responsibility for the quality of those activities.

The MD has full authority over all functions of the company, and he delegates authority and responsibility for selected functions to other appropriately qualified personnel, within the company as outlined in this QAPDM. The entire organisation is responsible for implementation of the QMS within their scope of operation and responsibilities.

Engineering Department personnel are responsible for the technical aspects of a project including design. Procurement, manufacturing, maintenance, and testing of storage/transport systems are under the control of the Operations Department. The Licensing Department assembles appropriate documentation and administers the process of application for approval to the Competent Authority. Each of these departments report to the General Manager, see Appendix 1.

Quality Assurance (QA) Department personnel are responsible for the development, implementation and administration of the QMS and administration of calibration of Measurement and Test Equipment (M&TE). The QA Department is independent from other departments and it reports directly to the General Manager. The QA Department has sufficient authority and organisational freedom to identify quality problems, implement corrective action and verify corrective action effectiveness and has sufficient independence from cost and schedule considerations. If the QA Department cannot resolve an issue, then they have the authority to bring that issue to the attention of the MD or General Manager for resolution.

The QA Manager is required to have sufficient expertise in the field of Quality Assurance to enable him to direct the quality functions in accordance with the applicable regulatory criteria invoked by this QAPDM. The QA Manager and other organisations utilised by Croft, are qualified for their responsibilities. Records supporting the QA Manager's qualifications are maintained as Quality Assurance Records.

The QA Manager is also responsible for delegating the performance of quality-related tasks to persons qualified by virtue of their education, training and experience and to evaluate the adequacy of performance of those delegated tasks.

The QA Manager has the authority to prevent the continued processing, fabrication, installation, delivery or use of unsatisfactory work.

The Organisation Chart for Croft is included in this QAPDM as Appendix 1.

Appendix 2 provides a cross reference table showing the alignment between the requirements of 10 CFR Part 71, Subpart H and Croft's existing QMS.

71.105 - Quality assurance program

A. General

i. Croft has established a QMS consistent with the regulations and codes defined in the Introduction of the QAPDM for the control of quality in the design, procurement, fabrication, handling, shipping, cleaning, assembly, inspection, modification, testing, operation, repair, and maintenance of storage and transport systems for radioactive materials.

ii. Croft's QMS is comprised of this QAPDM, the Croft QM and the CAP's and WI's, all of which are designed and administered to meet the requirements of 10 CFR Part 71, Subpart H where applicable.

iii. The Statement of Policy and Authority directs all Croft employees whose activities affect quality to comply with the provisions of the QMS which includes this QAPDM.

iv. The Statement of Policy and Authority directs that the applicable provisions of the QMS (and this QAPDM) be applied at approved supplier locations for quality related work subcontracted by Croft.

v. More specific details or methods of implementing the requirements of this QAPDM are defined in the CAP's and WI's. Applicability of other quality standards, unique owner requisites, or other contract considerations may dictate the need to address unique project requirements that are not specifically covered by the CAP's or WI's. These other requisites or considerations are required to be defined in the Project Quality Plan (PQP) for the applicable project. Further description of the review, approval, and control of a PQP, (and CAP's and WI's) is contained in Section 71.111 of this QAPDM, this addresses the requirements for instructions, procedures and drawings.

B. Preparation and control of the Croft Quality Assurance Program Description Manual (QAPDM) for 10 CFR Part 71, Subpart H

i. This QAPDM provides for the planning and accomplishment of activities identified in 10 CFR Part 71, Subpart H, affecting quality in a controlled manner.

ii. The QAPDM is prepared and reviewed by the QA Manager. It is required to be independently checked prior to approval for issue and implementation by the MD of Croft.

iii. The QA Manager is responsible for the maintenance and distribution of this QAPDM.

iv. All draft revisions to this QAPDM are monitored using the "track changes" function. Any changes to the QAPDM are required to be reviewed and approved in accordance with Croft's QMS. Changes do not need the approval of the NRC unless there are proposed changes which diminish the commitment to 10 CFR 71 requirements. A biennial declaration will be made to the effect that there have been no changes which diminish the commitments or resubmission of the QAPDM for NRC approval.

v. The QA Manager is responsible for issuing controlled copies of the QAPDM when requested and they are required to be assigned a unique number, which will appear on the title page of each controlled copy. The QA Manager is responsible for ensuring that current revisions are sent to all controlled copy holders.

C. Management Review of the QMS

i. The QA Manager regularly evaluates the QMS for adherence to baseline commitments in scope, implementation and effectiveness. The MD, is informed of the status, performance and adequacy of the QMS in the QMS Management Review report.

ii. An audit of the Croft's QMS is conducted annually by an external organisation independent of Croft; currently this is carried out by BSI Management Systems, who appoint an independent, appropriately qualified auditor.

iii. Internal auditing of departments is carried out by appropriately independent and qualified personnel. Internal audits assess the adequacy and effectiveness of the QMS as applicable to the department being audited. The audit report is transmitted to the respective department for correction of any observed deviations, with the findings being reported directly to the MD and in the next QMS Management Review report.

D. Induction and Training

i. Management ensure that QMS training is provided for all employees, at both induction and on an on-going basis.

ii. When necessary, training in project unique quality requirements is provided by an appropriately trained person, either within or without Croft.

iii. When required by applicable codes and standards, qualified personnel are appropriately certified in accordance with the required skill and/or qualification(s). Croft has a training development and delivery program, integral to the QMS, which is accredited by NEF (Nuclear) and Croft are also members of the National Skills Academy (Nuclear).

iv. Proficiency of Croft personnel who participate in the QMS is maintained by continued execution of their assigned responsibilities, retraining and/or recertifying as appropriate. If it is determined by Management that an individual's capabilities are not in accordance with specified requirements, that

individual is removed from that capacity until that person has been retrained and has demonstrated adequate proficiency for performing that activity.

v. Records of training and certification are maintained by the QA Department, to demonstrate implementation of any training program. Project unique training records are maintained in the same manner.

vi. Personnel performing audit activities are qualified in accordance with the QMS. Personnel who are designated as Lead Auditors are certified by an appropriately qualified body, as recognised by the International Registration scheme for Certified Auditors (IRCA) or ASME (NQA-1) and are required to meet Croft's requisites for qualification.

vii. All records of personnel qualification and certification, including previous certifications used in support of current qualifications, are retained as Training Records.

71.106 – Changes to Quality Assurance Program

Croft procedures have been established to control quality program change activities, to ensure that the following occur.

i. Any proposed change is documented on a form QF119 and reviewed to ensure there are no adverse effects due to the proposal.
ii. Changes which affect the NRC approval or the QAPDM but do not reduce the commitment to quality, are approved without NRC approval with these changes being submitted to the NRC every 24 months.
iii. Where changes affect the commitment to quality then NRC approval shall be gained prior to implementation of the changes.

71.107 - Package design control

A number of Croft procedures have been established to control design activities, to ensure that the following occur:

i. Design activities are planned, controlled and documented.

ii. Regulatory requisites, design requirements and appropriate quality standards are correctly translated into specifications, drawings and procedures.

iii. Competent engineering personnel, independent of design activities, perform design verification. Verification may include design reviews, alternative calculations or qualification testing. Qualification tests are conducted in accordance with approved test programs or procedures.

iv. Design interface controls are established and adequate.

v. Design, specification and procedure changes are reviewed and approved in the same manner as the original issue. In a case where a proposed design change potentially impacts licensed conditions, the QMS provides for ensuring that licensing considerations have been reviewed and are complied with or otherwise reconciled by amending licenses for transport applications.

vi. Design errors and deficiencies are documented, corrected and corrective action is taken to prevent recurrence.

vii. The activities of Croft's Design Department and their responsibilities and authorities are controlled through written procedures and the appropriate Management Procedure.

viii. Croft's Licencing Department's responsibilities and authorities are controlled through established procedures which ensure that appropriate documentation is prepared and submitted for approval by the Competent Authority.

ix. Appropriate testing is undertaken to ensure that package designs comply with current regulations. If regulations are updated, any necessary changes are applied to packages during the review process.

x. Materials, parts, equipment, and processes essential to the function of items that are important to safety are encompassed by the design and reappraised for suitability of application by the review process.

xi. Computer programs used for design, analysis or verification are not bespoke, these are used in accordance with the appropriate approved CAP's and WI's.

71.109 - Procurement document control

Croft procedures have been established to ensure that procurement documents are prepared to clearly define applicable technical and Quality prerequisites including codes, standards, regulatory necessities and contractual requirements. These documents serve as the principal documents for the procurement of structures, systems and components, and related services for use in the design, fabrication, maintenance, operation, inspection and testing of storage and/or transportation systems. The QMS ensures that purchased material, components, equipment and services adhere to the applicable requirements.

The assignment of quality prerequisites through procurement documents is administered and controlled in accordance with the approved procedures.

Procurement activities are performed in accordance with approved CAP's and WI's which delineate requirements for preparation, review, approval and control of procurement documents. Revisions to procurement documents are reviewed and approved by the Project Manager (PM).

Quality prerequisites are included in quality-related purchase orders. Croft personnel assign quality requirements within procurement documents, as applicable to the scope of the procurement referencing regulations, codes or standards as appropriate.

Croft procurement documents require suppliers to pass on appropriate quality assurance program requisites to sub-tier suppliers.

Croft procurement documents include provisions that suppliers either maintain or supply those Quality Assurance Records which provide evidence of conformance to the procurement documents. Additionally, procurement documents designate the supplier documents required for submittal to Croft for review and/or approval.

Croft maintains the right of access to supplier facilities and performance of source surveillance and/or audit activities, as applicable.

Procurement documents also address the need for reporting of defects, deviations and non-conformances.

71.111 - Instructions, procedures and drawings

Established Croft procedures ensure alignment with each of the applicable criteria of 10 CFR Part 71, Subpart H, for activities affecting quality, during design, fabrication, inspection, testing, use, maintenance, and operations as specified in instructions, procedures, and/or drawings.

Instructions, procedures and drawings are developed, reviewed, approved, utilised and controlled in accordance with the necessities of approved CAP's and WI's. These instructions, procedures and drawings include appropriate quantitative and qualitative acceptance criteria.

Changes to instructions, procedures and drawings, are developed, reviewed, approved, utilised and controlled using the same requirements and controls as applied to the original documents.

Compliance with these approved instructions, procedures and drawings is mandatory for Croft personnel while performing activities affecting quality.

71.113 - Document control

Croft procedures have been established to control the issuance of documents that prescribe activities affecting quality and to assure adequate review, approval, release, distribution, and use of documents and their revisions. Controlled documents may include, but are not limited to:

i. Design specifications

ii. Design and fabrication drawings

iii. Special process specifications and procedures

iv. QMS components (QM, QAPDM, CAP's and WI's)

v. Test procedures

vi. Operational test procedures and resulting data

Changes to documents which prescribe activities affecting quality, are reviewed (and approved), by the same organisation that performed the initial review/approval. Croft may appoint other qualified responsible organisations to undertake a review.

Documents that prescribe activities affecting quality are reviewed and approved for technical adequacy and inclusion of appropriate quality requirements prior to approval and issuance.

Measures are taken to ensure that only current documents are available at the locations where activities affecting quality are performed prior to commencing the work.

71.115 - Control of purchased material, equipment and services

Croft procedures are in place to ensure that purchased material, equipment and services conform to procurement documents.

Procurement documents are reviewed and approved by authorised personnel for acceptability of proposed suppliers based on the quality requirements of the items/services being purchased.

Approved suppliers are listed on the Croft Approved Suppliers List (CASL), for the items and/or services they provide. The CASL is controlled in accordance with the approved procedure.

As required, audits and/or surveys are conducted to determine supplier approval. These audits/surveys are based on one or all of the following criteria:

i. The supplier's capability to comply with the requirements of codes or standards that are applicable to the scope of work to be performed.

ii. A review of previous records may be used to establish the past performance of the supplier.

iii. Current certification to a recognised QA standard.

iv. A survey of the supplier's facilities and review of the supplier's QA Program to assess the adequacy and verify implementation of quality controls consistent with the prerequisites being invoked.

Qualified personnel conduct audits and surveys. Audit/survey results are documented and retained as Quality Assurance Records (QAR's). Suppliers are re-audited and/or re-evaluated at planned intervals to verify that they continue to comply with quality requirements and to assess the continued effectiveness of their QA Program. Additionally, interim periodic evaluations are performed of supplier quality activities, to verify implementation of their QA Program.

Suppliers are required to provide objective evidence that items or services provided meet the requirements specified in procurement documents. Items are identified to appropriate records that are available to allow verification of conformance with procurement documents. Any procurement prerequisites not met by suppliers are reported to Croft for review and approval. These conditions are reviewed by technical and quality personnel to ensure that they have not compromised the quality of the item or service.

Periodic surveillance of supplier in-process activities is performed as necessary to verify supplier procurement documents. When deemed necessary, the need for surveillance is noted in approved quality or project planning documents, and surveillances are performed and documented in accordance with approved procedures. Personnel performing surveillance of supplier activities are trained and qualified in accordance with approved procedures.

Quality planning for the performance of source surveillance, test, shipping and/or receiving inspection activities to verify compliance with approved design and licensing requirements, applicable regulatory criteria, procurement document prerequisites, or contract specifications is performed in accordance with the approved procedure.

For commercial "off-the-shelf" items, where specific quality controls appropriate for nuclear applications cannot be imposed in a practical manner, additional quality verification is performed to the extent necessary to verify the acceptability and conformance of an item to procurement document prerequisites. When qualification of a commercial grade item is required for use in a quality-related application, such qualification is performed in accordance with the approved CAP or WI.

71.117 - Identification and control of materials, parts and components

Croft procedures have been established to identify and control materials, parts and components. These procedures ensure identification of items by appropriate means during fabrication, installation and use of the items and prevent the inadvertent use of incorrect or defective items.

Requirements for identification are established during the preparation of procedures and specifications.

Methods and location of identification are selected so as to not adversely affect the fit, function or quality of the items being identified.

Items having limited shelf or operating life are controlled to prevent their inappropriate use.

71.119 - Control of special processes

Specific Croft procedures have been established to control special processes used in the fabrication and inspection of storage/transport systems. These processes may include welding, non-destructive examination, phenolic resin filling or other special processes as identified in procurement documents.

Special processes are only performed in accordance with written approved procedures.

Personnel who perform special processes are trained and qualified in accordance with applicable codes, standards, specifications, or other special requirements. Records of qualified procedures and personnel training are filed and kept current by the organisation that performs the special processes.

71.121 - Internal inspection

Croft procedures have been established to ensure that inspection and/or surveillance is performed to verify that materials, parts, processes or other activities affecting quality conform to documented instructions, procedures, specifications, drawings, or procurement documents.

Personnel performing inspection and surveillance activities are required to be trained and qualified in accordance with written approved procedures.

Inspections and surveillances are performed by individuals other than those who performed or supervised the subject activities.

Inspection, surveillance and process monitoring may be required when one by itself may not provide assurance of quality.

Modifications and/or repairs to and replacements of safety-related and important-to-safety structures, systems and components are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

Mandatory hold points, inspection equipment requirements, acceptance criteria, personnel qualification prerequisites, performance characteristics, reference documents, and other necessities are considered and included, as applicable, during inspection and surveillance planning.

71.123 - Test control

Croft procedures have been established to assure that required proof, acceptance and operational tests, as identified in design or procurement documents, are performed and appropriately controlled.

Test personnel are required to have appropriate training and be qualified for the level of testing which they are performing and be qualified in accordance with approved written instructions, procedures and/or checklists.

Tests are performed by qualified personnel in accordance with approved written instructions, procedures and/or checklists. Test procedures contain or reference the following information, as applicable:

i. Acceptance criteria contained in the applicable test specifications, or design and procurement documents.

ii. Instructions for performance of tests, including environmental conditions.

iii. Test prerequisites such as test equipment, personnel qualification and the operational status of the items to be tested.

iv. Provisions for data recording and record retention.

Test results are documented and evaluated to ensure that acceptance criteria have been met.

Tests to be conducted after modifications, repairs or replacements of safety-related and important-to-safety structures, systems or components, are performed in accordance with the original design and testing requirements or acceptable alternatives.

71.125 - Control of measuring and test equipment

Croft has a procedure to ensure that tools, gauges, instruments and other measuring and test equipment (M&TE) used in activities affecting quality, are properly controlled, calibrated and adjusted to maintain accuracy within required limits.

M&TE is calibrated at scheduled intervals against certified standards having known valid relationships to national standards. If no national standards exist, the basis for calibration is required to be documented. Calibration intervals are based on required accuracy, precision, purpose, amount of use, stability characteristics and other conditions that could affect the measurements.

Calibrations are performed in accordance with approved written procedures. Inspection, measuring and test equipment are marked to indicate calibration status.

M&TE is identified with a unique serial number and it has a label attached or is tagged indicating the next required calibration due date: all have traceable calibration records.

If M&TE is found to be out of calibration, an evaluation is performed and documented regarding the validity of inspections or tests performed and the acceptability of items inspected or tested since the previous acceptable calibration. The current status of M&TE is recorded and maintained. Any M&TE that is consistently found to be out of calibration is required to be repaired or replaced.

Special calibration and control measures on rules, tape measures, levels and other such devices are not required where normal commercial practices provide adequate accuracy.

71.127 - Handling, storage and shipping control

Croft procedures have been established to ensure that materials, parts, assemblies, spare parts, special tools, and equipment are handled, stored, packaged and shipped in a manner to prevent damage, loss of identity or deterioration.

When necessary, storage procedures address special requirements for environmental protection, such as an inert gas atmosphere, moisture control, temperature levels, etc.

71.129 - Inspection, test and operating status

Croft procedures have been established to ensure that the inspection and test status of materials, items, structures, systems and components throughout fabrication, installation, operation and test are clearly indicated by suitable means, (e.g., tags, labels, cards, form sheets, check lists, etc.).

By-passing of required inspections, tests, or other critical operations will not be authorised or permitted, when using approved instructions or procedures.

As appropriate, the operating status of nonconforming, inoperative or malfunctioning components of a storage/transport system (e.g., valves, switches, etc.) is required to be indicated, to prevent inadvertent operation. The application and removal of status indicators are performed in accordance with approved instructions and procedures.

Any non-conforming items are identified and controlled in accordance with the appropriate CAP's and WI's, these are referenced in Section 71.131 of this QAPDM.

71.131 – Non-conforming material, parts or components

Croft procedures have been established to control materials, parts, and components that do not conform to requirements, so as to prevent their inadvertent use in manufacturing operations or during service.

Non-conforming items include those items that do not meet specification or prerequisites shown on approved drawings. Additionally, nonconforming items are required to include items that are not fabricated or tested in the following manner:

i. In accordance with approved written procedures,
ii. By qualified processes, and
iii. By qualified personnel; where the use of such procedures, processes or personnel are required by the fabrication, test, inspection or quality assurance requirements.

Non-conforming items are identified and/or segregated to prevent their accidental use, until properly dispositioned. The identification of non-conforming items is by marking, tagging or other methods that do not adversely affect the end-use of the item. The identification is required to be legible and easily recognisable. When identification of each non-conforming item is not practical, the container, package, or segregated storage area, as appropriate, is required to be identified.

Non-conforming conditions are documented in an NCR database and on a Non-conformance Report (NCR) and the affected organisations are notified. The NCR includes a description of the non-conforming condition, this may also result in a corrective action, see Section 71.133 in this QAPDM. Non-conforming items are identified as use-as-is, reject, repair, or rework.

Inspection or surveillance requirements for non-conforming items following rework, repair or modification are detailed in the non-conformance reports and approved following completion of the disposition.

Acceptability of rework or repair of non-conforming materials, parts, and components is verified by re-inspecting and/or re-testing the item to the original prerequisites or equivalent inspection/testing methods. Inspection, testing, rework, and repair methods are documented and controlled.

The disposition of non-conforming items as use-as-is or repair includes technical justification and independent verification to assure compliance with design, regulatory and contractual requirements.

Items identified as rework or repair are re-inspected and retested in accordance with the original inspection and test requisites or acceptable alternatives that are in compliance with the specified acceptance criteria.

When specified by contract requirements, non-conformances that result in a violation of client contract or specification prerequisites are submitted for client approval.

Non-conformance reports are made part of the inspection records and are periodically reviewed to identify quality trends. Unsatisfactory quality trends are documented on a

Corrective Action Report (CAR), as detailed in Section 71.133 of this QAPDM. The results of these reviews are reported to management.

Non-conformance reports related to activities internal to Croft are issued to the management of the affected organisation. The QA Manager approves their disposition and performs follow-up activities to ensure proper closure.

71.133 – Corrective action

Croft procedures have been established to identify significant conditions adverse to quality. Significant and/or repetitive failures, malfunctions and deficiencies in material, components, equipment and operations are promptly identified and documented on a Corrective Action Report (CAR) or a Corrective Action Note (CAN) and reported to appropriate management. The cause of the condition and corrective action necessary to prevent recurrence are identified, implemented and followed up to verify corrective action is completed and effective.

In the QMS Management Review report, all corrective actions raised in that period are reported, with links to NCR being noted. Annually the analysis is extended to look for any trends.

The QA Manager is responsible for ensuring implementation of the corrective action program, including follow up and close-out actions

71.135 – Quality assurance records

Croft procedures have been established to ensure the control of quality records. The purpose of the quality assurance record system is to ensure that documented evidence pertaining to quality related activities is maintained and available for use by Croft, its customers, and/or regulatory agencies, as applicable.

Lifetime and non-permanent records are retained by Croft or its customers, as appropriate. Records are identified, indexed and stored in accessible locations.

Quality Assurance Records are maintained for periods specified in regulations to furnish evidence of activities affecting the quality of structures, systems and components that are safety-related or important-to-safety. These records include records of design, procurement, fabrication, assembly and testing.

When Croft performs maintenance, these records include the use of operating logs; results of reviews, inspections, tests, and audits; results from monitoring of work performance and material analyses maintenance, modification, and repair activities; qualification of personnel, procedures and equipment; records of calibration of measuring and test devices; and related instructions, procedures, and drawings.

Requirements for indexing, record retention period, storage method(s) and location(s), classification, preservation measures, disposition of non-permanent records, and responsibility for safekeeping, are specified in approved CAP's and WI's.

Croft retains required records indefinitely, under the scope of this QAPDM, any superseded specification, procedure or instruction is retained as a Quality Assurance Record.

71.137 - Audits

Croft procedures have been established to ensure that periodic audits are conducted to verify compliance with all aspects of the QMS and to determine its effectiveness. Those areas and activities to be audited, such as design, manufacturing, maintenance, licensing, top management and quality of storage/transportation systems, are identified in Croft's audit planning.

Croft audits supplier's Quality Assurance Programs, their procedures and implementation activities to evaluate and verify that procedures and activities are adequate and comply with applicable requirements.

Audits are planned and scheduled in a manner to provide coverage and co-ordination with on-going Quality Assurance Program activities, commensurate with the status and importance of the activities.

Audits are performed by trained and qualified personnel not having direct responsibilities in the areas being audited and are conducted in accordance with written plans and checklists. Audit results are documented and reviewed with management having responsibility for the area audited. Corrective actions and schedules for implementation are established and recorded. Audit reports include an objective evaluation of the quality-related practices, procedures and instructions for the areas or activities being audited and the effectiveness of implementation.

Responsible management is required to undertake corrective actions as a follow-up to audit reports when appropriate. The QA Manager evaluates audit results for indications of adverse trends that could affect quality. When results of such assessments so indicate, appropriate corrective action is implemented.

The QA Manager follows up on audit findings to ensure that appropriate corrective actions have been implemented and directs the performance of re-audits when deemed necessary.

References

1. Title 10, Code of Federal Regulations, Part 71, Subpart H – Packaging and Transportation of Radioactive Material, Quality Assurance

2. International Standard ISO 9001:2015, Quality management systems – Requirements

3. International Atomic Energy Authority (IAEA) Regulations For The Safe Transport of Radioactive Material, IAEA Safety Standards Series No. TS-R-1 (2009)

4. International Atomic Energy Authority (IAEA) Regulations For The Safe Transport of Radioactive Material, IAEA Safety Standards Series No. SSR-6 (2012)

Abbreviations

BS: British Standard

BSI: British Standards Institute

CAP: Croft Associates Procedure

CAN: Corrective Action Note

CAR: Corrective Action Report

CASL: Croft Approved Supplier List

MD: Managing Director

Croft: Croft Associates Ltd

IRCA: International Registration scheme for Certified Auditors

M&TE: Measuring and Test Equipment

NCR: Non-conformance Report

NRC: U.S. Nuclear Regulatory Commission

PM: Project Manager

PQP: Project Quality Plan

QA: Quality Assurance

QAPDM: Quality Assurance Program Description Manual

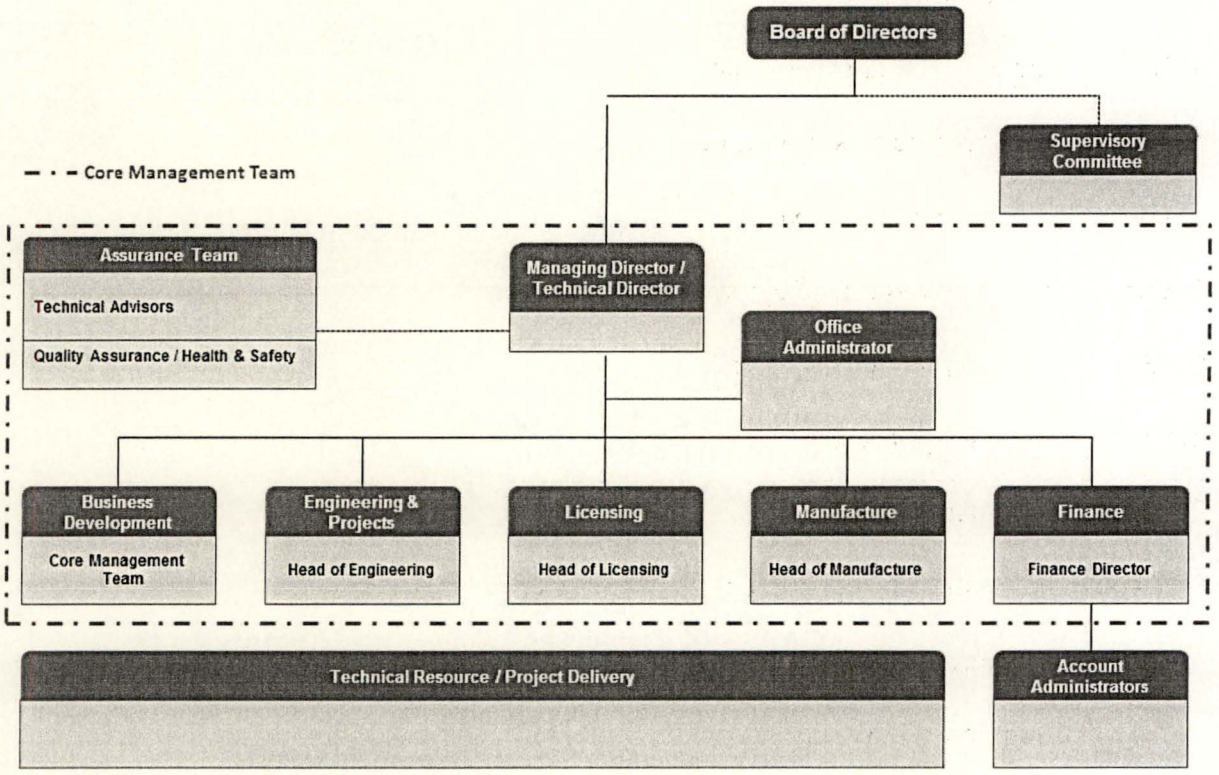
QAR: Quality Assurance Report

QM: Quality Manual

QMS: Quality Management System

WI: Work Instruction

Croft's Organisation Chart - Appendix 1



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10 CFR Part 71 Subpart H alignment with Croft's QMS - Appendix 2

10 CFR Part 71 Subpart H reference	Croft primary QMS reference(s)
71.103 QA organisation	Croft QM Sections 3 and 4 CAP 12-02 QMS Review CMM 01-04 Responsibilities CAP 01-13 Staff roles, document compilation, checking and approval authorities
71.105 QA program	Croft QM Section 5 WI 01-01 Document Numbering System WI 01-03 Change Control of Documents WI 01-06 Issuing Documents WI 01-10 CAP's & WI's CAP 02-02 Quality Plan CAP 02-03 Project Control CAP 12-01 Audit Procedure CAP 12-02 QMS Review CAP 13-01 Training and Competence Records CAP 13-04 Development of in house training CMM 03-02 Staff appraisals BSI Management System assessment reports Customer audits Quality assurance records (QARs) Training records
71.106 Changes to QA Program	QA Manual WI 01-03 Change Control of Documents

71.107 Design control	CAP 01-03 Staff roles, document compilation, checking and approval authorities WI 01-03 Change control of documents WI 01-05 Document Review WI 01-09 Reference document control CAP 02-02 Quality Plans CAP 02-03 Project Control CAP 02-04 Project Specifications CAP 03-02 Design Review CAP 03-03 Design Control WI 04-02 Preparation of Drawings / Related Documents WI 04-03 Master drawing control WI 04-04 Modification of Drawings CAP 05-06 Product Non Conformance Control CAP 09-02 Control of testing CAP 10-01 Competent Authority Licensing CAP 10-07 Update of UK Competent Authority Approvals WI 10-08 Packaging serial numbers WI 10-09 Reviewing existing packaging CAP 10-10 Update of Foreign Competent Authority Approvals CAP 12-03 QMS Corrective Actions CAP 12-04 Preventative Action

10 CFR Part 71 Subpart H reference	**Croft primary QMS reference(s)**
71.109 Procurement document control	WI 01-09 Reference document control CAP 02-01 Contract review CAP 02-02 Quality Plan CAP 02-03 Project Control CAP 05-01 Manufacturing Control CAP 05-07 Sub-contractor Control CAP 05-08 Product Release CAP 06-01 Purchasing CAP 06-04 Goods Receiving Checks CAP 06-06 Approved Supplier WI 06-07 Approved Supplier Database User Instructions WI 14-11 Response to Invitation to Tender
71.111 Instructions, procedures and drawings	Croft QM Section 5 CAPs as referenced in Sections 71.107 and 71.109, plus WI 01-01 Document Numbering System WI 01-02 Drafting Documents WI 01-06 Issuing Documents WI 05-04 Special Process Control CAP 09-02 Control of Testing
71.113 Document control	WI 01-01 Document Numbering System WI 01-02 Drafting Documents

	WI 01-03 Change Control of Documents WI 01-05 Document Review WI 01-06 Issuing Documents WI 01-09 Reference Document Control
71.115 Control of purchased material, equipment and services	CAPs as referenced in Section 71.113 - Croft primary QMS references in this appendix, plus CAP 02-02 Quality Plans CAP 02-03 Project Control CAP 05-01 Manufacturing Control CAP 05-07 Sub-contractor Control CAP 05-08 Product Release CAP 05-12 Stores CAP 06-01 Purchasing CAP 06-04 Goods Receiving Checks CAP 06-06 Approved Supplier WI 08-01 Control of Packages at Maintenance WI 08-02 Radiological Controls of Packaging with DU Shielding during Manufacture and Testing CAP 12-01 Audit Procedure WI 14-10 Packing and Despatch
71.117 Identification and control of materials, parts and components	WI 01-01 Document numbering system WI 01-02 Drafting of Documents WI 01-03 Change control of documents WI 01-05 Document review procedure CAP 01-09 Reference document control CAP 02-02 Quality Plans CAP 02-03 Project control CAP 05-01 Manufacturing control WI 08-01 Control of package maintenance

10 CFR Part 71 Subpart H reference	**Croft primary QMS reference(s)**
71.119 Control of special processes	CAP 02-02 Quality Plans CAP 02-03 Project Control CAP 05-01 Manufacturing Control WI 05-04 Special Process Control CAP 09-02 Control of Testing CAP 13-01 Training and Competence records CAP 13-04 Development of in house training courses
71.121 Internal inspection	WI 01-05 Document Review CAP 02-02 Quality Plans CAP 05-01 Manufacturing Control CAP 07-04 Inspection WI 08-01 Control of Package at Maintenance CAP 09-02 Control of Testing CAP13-08 ASNT TC-1A qualification for He MSLD
71.123 Test control	As Section 71.119 - Croft primary QMS references in this appendix

71.125 Control of measuring and test equipment	CAP 7-01 Calibration WI 07-05 Calibration of Torque Wrenches WI 07-07 Calibration of Scales and balances WI 07-08 Calibration of durometer
71.127 Handling, storage and shipping control	CAP 05-12 Stores CAP 06-04 Goods Receiving Checks WI 14-10 Packing and Despatch
71.129 Inspection, test and operating status	As section 71.121 – Croft primary QMS references in this appendix
71.131 Non-conforming materials, parts or components	CAP 05-01 Manufacturing Control CAP 05-06 Product Non-conformance Control CAP 05-07 Sub-contractor Control WI 05-21 NCR Database user instructions QAR
71.133 Corrective actions	CAP 05-06 Product Non-conformance Control WI 05-15 CAN Database User Instructions CAP 12-03 QMS Corrective Action CAP 12-04 Preventative Actions CAP 14-12 Customer Complaints WI 12-05 CAR Database User Instructions WI 12-06 PAN Database User Instructions QAR
71.135 Quality assurance records	As section 71.111 – Croft primary QMS references in this appendix CAP 02-03 Project Control CAP 02-04 Project Specifications CAP 05-01 Manufacturing Control CAP 05-07 Sub-contractor Control CAP 07-01 Calibration
71.137 Audits	CAP 12-01 Audit Procedure CAP 12-02 QMS Review CAP 12-03 Corrective Action CAP 12-04 Preventative Actions CAP13-09 NQA-1 Lead Auditor qualification

Packaging for transportation
of radioactive materials

CROFT

Mr Steve Ralls

Quality Manager

Croft Associates Limited
F4 Culham Science Centre,
Culham, Abingdon, Oxon,
OX14 3DB, United Kingdom

T: +44 (0)1865 407740
F: +44 (0)1865 407449

E: stephen.ralls@croftltd.com

www.croftltd.com