QUALITY MANAGEMENT SYSTEM MANUAL

SECTION 0 - INDEX AND REVISION STATUS Rev. A

SECTION 1 - SCOPE Rev. A

1.1 Quality Policy

1.2 Introduction

1.3 Application

1.4 Exclusions

SECTION 2 - REFERENCE DOCUMENTS Rev. A

SECTION 3 - TERMS AND DEFINITIONS Rev. A

SECTION 4 - QUALITY MANAGEMENT SYSTEM Rev. A

4.1 Quality System Processes

4.2 Documentation and Records

SECTION 5 - MANAGEMENT RESPONSIBILITY Rev. A

5.1 Management Commitment

5.2 Customer Focus

5.3 Quality Policy

5.4 Quality System Planning

5.5 Organization and Communication

5.6 Management Review

SECTION 8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT Rev. A

6.1 Planning of Monitoring and Measurement

6.2 Monitoring and Measurement

6.3 Control of Nonconforming Product

6.4 Analysis of Data

6.1 Continual Improvement

1.0 SCOPE

1.1 Quality Policy

UVC Personnel (UVCP) is committed to meeting customer requirements and enhancing customer satisfaction through continual improvement of its products, services and the quality management system.

UVCP will:

- Be responsive to customers needs.
- Provide effective engineering maintenance solutions.
- Provide reliable consultation and support.
- Ensure effective and efficient use of resources.
- Meet or exceed customer requirements.
- Enhance customer satisfaction through a feedback process.
- Continually improve its products, services and Quality Management System (QMS)
- Identify improvement opportunities.

1.2 Introduction

1.2.1 UVCP developed and implemented a QMS to demonstrate its ability to consistently provide product (service) that meets customer and regulatory requirements, and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformity.

1.2.2 This QMS complies with the international standard ISO 9001:2000, and Technical Specification series.

1.2.3 The manual is divided into eight sections modeled on the sectional organization of the ISO 9001:2000 standard. Sections are further divided into several subsections representing main QMS processes. Each subsection defines general policies and basic principles for the pertinent quality system process; summarizes responsibilities and methods; and references relevant operational procedures and other documents.

1.2.4 The purpose of this manual is to:

- Define and describe the quality system
- Define authorities and responsibilities of the management personnel involved in the operation of the system
- Provide a general description of all processes comprising the QMS.
- Present and inform customers, suppliers, and other external interested parties of what specific controls are implemented at UVCP to assure quality.

1.3 Application

1.3.1 The quality management system (QMS) defined in this manual applies to maintenance, installation and troubleshooting services offered by UVCP.

1.3.2 A specific “Quality Plan” will be written for a specific project when required by the customer or applicable government specification.

1.3.3 The procedures in this QMS will establish the management practices for customer satisfaction in the absence of specific references to quality procedures by the customer.

1.4 Exclusions

1.4.1 The QMS shall be relevant to the nature of our organization and products, and to customer and regulatory requirements. For this reason, those requirements of ISO 9001 that do not apply are excluded from the scope of our quality system.

1.4.2 An ISO 9001 requirement may be excluded only when three conditions are met:

- The requirement must be within ISO 9001 Clause 7, Product Realization;
- The exclusion may not affect our ability, nor absolve us from the responsibility, to provide product that meets specified requirements; and
- The exclusion may not affect our ability to carry out corrective action.

1.4.3 Processes which are applicable, but which are performed by outside contractors, do not qualify for exclusion. They are accounted for in the QMS to ensure control over such outsourced processes.

1.4.4 The QA Manager is responsible for identifying those requirements of ISO 9001 that do not apply to our organization or products, and to propose to the top management that such requirements be excluded from the scope of the QMS.

1.4.5 Top management evaluates the proposed exclusions and determines whether they are appropriate. The evaluation and approval of exclusions are conducted within the framework of management reviews of the QMS (refer to Operational Procedure QOP-56-01, Management Review).

1.4.6 Any exclusions taken are documented in this section of the QMS manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

CLAIMED EXCLUSIONS

No Exclusions taken

4.0 QUALITY MANAGEMENT SYSTEM

4.1 General Requirements

4.1.1 Quality Management System processes

4.1.1.1 The Quality Management System (QMS) is designed as a system of interrelated processes. All main activities of the system are defined as Quality System Processes (QSPs) and are grouped into the following four categories (refer to the Quality System Processes Map on next page):

- Product Realization Processes (PRP),
- Measurement, Analysis and Improvement Processes (MIP),
- Management Responsibility Processes (MRP), and
- Resource Management Processes (RMP)

And are organized into a Plan-Do-Check-Act loop.

4.1.1.2 The sequence and interrelation between the four groups and individual QSPs are illustrated in the QMS Processes Map diagram. Each QSP is further broken down into its sub-processes, as defined in the QMS Processes Matrix included after the diagram.

4.1.1.3 QSPs and their sub-processes are documented in this quality manual and in associated operational procedures and work instructions. This documentation defines the quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.

4.1.1.4 QMS documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

4.1.2 Resources and information

4.1.2.1 The Management Representative is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to the top management.

4.1.2.2 Top management is responsible for ensuring the availability of necessary resources and information.

4.1.3 Monitoring and measurement

4.1.3.1 Performance of QMS processes is systematically monitored and measured. This is to ensure their effectiveness and identify opportunities for improvement.

4.1.3.2 Performance of QMS processes is monitored through internal quality audits (refer to ***QMS-08 Section 8.2*** and ***QOP-82-02 Internal Quality Audits***). To help with the auditing, the Quality System Process Matrix defines for each process the areas to be audited and the reference clauses of ISO 9001.

4.1.3.3 The overall performance of the QMS is monitored by measuring customer satisfaction (refer to ***QMS-08 Section 8.2*** and ***QOP-82-01 Customer Satisfaction***).

4.1.3.4 QMS processes are reviewed and analyzed by the management review of the quality system (refer to ***QMS-05 Section 5.6*** and ***QOP-56-01 Management Review***).

4.1.4 Continual improvement

4.1.4.1 QMS processes are regularly reviewed by the top management to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and through quality objectives.

4.1.4.2 ***QMS-08 Section 6.1, QOP-56-01 Management Review*** and ***QOP-85-03 Corrective and Preventive Actions***, define how the quality management system itself ensures its own compliance and continual improvement.

4.1.5 Outsourced processes

4.1.5.1 When processes that affect product conformity are outsourced, special controls are implemented to ensure that these processes meet specified requirements. Such controls include, as applicable:

- Evaluation and pre-qualification of suppliers;
- Flow-down of customer (contract) requirements,
- Monitoring of supplier quality performance;
- Requirements for process control, inspection, testing and other such records demonstrating product conformity; and
- Receiving inspection of the supplied product.

4.1.5.2 ***QMS-07 Section 7.4, QOP-74-01 Supplier Evaluation and Monitoring, QOP-74-02 Purchasing***, and ***QOP-74-03 Verification of Purchased Product***, define these purchasing control processes.

4.1.5.3 Ensuring control over outsourced processes does not absolve UVCP of the responsibility to conform to all customer and regulatory requirements.

4.2 Documentation and Records

4.2.1 Documentation

4.2.1.1 UVCP QMS documentation comprises the following categories of documents:

- QMS manual, including a Quality Policy and objectives;
- Operational procedures, Work instructions, Forms;
- Product, labeling and packaging specifications;
- Manufacturing, installation and servicing specifications;
- Quality assurance/control procedures, specifications; records; and
- Standards and codes.

4.2.1.2 These categories are further defined in ***QOP-42-01 Control of Documents.***

4.2.2 QMS Manual Requirements

4.2.2.1 UVCP will establish and maintain this QMS manual that includes:

- The scope of the QMS, including details and justification for any exclusion.
- The documented procedures established for the QMS, or reference to them, and
- A description of the interaction between the processes of the QMS.

4.2.3 Control of Documents

4.2.3.1 UVCP is gradually transitioning from paper to electronic documentation. As this transition progresses, new categories of documents are transferred from paper to electronic document control system. Both systems are currently used, and are defined in ***QOP-42-01 Control of Documents***.

4.2.3.2 The document control system defined in ***QOP-42-01 Control of Documents*** ensures that:

- Documents are reviewed for adequacy and are approved prior to release;
- Documents are reviewed and updated as necessary, and revised documents are re-approved;
- Documents are identified, to include their current revision status and changes;
- Documents are distributed to, and are available at locations where they are used;
- Documents remain legible and readily identifiable;
- Document distribution is controlled; and
- Obsolete documents are withdrawn from points of use, and/or are clearly identified to prevent their unintended use.

4.2.3 Control of records

4.2.4.1 Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS.

4.2.4.2 Records will remain legible, readily identifiable and retrievable.

4.2.4.2 Records are organized into the following categories:

- Project Deliverable documentation
- Annual Quality Assessments
- QMS Manual and Revisions thereto
- QMS Master Records
- Project files and their documentation
- Sub-contractor Quality Records

4.2.4.3 ***QOP-42-02 Control of Records*** defines more specifically what records are maintained in each category and designates their storage locations and retention periods. It also defines the process for ensuring that records are clearly identified, are stored in appropriate locations and conditions, are adequately protected, and are easily retrievable.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

5.1.2 Top management is committed to communicate the importance of meeting customer as well as statutory and regulatory requirements. Management Representative is responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization. This responsibility of Management Representative is defined in ***Section 5.5*** of this procedure**.**

5.1.3 Top management establishes the Quality Policy and ensures the objectives for the QMS are established. They are documented and communicated in the form of quality policy and quality objectives. Processes for establishing the quality policy and quality objectives are defined in ***Section 5.3*** and ***Section 5.4*** of this procedure, and are further detailed in ***QOP-56-01 Management Review***.

5.1.4 Top management periodically reviews the quality management system to ensure its continuing suitability, adequacy, and effectiveness. The review evaluates current status and performance of the quality system and initiates actions to further improve the system. The process for conducting management reviews is defined in ***QOP-56-01 Management Review***.

5.1.5 Top management is committed to providing resources necessary for establishing, implementing, and improving the quality management system. ***QMS-06, Section 6.1*** defines processes for identifying resource requirements and allocation of resources for specific activities and projects.

5.2 Customer Focus

5.2.1 The principal objective of the QMS is to focus our organization on the customer, and in particular, on customer satisfaction. The key to achieving high customer satisfaction is an accurate determination of customer requirements and an effective verification that the requirements are met.

5.2.2 Top management ensures that customer requirements are determined and are well understood. This is done through the process of order and contract review, as defined in this manual in ***QMS-07, Section 7.2.1*** and ***Section 7.2.2***, and in associated operational procedures.

5.2.3 Top management ensures that customer requirements are met by inspecting and testing products at various stages of production and upon completion, as defined in this manual in ***QMS-08, Section 8.2.4*** and in associated operational procedures.

5.2.4 Top management ensures that customer satisfaction is systematically monitored as a measure of performance in determining and meeting customer requirements. This process is defined in this manual in ***QMS-08, Section 8.2.1***, and in associated operational procedures.

5.3 Quality Policy

5.3.1 The “Quality Policy” is documented in ***QMS-01, Section 1.1***.

5.3.2 The “Quality Policy” is established by the by the Chief Operating Officer (COO). In formulating the quality policy, the COO ensures that the policy is appropriate to the purpose of the UVCP, and includes a commitment to comply with the requirements and continually improve the effectiveness of the QMS.

5.3.3 The “Quality Policy” provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort. The use of quality policy in setting quality objectives is addressed in ***Section 5.4.1 of this procedure*** and in ***QOP-56-01 Management Review***. The use of the policy to facilitate continual improvement is explained in ***QOP-85-01 Continual Improvement***.

5.3.4 The “Quality Policy” is communicated throughout the UVCP, and its role is explained and discussed at the general orientation training provided to all employees.

5.3.5 The “Quality Policy” is periodically reviewed within the framework of management reviews of the QMS to ensure its continual relevance and suitability. The process for reviewing the quality policy is defined in ***QOP-56-01 Management Review***.

5.4 Quality Management System Planning

5.4.1 Quality objectives

5.4.1.1 Quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products (services) and processes, and to improve the QMS and quality performance.

5.4.1.2 Quality objectives are established at the management reviews of the quality system. Management reviews also initiate and monitor projects for achieving quality objectives. These processes for establishing, implementing and monitoring quality objectives are defined in ***QOP-56-01 Management Review***.

5.4.1.3 Quality objectives define the direction and priorities for continual improvement. Use of quality objectives for facilitating continual improvement is explained in ***QOP-85-01 Continual Improvement***.

5.4.1.4 Quality objectives will be measurable and consistent with the quality policy.

5.4.2 Quality Management System planning

5.4.2.1 QMS processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the QMS is to:

- Achieve the quality objectives and ultimately the Quality Policy;
- Ensure and demonstrate our ability to provide Engineering Maintenance solutions that consistently meet customer requirements and applicable regulatory requirements;
- Ensure high level of customer satisfaction;
- Facilitate continual improvement; and
- Comply with requirements of the ISO 9001 standard and other applicable requirements for quality management systems.

5.4.2.2 The output of QMS planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all processes of the QMS (refer to ***QMS-04, Section 4.1.1***).

5.4.2.3 Changes to the QMS are planned within the framework of management reviews (refer to ***QOP-56-01 Management Review***). These changes may be in response to changing circumstances, such as product, process, capacity, or other operational or organizational changes; or to improve the effectiveness and efficiency of the QMS.

5.5 Organization and Communication

5.5.1 Responsibility and authority

5.5.1.1 Interrelation of all personnel who manage, perform and verify work affecting quality is identified in the Organizational Chart enclosed at the end of this ***section 5.5.1***, and in operational procedures and other documents defining these activities. Top management ensures that the personnel have sufficient independence and authority to perform these tasks, in particular, internal auditors and personnel responsible for monitoring experience from the post-production stage and reporting adverse events.

5.5.1.2 The COO has the overall responsibility for the:

- Management of technical services in all areas of consulting engineering, engineering management and other operations support.
- Technical adequacy, planning, scheduling and execution of project activities

5.5.1.3 Program Managers are responsible for:

- The effective implementation and day-to-day management of the QMS process.
- Requesting assistance from their peers or from the Management Representative in performing quality reviews and audits within their areas of responsibilities.

5.5.1.4 All departments and functions in the UVCP are responsible for implementing, maintaining, and improving the QMS.

5.5.1.3 Authorities and responsibilities for specific processes of the QMS are defined:

- Throughout this quality manual and in every operational procedure where the specific quality system process or activity is documented; and
- In Quality System Process sheets in ***QMS-04, Section 4.1*** (as Process Owners).

6.1 Improvement

6.1.1 Continual improvement

6.1.1.1 UVCP Inc. continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. ***QOP-85-01 Continual Improvement*** defines this process.

6.1.1.2 Internal audit results and quality performance data are analyzed by management review to assess the effectiveness of the quality system and current organizational performance. Opportunities and priorities for improvement are identified by comparing present quality performance to goals and aspirations defined in the quality policy. This process is defined in ***QOP-56-01 Management Review***.

6.1.1.3 Improvement projects are defined either as corrective and preventive actions or as quality objectives. These processes are defined in ***QOP-85-03 Corrective and Preventive Actions***, and ***QOP-56-01 Management Review***, respectively.

6.1.2 Corrective action

6.1.2.1 Customer complaints

6.1.2.1.1 Customer complaints that allege deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product are logged and documented.

6.1.2.1.2 Complaints that involve a possible failure of a product, labeling, or packaging to meet any of its specifications are always investigated, and the results of the investigation are documented.

6.1.2.1.3 The system for receiving, logging, investigating and responding to customer complaints is defined in ***QOP-85-02 Customer Feedback and Complaints***.

6.1.2.2 Corrective and preventive action

6.1.2.2.1 Corrective actions are taken to eliminate causes of actual nonconformities in order to prevent their recurrence.

6.1.2.2.2 Preventive actions are implemented to eliminate causes of potential nonconformities in order to prevent their occurrence.

6.1.2.2.3 The process for taking corrective and preventive actions includes requirements for:

- Reviewing nonconformities and potential nonconformities,
- Determining causes for actual and potential nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur and that potential nonconformities are prevented,

- Determining and implementing actions needed, including, if appropriate, updating documentation,
- Recording the results of any investigations and of actions taken, and
- Reviewing the corrective or preventive action taken and its effectiveness.

This process is defined in ***QOP-85-03 Corrective and Preventive Action***.

UVC personnel. 410 Laurie House, Colyear Street, Derby DE1 1LA: Tel: +44 203 239 1228 Mob: +44 7983 897 224.
EM: admin@ uvcpersonnel.net
WEB: www.uvcpersonnel.net