General Quality Assurance Procedure

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Subject: Quality System Principles and Internal Audit

Approved By: Tony Casillas – QA/Engineering Systems Manager

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I. Purpose

To establish the quality loop within **Industrial Welding & Engineering (IWE) and MTC Engineering (MTC)** which applies to interactions between marketing, engineering, purchasing, process planning and control, production and manufacturing, inspection and testing, packaging and storage, sales and distribution, installation and technical support. Also to establish how this interaction comprises the Quality System and system review at **IWE and MTC**.

II. Policy

To achieve its stated quality goals and objectives, a strong interaction, defined as the quality loop, shall take place between the various functions whose combined effort results in the development and production of the company's products. The quality related activities of all personnel in the quality loop should be defined in the Quality system under the direction and control of QA/Engineering and individual Project Managers. During the earliest practical stage of contract performance, all new incoming contracts/orders shall be reviewed to ensure that the requirements are clearly defined and documented and do not differ from those in the Company's proposal/quote, purchase order or sales offer. The contract review process shall also be used to determine that **IWE and MTC** has the capability to meet all contractual requirements and are maintained in the on-line system and master job folder.

III. Responsibilities and Procedures

5.1 Quality Loop

- 5.1.1 The **IWE and MTC** quality system applies to all activities pertinent to the quality of a product, from design through delivery and installation.
- 5.1.2 The following activities are phases included in the quality loop:
 - a) Marketing and market research;
 - b) Design/specification engineering and product development;
 - c) Procurement/purchasing from outside sources;
 - d) Process planning and development;
 - e) Production;
 - f) Inspection, testing and examination;
 - g) Preserving, packaging and storage;
 - h) Sales and distribution;
 - i) Installation and operation;
 - j) Technical support and maintenance;
 - k) Disposal after use.
- 5.1.3 The Project Manager or designee shall have the responsibility for determining and defining customer

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needs, expectations and product requirements so that they can be produced conforming to defined requirements at optimum cost.

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5.2 Contract Review

- 5.2.1 Upon receipt of a new contract or order, QA/Engineering, the Project Manager or designee shall be responsible for the initial contract review. The respective Project Manager shall be responsible for documenting each contract review on QA Form QA 013 and establishing a master job folder.
- 5.2.2 The contract review process shall be used to make the following determinations:
 - a) that all contractual requirements are clearly defined and documented;
 - b) that the stated requirements do not differ from the original proposal and/or sales offer;
 - c) if there are unusual quality requirements such as special processes or testing;
 - d) if further clarification of the requirements are needed from the customer.
 - e) define quality/inspection requirements
 - f) define packaging and shipping requirements
- 5.2.3 Based on the contract review, the Project Manager or designee shall be responsible for developing the quality plan including the need for special quality and documentation requirements and the formal distribution thereof including all activities related to the master schedule and job processing to completion.

5.3 Structure of the Quality System

- 5.3.1 Senior Management shall be responsible for establishing the quality policy and for establishing the quality system. Control of quality shall be clearly defined as a function of all personnel of all the Departments in the quality loop participating in the engineering, development, fabrication, processing, assembly, test, maintenance, packaging, shipping, storage and site installation processes.
 - 5.3.1.1 Management of all organizational elements in the quality loop shall be responsible to ensure that quality consideration is an integral part of all processes and to enforce compliance to the quality system.
 - 5.3.1.2 Each Manager is responsible for assessing their internal compliance with the requirements of the ISO 9001:2008 standards and MIL-Q-9858A with the assistance of QA/Engineering, the Project Manager. Necessary departmental policies and procedures shall be established on an as need basis to comply with these requirements. Changes to policy statements or procedures referenced in the individual Department programs shall be submitted for review and inclusion in the Quality

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System by senior management.

5.3.2 QA/Engineering, the Project Manager or designee shall define which activities within the organization directly or indirectly affect quality so that these activities may be controlled under the quality system.

5.3.3 QA/Engineering, the Project Manager or designee may, at their option, delegate certain responsibilities for the controlling of designated activities that are under his/her control. Whenever such delegation occurs, the person receiving this responsibility shall have independence from the activity being reported on or monitored.

- 5.3.4 QA/Engineering, the Project Manager or designee shall act as the control point for all interface and interaction between different activities related to controlling quality.
- 5.3.5 The organizational structure of the quality system shall be consistent with the need for continuous quality improvement and the need to identify potential quality problems and the implementation of preventive measures.
- 5.3.6 It is the responsibility of senior management to provide adequate resources and personnel to implement quality policies and achieve stated quality objectives. Said resources include the following:
 - a) human resources and specialized skills;
 - b) design and development equipment;
 - c) manufacturing equipment;
 - d) inspection, test and examination equipment;
 - e) instrumentation and computer software.
- 5.3.7 It is the responsibility of senior management to determine the level of competence, experience and training necessary to ensure that personnel performing quality related tasks are qualified.
- 5.3.8 The quality system shall provide operational procedures to provide continuous control over all activities affecting quality. QA/Engineering, the Project Manager or designee is responsible for issuing such procedures.
- 5.3.9 The written operational procedures issued by QA/Engineering, the Project Manager or designee shall provide clear, unambiguous direction as to how corporate quality objectives are to be implemented. These shall be consistent with the emphasis on preventive actions while not sacrificing the ability to respond to quality problems and take appropriate corrective action.

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5.4 Documentation of the System

- 5.4.1 The QA/Engineering Manager, Project Manager or designee shall issue appropriate documentation necessary for an orderly implementation of the quality management system. Such documentation shall ensure a common understanding of the company's quality policies and procedures. Provisions shall be made for the proper identification and collection of complete and reliable quality records pertinent to the documentation of the system which will demonstrate the existence of control of those activities related to quality.
 - 5.4.1.1 Records are maintained as prescribed by contract requirements retention periods, and as deemed essential to the effective and economical control of product quality. An on-line Master Job Folder is maintained to ensure documentation of evidence that all functions affecting product quality, from the determination and development of requirements through the production and evaluation of items and their assembly into deliverable end items or systems and their evaluation, are available for review and evaluation upon internal or customer request.
- 5.4.2 The main document establishing the quality management program and quality system of **IWE and MTC** shall be the Quality Assurance Manual (QAM). The quality system documented in this manual is comprised of many procedures, individual records, instructions and other documents required assuring adequate controls throughout all areas of the company.
 - 5.4.2.1 The primary purpose of the quality manual is to provide a description of the system and serve as a permanent reference point for the implementation and maintenance of the system. The secondary purpose of the manual is to demonstrate to our customers that a comprehensive quality system is in place at IWE and MTC.
 - 5.4.2.2 Procedures shall be established for making changes to the manual on a controlled basis so that modifications and revisions are issued simultaneously to all holders of the quality manual.
 - 5.4.2.3 The quality assurance manual of **IWE and MTC** is issued on a controlled copy basis. No recipient of the hard-copy manual shall be authorized to make copies and each recipient is responsible for maintaining his/her manual up to date. The QA/Engineering Manager or designee is the only person authorized to issue manuals and issue revisions or modifications.
 - 5.4.2.4 Electronically issued copies of the QAM are not considered controlled copies and are issued for reference only. Although all electrically issued copies are issued in a non-editable format, IWE AND MTC hold no responsibility for such copies issued for reference only.

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5.4.2.5 One master hard-copy of the QAM in printed version is maintained by the QA/Engineering Manager. Access to the QAM and supporting QAP's and subsequent supporting work Instructions from other internal departments is via the on-line QAM and is available to all company employees for review.

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- 5.4.3 For projects involving new products or processes, QA/Engineering, the Project Manager or designee shall prepare and issue quality plans on QA form QA 010 or as noted in the QAM detailing objectives to be attained, assignment of responsibility and authority, specific procedures and work instructions and necessary testing or inspection. Quality plans for special projects shall be consistent with the quality management program and quality system as defined in the QAM.
 - 5.4.3.1 For all contracts including government contracts, a contract review via QA form QA 013 shall be conducted prior to and upon receipt of award to identify special or unusual requirements, to assess the company's ability to perform the statement of work and to provide for basic program planning as required. Special requirements that are identified shall be assigned to the responsible department for analysis and solution. The means of testing and proving successful compliance with the requirements shall be determined during initial quality planning.

5.5 Internal Auditing of the Quality System

- 5.5.1 The QA/Engineering Manager, Project Manager or designee shall conduct internal quality audits. The purpose of such audits shall be to determine internal compliance with all stated company quality objectives and goals as defined in the QAM as well as compliance with contractual requirements. The audits shall also evaluate the adequacy of operational methods and compliance to established procedures.
 - 5.5.1.1 If required, an audit report QA form QA 002 with observations, recommendations and action due dates shall be prepared and distributed at the completion of the audit. The QA/Engineering Manager, Project Manager or designee shall maintain a record of audit reports and actions taken as a result of audit findings in the on-line Master QA System folder.
- 5.5.2 The internal audit procedure shall include the preparation of an audit plan that covers the following items:
 - a) specific areas and activities to be audited;
 - b) qualification of personnel performing the audit;
 - c) type of audit (regular or special);
 - d) procedure for and content of audit report.

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5.5.3 The Internal Audit form QA 002 findings shall be reported to the CEO and/or senior management who in turn will establish any corrective action requirements, if needed and issue as CAR on QA form QA 001. Audit findings shall, at a minimum, cover the following:

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- a) specific examples of deficiencies found and non-compliance;
- b) possible reasons for deficiencies and non compliance;
- c) suggestions for appropriate corrective action;
- d) review and assessment of corrective action taken in previous audits;
- e) provide a schedule for corrective action follow-up.
- 5.5.4 If the audit yields no deficiencies, then no additional actions are required to be documented and the completed QA form QA 002 shall be closed complete and filed in the QA System Folder on line.
- 5.6 Review/Evaluation of Quality Management System
 - 5.6.1 The QA/Engineering Manager, Project Manager or designee shall secure the services of an accredited independent organization or utilize a qualified representative of management to review and evaluate the quality management system when required by contract or when requested by a customer representative.
 - 5.6.2 The review and evaluation of the quality management system shall be well structured and comprehensive. Specifically, the following items shall be included in this review:
 - a) review of internal audit findings and corrective action taken;
 - b) effectiveness of the system in achieving stated quality goals;
 - c) evaluation of possible updating of the system.
 - 5.6.3 The results of this review and evaluation shall be documented and submitted to the CEO and/or senior management for proper action. Such evaluation shall be conducted a minimum of once per year, but can be used on an as need basis.
- 5.7 Government/Customer Inspection
 - 5.7.1 As a supplier to the U.S. Department of Defense, **IWE and MTC** has a contractual obligation to submit a controlled copy of the QAM to the designated DCMA representative for evaluation and approval. The QA/Engineering Manager or designee is responsible for submitting the QAM and supporting system procedures, if requested, to DCMA and for taking appropriate action to ensure compliance with DoD requirements. Changes and modifications to the system shall also be submitted to the Government representative for his/her review and approval.

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5.7.2 On certain DoD prime and sub-contracts, IWE and MTC may be required to submit to source inspection prior to shipment. In such instances, when contractually required to do so, the QA/Engineering Manager, Project Manager or designee shall provide the Government representative with access to the material or product including access to the necessary test and measuring equipment as well as personnel to operate the equipment if necessary.

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5.8 Reference Documents

- QAM
- QAP 17.0 Internal Quality Audits
- QAP 18.0 Training
- QAP 22.0 Continuous Improvement •
- Internal Audit Report QA 002
- Quality Control Plan QA 010
- Contract Review QA 013