TECO Westinghouse

Quality Assurance Manual

Revision 8

3/16/18

Uncontrolled Copy

SYSTEM CERTIFICATION ISO 9001 SGS

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

Table of Contents

1.0 SCOPE

1.1 General

This manual describes the Quality Management System (QMS) for the Round Rock, Texas site of TECO-Westinghouse Motor Company (TWMC). The manual complies with the requirements of ISO 9001:2015, and when contractually required, 10CFR50-Appendix B, 10CFR21, ASME NQA-1 1994 Edition, EPRI NP-XXXX, NRC-Generic Letter XX-XX, MIL-Q-9858A, MIL-I-45208A and C-TPAT.

1.2 Application

The manual establishes the policies and commitments of TWMC including meeting the requirements of our Interested Parties and serving as the guiding document to employees whose actions affect product quality. This manual may also be used to inform our customers and third party auditors about the content of our QMS, but remains the property of TWMC and is not to be used for other purposes without prior written approval.

2.0 NORMATIVE REFERENCE

The normative reference for this manual is:

ISO 9001, Quality Management Systems - Fundamentals and vocabulary.

3.0 TERMS AND DEFINITIONS

The following terms and definitions from ISO 9000 apply.

- Throughout the text, wherever the term "product" occurs, it can also mean "service."
- "Quality System," "Quality Management System," and "QMS" can be used interchangeably.
- Additionally, the following verbal forms are used:

  "shall" indicates a requirement

  "should" indicates a recommendation

  "may" indicates a permission

  "can" indicates a possibility or a capability.
- Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

4.0 CONTEXT OF THE ORGANIZATION

4.1 Understanding the Organization and its Context

The organization has determined external and internal issues that are relevant to the purpose and the strategic direction of the company. These issues can affect our ability to achieve the intended result(s) of the QMS - customer satisfaction and delivery of quality product and/or service.

The organization monitors and reviews information about the external and internal issues.

The internal context is the environment in which we aim to achieve our objectives. Internal context can include our approach to governance, and contractual relationships with customers and interested parties. These are defined on our internet Company page under: About Us, Our Mission, Scope, and Company Values.

4.1.1 Internal issues that affect our organization

1. Results of customer reviews, audits, complaints and feedback
2. Organizational performance
3. Interested parties needs and expectations
4. Internal audit results.

4.1.2 External issues that affect our organization

1. Economic shifts in the organization's market
2. Government regulations and changes in the law
3. Competitive products and services
4. Events that may affect corporate image
5. Changes in technology.

External context takes into account issues arising from social, technological, environmental, ethical, political, legal, and economic environment.

4.2 Understanding Needs and Expectations of Interested Parties

Our Interested Parties are the team players involved to make our business a success. Each of these parties has different requirements needed to accomplish their responsibilities. Listed on our intranet are the stakeholders, the requirements, and the Departmental processes necessary to meet those requirements. We monitor and review information about these stakeholders and their relevance.

4.3 Determining the Scope of the Quality Management System

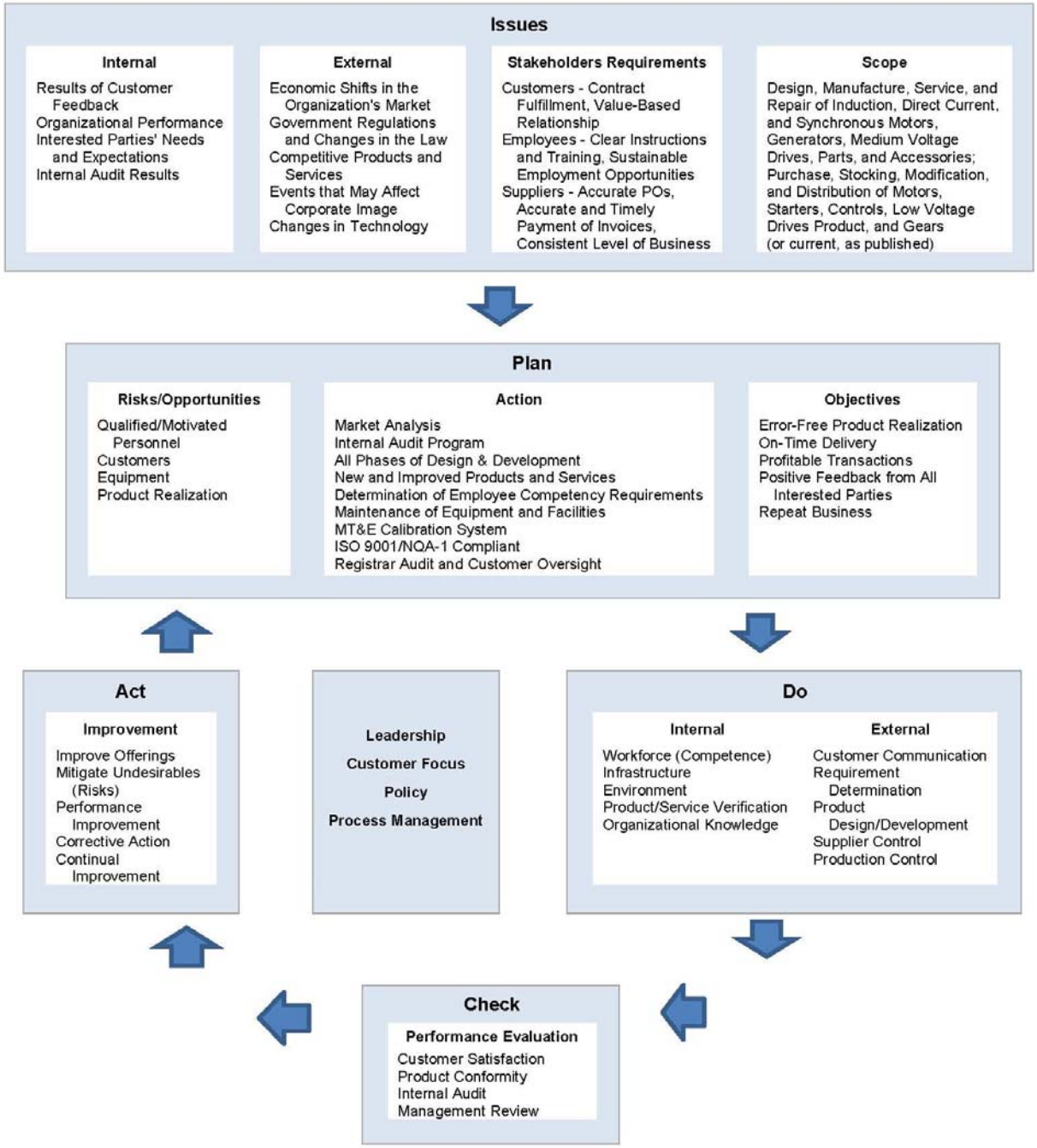
The QMS/this manual covers the business activities listed on our ISO certificate and as defined on the TWMC Internet page.

4.4 Quality Management System and its Processes

4.4.1 This section outlines the way in which TWMC's QMS is established, documented, implemented, and maintained, and how the Company will continually improve its effectiveness.

Note: For a further breakdown of processes needed and their interactions, review the TWMC Process Matrix.

The President has overall responsibility for establishing expectations for effective implementation of the QMS. He ensures that all procedures and instructions considered necessary are in place. Then, because quality is achieved and maintained by those assigned responsibility for performing the work, each department manager is responsible for ensuring that their departmental procedures are compliant with the Manual and accurately detail the work processes necessary to support the QMS requirements.



To ensure procedures are compliant and accurately detail work processes, each department manager has:

a) Determined inputs required and outputs expected from these processes

b) Determined the sequence and interaction of these processes

c) Determined and applied criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes

d) Determined resources needed for these processes and ensures their availability

e) Assigned responsibilities and authorities for these processes

Additionally, department manager will continually:

f) Address the risks and opportunities associated with requirements

g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results

h) Work to improve the processes and the QMS.

The Quality Manager monitors the status of the QMS and supporting documents through the Internal Audit program. The status of the QMS is reported to the Office of the President in accordance with the Management Review process.

4.4.2 TWMC maintains and retains documented information to support the operation of its processes and to verify that the processes are being carried out as planned. For details see sections covering documented information.

5.0 LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General

The President and each Executive reporting to the Office of the President demonstrate leadership and commitment with respect to the QMS by:

a) Taking accountability for the effectiveness of the QMS

b) Ensuring that the quality policy and quality objectives are developed and are compatible with the context and strategic direction of TWMC

c) Ensuring the integration of the QMS requirements into business processes

d) Promoting the use of the process approach and risk-based thinking

e) Ensuring that resources needed for the QMS are available

f) Communicating the importance of effective quality management and of conforming to the QMS requirements

g) Ensuring that the QMS achieves its intended results

h) Engaging, directing and supporting persons to contribute to the effectiveness of the QMS

i) Promoting improvement

j) Supporting other relevant management roles to demonstrate leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

The Office of the President is committed to customer focus. Our Company Values include Customer Focus, Continuous Improvement, Teamwork, and Leadership. Everything we do is done with our customers in mind, both internal and external. This helps us deliver high quality products, services, and solutions on time. We want to be our customers' first choice. To accomplish this we ensure that:

a) Customer and applicable statutory and regulatory requirements are determined, understood, and consistently met

b) Risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed

c) The focus on customer satisfaction is maintained.

5.2 Policy

5.2.1 Establishing the Quality Policy

The President has established, implemented and maintained a quality policy that:

a) Is appropriate to our Mission, Company Values, and context of organization

b) Provides a framework for setting company-wide quality objectives

c) Includes a commitment to satisfy applicable requirements and continual improvement of the QMS.

5.2.2 Communicating the Quality Policy

TWMC's Quality Policy has been combined with our Environmental Policy as our published Quality and Environmental Policy.

Communication of the Quality Policy is included in the new employee orientation process.

Copies of the Quality Policy are prominently displayed throughout the Company premises, and can also be found on the website and intranet.

5.3 Organizational roles, responsibilities and authorities

The President has ensured that the responsibilities and authorities for relevant roles have been assigned, communicated, and understood within the organization.

This responsibility and authority includes:

a) Ensuring that the QMS conforms to the requirements of the International Standard

b) Ensuring that processes are delivering their intended outputs

c) Reporting on the performance of the QMS and on opportunities for improvement

d) Ensuring promotion of customer focus throughout the organization

e) Ensuring that the integrity of the QMS is maintained when changes are planned and implemented.

The President has nominated a Management Representative because quality achievement must be verified by those not directly responsible for performing the work. The Quality Manager has been nominated as the Management Representative for the QMS. The Management Representative may delegate work to others, but shall retain responsibility therefor.

5.3.1 Responsibility and Authority

Appendix 5.3 features an organization chart which demonstrates lines of organizational authority.

Appendix 4.4 features a responsibility matrix which matches departments to primary Quality Management System responsibilities.

5.3.2 Management Representative

The Quality Manager acts as the liaison for the QMS for customer audits and registration bodies.

6.0 PLANNING

6.1 Actions to Address Risks and Opportunities

6.1.1 TWMC considers the context of the organization and the needs and expectations of interested parties to determine the risks and opportunities that need to be addressed in order to:

a) Give assurance that the quality management system can achieve its intended result(s)

b) Enhance desirable effects

c) Prevent, or reduce, undesired effects

d) Achieve improvement.

Categories Include:

- Qualified/motivated personnel
- Customers
- Equipment
- Product realization

6.1.2 TWMC has the following actions in place to address risks and opportunities. These actions have been integrated and implemented into the QMS processes.

- Market analysis
- Internal audits
- All phases of design and development
- New and improved products and services
- Determination of employee competency requirements
- Maintenance and upkeep of equipment and facility
- Management Review
- ISO 9001/NQA-1 compliance
- Customer and registrar audits

NOTE: Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

6.2 Quality Objectives and Planning to Achieve Them

6.2.1 Company goals and objectives are established by executive management at relevant functions, levels, and processes. Each department then establishes objectives within the department to support the company objectives. The quality objectives shall:

a) Be consistent with the quality policy

b) Be measurable

c) Take into account applicable requirements

d) Be relevant to conformity of products and services and to enhancement of customer satisfaction

e) Be monitored

f) Be communicated

g) Be reviewed and updated as appropriate.

6.2.2 When planning to achieve its quality objectives, TWMC will determine:

a) What will be done

b) What resources will be required

c) Who will be responsible

d) When it will be completed

e) How the results will be evaluated.

6.3 Planning of Changes

When TWMC determines the need for changes to the QMS, the changes shall be carried out in a planned manner.

The following will be considered:

a) Purpose of the changes and their potential consequences

b) Integrity of the QMS

c) Availability of resources

d) Allocation or reallocation of responsibilities and authorities.

Note: The TWMC Process Matrix is a tool to facilitate planning of changes.

7.0 SUPPORT

7.1 Resources

7.1.1 General

Executive management shall determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of the QMS. These resources are charged with authority and responsibility. Additionally, they will consider the capabilities of, and constraints on, existing internal resources and, if required, resources needed from external parties.

7.1.2 People

Executive management shall determine and provide the persons necessary for the effective implementation of its QMS and for the operation and control of its processes. This includes ensuring that personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills, and experience.

7.1.3 Infrastructure

The company is committed to providing and maintaining the infrastructure needed to achieve conformity to product and services requirements under controlled conditions. Infrastructure includes buildings, workspaces, utilities, appropriate equipment, software, computer networks, transportation, and other supporting services.

Production equipment is subject to routine and preventive maintenance activities. Production and Maintenance share responsibility for the equipment maintenance and retention of records verifying that maintenance is performed.

Building Services is responsible for the proper maintenance of buildings, heating, ventilation, and air conditioning equipment, as well as regular cleaning of production areas to ensure a suitable working environment.

Information Systems is responsible for maintaining and controlling software and computer networks and tools for reporting in assorted data bases.

Product Warehouses and Shipping & Logistics are responsible for packaging and coordinating the transportation for shipping of product.

Department work instructions identify equipment requiring qualification, provide for equipment maintenance, and assign responsibilities for performing these activities.

7.1.4 Environment for the Operation of Processes

The company is committed to providing a suitable work environment in order to achieve conformity of product and service requirements. The term "work environment" relates to those conditions under which work is performed including a combination of human and physical factors such as: social (e.g., non-discriminatory, calm, non-confrontational); psychological (e.g., stress-reducing, burnout prevention, emotionally protective); physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise); transportation resources; information and communication technology.

These factors can differ substantially depending on the products and services provided.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

TWMC has determined and provides resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

Quality Assurance, Manufacturing Engineering, Engineering, and Production ensure that the resources provided:

a) Are suitable for the specific type of monitoring and measurement activities being undertaken

b) Are maintained to ensure their continuing fitness for their purpose

c) Have the environmental conditions suitable for the calibration, inspection, or measurement being conducted.

Quality Assurance coordinates and administers the calibration system. Equipment used by Quality Assurance, Production, and Engineering for the purposes of accepting or qualifying products or processes is controlled and subject to the calibration system. All such equipment is uniquely identified. Appropriate documented information is maintained.

7.1.5.2 Measurement Traceability

Measurement traceability is a requirement when it involves acceptance of product. It is considered an essential part of providing confidence in the

validity of measurement results. Measuring equipment in this category shall be:

a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification will be documented in applicable work instruction

b) Identified in order to determine their status

c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

When calibration is done in-house, work instructions are provided that contain details of equipment type, identification numbers, location, frequency of checks, check method, and acceptance criteria. Calibration performed outside of the Company's facilities shall be carried out by an approved calibration facility which meets the requirements of Appendix 8.4.3.

Where possible, calibration status and date of next check is shown on the equipment. All other equipment is traceable through a unique identification number to a calibration record. Records of calibrations are maintained to provide details of results, traceability, and check frequencies.

7.1.6 Organizational Knowledge

TWMC determines the knowledge necessary for the execution of its processes and to achieve conformity of products and services. This knowledge is maintained and can be made available as required.

Retention methods include:

- Succession planning
- OJT and cross-training
- Lessons learned/process improvements
- Drawings, Process Specifications and Work Instructions
- Industry education through standards, training, conferences, or customers.

When addressing changing needs and trends, TWMC considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

The Company regards the use of appropriately trained staff to be essential. This section outlines the way in which training requirements are identified, implemented, monitored, and evaluated throughout the Company. All Company personnel involved with activities affecting the conformity of products or services requirements receive instruction in the requirements of the QMS.

7.2.1 Executive Management

Executive management shall:

a) Determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS

b) Ensure that these persons are competent on the basis of appropriate education, training, or experience

c) Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken

d) Ensure we retain appropriate documentation as evidence of competence.

7.2.2 Quality Assurance (QA)

A general overview of the QMS is given as part of new employee orientation by QA.

7.2.3 Human Resources (HR)

HR administers the establishment and maintenance of Employee Records and Job Descriptions and is responsible for maintenance of a centralized training database for maintaining records of education, non-job specific training, skills, and experience. HR is responsible for coordinating new employee orientation with the responsible department manager.

7.2.4 Department

Detailed QMS training is provided by the responsible department management as part of the defined training for specific job classification.

All training provided will be evaluated by the appropriate manager for effectiveness. The evaluation can take many forms, i.e., report, score sheet, surveys/questionnaires or records of reviews.

All job functions requiring training in order to assure conformity of the Company's products and services requirements are identified by the responsible manager. Only individuals with the required combination of education, training and/or experience are assigned to these job functions.

Training needs and status are reviewed and recorded at defined intervals by the responsible managers. Records of training, education, and experience are maintained.

Managers institute a training and/or qualification plan when:

a) Task could affect the conformity of product requirements and the personnel selected for the task lack the combination of education and experience which could assure product conformance

b) Task is too complex to be adequately described in instructions

c) Industry standards require continuing qualification (certification) to perform a task

d) Task involves a special process

e) Task involves verifying conformity of product requirements.

Work instructions are required only if the department maintains training records that are not kept by Human Resources. Department responsibilities are identified in Appendix 4.4.

7.3 Awareness

This section outlines awareness training responsibilities.

7.3.1 Executive management shall ensure that persons doing work under the organization's control are aware of:

a) The Quality Policy

b) Relevant quality objectives

c) Their contribution to the effectiveness of the QMS, including the benefits of improved performance

d) The implications of not conforming to the QMS requirements.

7.3.2 Quality Assurance

QA is responsible for conducting new employee quality awareness training of personnel performing activities affecting conformity to product requirements. The awareness training covers the following items:

a) TWMC Quality Policy

b) DocuShare On-Line Document System

c) Overview of the processes of the QMS

d) Review of Appendix 5.3 - Organization Chart

e) Review of Appendix 4.4 - Responsibility Matrix

f) Overview of applicable codes and standards (Welding, NDE, NQA-1, API, IEEE)

g) Review of Appendix 8.2.1 - 10 CFR 21 Reporting

h) Review of the Defense Priorities & Allocations System (DPAS)

7.3.3 Department Managers

Department managers are responsible for conducting QMS awareness training for their respective departments. The extent of this training is based on a review of the Quality Assurance Manual and the responsibilities identified in Appendix 4.4. At a minimum, the departmental quality awareness training should include:

a) Company Mission, Profile, Scope and Values

b) TWMC Quality Policy

c) Quality Objectives / Department Objectives

d) Specific Department Quality Management System Responsibilities

e) Department Work Instructions

Each department manager is responsible for supporting HR in the preparation and revision of Job Descriptions appropriate for the work performed in their departments.

Managers are responsible for ensuring that personnel have adequate resources to perform tasks in conformance to requirements and that employees have the combination of education, experience, and/or training required to perform tasks. Job descriptions specify the education and/or experience required to perform the job.

Managers identify departmental tasks which require training and/or qualification of personnel and the minimum requirement for such personnel. Additionally, if all training for employees is maintained in HR's centralized training database, department records are optional unless otherwise specified.

No activity which could affect the conformity of product requirements is assigned to a temporary employee until the responsible manager has ensured that the temporary can perform the task in accordance with requirements.

7.4 Communication

TWMC has determined the internal and external communications relevant to the quality management system, including:

a) On what it will communicate

b) When to communicate

c) With whom to communicate

d) How to communicate

e) Who communicates.

7.4.1 Internal Communication

The company conducts new employee orientation, all-employee, management and workplace meetings, where quality concerns are reviewed and discussed. Executive and department managers ensure objectives and status are reviewed at management or departmental meetings and individual performance reviews as appropriate.

7.4.2 External Communication

The applicable departments are responsible for communicating with customers or suppliers based on the scope and nature of the inquiry or service requested.

Procedures for identification, evaluation and reporting of defects and noncompliance as required by 10CFR21 are described in Appendix 8.2.1.

7.5 Documented Information

7.5.1 General

The company has a documented Quality Policy and published Quality Objectives.

Other documented information is divided into three levels.

Level 1 - Quality Assurance Manual

The Quality Assurance Manual describes the Company's approach to the requirements of ISO 9001. Additional information which is subject to frequent changes is contained in the Appendi**x**es to this manual.

Level 2 - Department Work Instructions

Work Instructions are procedures, plans, instructions, drawings, or other documents relating to specific contracts, products or processes, which give methods on how a work process is to be carried out in order to meet customer requirements.

Level 3 - Forms and Records

These documents provide the means and objective evidence that requirements have been satisfied in accordance with level 1 policy and level 2 instructions.

7.5.2 Creating and Updating

Documents are originated or revised according to a standardized format. Format guidelines for QMS documents are provided in Appendix 7.5.

Documents are reviewed and approved by authorized personnel prior to issue. Prescribed approval, issuance, removal, and obsolescence procedures are defined in department work instructions.

Document control procedures shall provide for a master list, or other means for identifying the current revision levels and revision dates of issued documents. The revision status of all QMS documents is maintained and readily available for reference.

When changes or revisions to documents or data are required to correct observed errors, the individual who makes the change must have the same level of authority as the individual who entered the original information.

7.5.3 Control of Documented Information

The company's current controlled electronic document retrieval system is DocuShare.

Read access is provided to all employees for departmental procedures and company policies and procedures.

The program is available on all company workstations.

Program content is controlled by QA.

Documents of external origin determined by TWMC to be necessary for the planning and operation of the QMS are identified, and their distribution is controlled.

Additional information is available in the applicable appendixes to this manual.

8.0 OPERATION

8.1 Operational Planning and Control

Each department manager will plan, implement and control the processes needed to meet the requirements for the provision of products and services, and to implement the actions to address risks and opportunities by:

a) Determining the requirements for the products and services

b) Establishing criteria for:

   1) The processes

   2) The acceptance of products and services

c) Determining the resources needed to achieve conformity to the product and service requirements

d) Implementing control of the processes in accordance with the criteria

e) Determining, maintaining and retaining documented information to the extent necessary:

   1) To have confidence that the processes have been carried out as planned;

   2) To demonstrate the conformity of products and services to their requirements.

Note: The TWMC Process Matrix is a tool that is used as a guide in this process.

The output of this planning will ensure suitability of the organization's operations.

Department manager shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Additionally, they shall assist in ensuring that outsourced processes are controlled.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

The applicable departments are responsible for communicating with customers based on the scope and nature of the inquiry or service requested.

a) National Sales - inquiries, quotes and negotiations, product information, contract terms and conditions, scope of work, and customer satisfaction feedback

b) Commercial Sales - inquiries, quotes and negotiations, product information, contract terms and conditions, scope of work, and customer satisfaction feedback

c) Aftermarket Services - inquiries, quotes and negotiations, product information, contract terms and conditions, scope of work, warranty issues, customer satisfaction feedback, motor repair, servicing, engineering services, and renewal parts

d) Projects - contract software, manufacturing and test schedules, contract changes, scope of work, and customer satisfaction feedback

e) Stock Product Sales - inquiries, quotes and negotiations, product information, contract terms and conditions, and scope of work (includes drives, controls, gears, etc.)

f) Logistics and Stock Products Customer Service - stock order entry, order/RMA verification, customer satisfaction feedback, and product availability

g) Quality Assurance - customer audits, inspections, and corrective and preventive actions.

Communication with customers will include:

- Providing information relating to products and services
- Handling inquiries, contracts or orders, including changes
- Obtaining customer feedback relating to products and services, including customer complaints
- Handling or controlling customer property
- Establishing specific requirements for contingency actions, when relevant.

Detailed procedures for accomplishing this quality process are defined in department work instructions.

8.2.2 Determining the Requirements for Products and Services

Prior to accepting an order, TWMC must determine:

- Requirements specified by the customer, including the requirements for delivery and post-delivery activities
- Requirements not stated by the customer but necessary for specified or intended use, where known
- Statutory and regulatory requirements applicable to the product and services

- Any additional requirements considered necessary by TWMC.

The applicable group coordinates review as appropriate to the scope and nature of the inquiry, contract, and/or requested change. Departmental review responsibility is assigned as follows:

a) National Sales, Commercial Sales, Stock Product Sales, and Aftermarket Services - contract terms and conditions, scope of work

b) Projects - contract terms and conditions, scope of work, schedule

c) Engineering - technical and design requirements

d) Operations - capacity, scheduling, and manufacturability

e) Quality Assurance - nuclear, government, and special quality requirements.

If any required resources are unavailable, any requirement needs amplification, or if specifications cannot be met, appropriate action including contacting the customer, if required, is taken until the situation is resolved. Final result must be documented and maintained.

8.2.3 Review of the Requirements for Products and Services

8.2.3.1 Prior to committing to an order, TWMC will confirm customer requirements and perform a review.

This review should include an assessment to ensure the customer requirements are within normal and reasonable manufacturing capability, and that TWMC can meet all requirements. This assessment should include:

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities. Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

b) Requirements not stated by the customer, but necessary for the specified or intended use, when known

c) Requirements specified by TWMC

d) Statutory, regulatory, environmental and safety requirements applicable to the products and services

e) Contract or order requirements differing from those previously expressed. TWMC shall ensure that any requirements differing from those previously defined are resolved.

f) Necessary manufacturing processes are developed

g) Special requirements (quality, packaging, delivery, etc.) can be met.

Any differences or ambiguities shall be resolved prior to committing to the order.

NOTE: In some situations, such as phone orders or internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

8.2.3.2 Appropriate department retains documented information, as applicable:

a) On the results of the review

b) On any new requirements for the products and services.

Contractual requirements, which define the basic design or manufacturing parameters, are identified and documented within the order entry processes. Incomplete, ambiguous, or conflicting issues are resolved prior to processing the design, if possible.

Unresolved issues and changes to design or manufacturing requirements that may compromise contract compliance are controlled and documented through the customer Change Notice system.

Detailed procedures for accomplishing this quality process are defined in department work instructions.

8.2.4 Changes to Requirements for Products and Services

After approval, a shop order number is assigned and the transaction becomes a contract. Changes to the contract, either at customer or Company request, must be confirmed in writing. When approved, the Company identifies and records the amendment and ensures that the amendment is correctly communicated to the appropriate departments.

8.3 Design and Development of Products and Services

8.3.1 General

TWMC has established, implemented, and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services. Engineering maintains records for all design and development activities to include changes of products and services.

8.3.2 Design and Development Planning

This section describes what is considered and the means by which design and development activities are defined, controlled, and verified to ensure that specified requirements are met.

Engineering is responsible for design and development planning. During the design and development planning, Engineering determines all design and development stages related to product or service. Engineering also determines the review, verification, and validation that are appropriate to each design and development stage, and the responsibilities and authorities for design and development. Engineering and Information Systems share responsibility for the development of Design and Test Software. Engineering is responsible for the control of Design and Test Software.

Each design and development planning activity is described by a design plan that supports required activities and schedules, defines assigned qualified personnel or external resource needs which could include customer or end user, and provides for internal and external interface plus the coordination of levels of control expected by customers and other relevant interested parties.

Schedule plans are updated as the design develops. The level of the plan's complexity is dependent upon the design's complexity, the product's intended

application, the degree(s) of innovation required, and the degree(s) of standardization and similarity with proven designs.

All internal and external groups related to design activities are identified and the flow of information among them controlled as defined within the department work instructions.

Design and development review, verification, and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

8.3.3 Design and Development Inputs

Design and development input formally documents the expected features and characteristics of the product or service being designed. The inputs are appropriately specified on a timely basis and correctly translated into design and development documents. Included is all information regarding the rating, loading, function, performance requirements and potential consequences of failure of the product. Also included are any special considerations regarding machine options, service environment, test requirements, shipping and handling, etc., as well as references to applicable product design specifications, standards or codes of practice that the organization has committed to implement and regulatory and statutory requirements. Additionally, information derived from previous similar designs, and other requirements essential for design and development are utilized.

The inputs are reviewed for adequacy. All requirements must be complete, unambiguous, and concise, and any conflicts resolved.

8.3.4 Design and Development Controls

8.3.4.1 Design and Development Review

Design and development reviews define the results to be achieved. Reviews may vary in degree depending on the complexity of the contract, and are planned, conducted, and documented at appropriate design stages as specified in department work instructions. Design and development reviews are held to evaluate the ability of the results of design and development to meet requirements, and to identify any problems and propose necessary actions. Issues such as reliability, serviceability, manufacturability, capability to inspect and test, and the availability of capable and qualified suppliers to provide specified materials and components can be addressed. Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed.

8.3.4.2 Design and Development Verification

Design and development are performed in accordance with planned arrangements and verified by an engineer's review of calculations, which are either computer or manually generated, or compared with similar design when available.

Design and development verification (including, but not limited to, testing to specification) is performed during manufacture and final test under defined conditions to ensure that the design and development outputs have met the design and development input requirements.

8.3.4.3 Design and Development Validation

Design and development validation activities are performed in accordance with planned arrangements to ensure that the resulting products and services meet the requirements for the specified application or intended use and are validated by approval of the performance testing results.

Specific customer requirements, and/or related industry standards, are used to judge and validate the design.

Software that is used to design and develop or test product shall be validated prior to initial implementation and each time a new version is incorporated. Engineering shall establish and maintain software validation and version control procedures appropriate to the type of software application. These controls apply to purchased and TWMC-developed software programs.

Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services. There are adequate controls in the processes to ensure any necessary actions to be taken on problems determined during the reviews, or verification and validation activities are resolved.

When required by contract, department instructions shall be established to provide detailed instructions for compliance with 10CFR50.

8.3.5 Design and Development Outputs

Design and development outputs address and must meet all design and development input requirements. Primary design and development output shall consist of documents which define the final product configuration and characteristics. These outputs provide appropriate information for purchasing, production, and service provision, and specify the characteristics of the product that are essential for its safe and proper use. These documents shall include control plans, drawings, specifications, procedures, and acceptance criteria. Secondary design and development output shall consist of documents supporting the design. These documents shall include calculations, analysis, test requirements, and references to other documents supporting the design.

Design and development output is reviewed and approved prior to release and will list all required drawings and specifications necessary to comply with requirements. Acceptance criteria and characteristics determined to be crucial are identified on the drawings and referenced specifications.

8.3.6 Design and Development Changes

TWMC identifies, reviews, and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. These changes can include field changes, modifications to operating facilities, and a review, justification, verification, and validation of nonconforming item.

The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Documented

information is retained to include design and development changes, authorization for the changes, results of reviews, and actions taken to prevent adverse impacts.

Detailed procedures for accomplishing this quality process are defined in department work instructions.

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

TWMC ensures that externally provided processes, products and services conform to requirements. We also determine the controls to be applied to externally provided processes, products and services when:

a) Products and services from external providers are intended for incorporation into the our products and services

b) Products and services are provided directly to the customer(s) by external providers on our behalf

c) A process, or part of a process, is provided by an external provider as a result our capacity.

TWMC determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. We retain documented information of these activities and any necessary actions arising from the evaluations.

The Purchasing, Stock Product Group, Projects, Shipping & Logistics, Engineering, Aftermarket Services, Quality Assurance, and all product Warehouses share responsibility for the selection and assessment of suppliers. The method chosen follows written guidelines and is dependent on the type and application of the commodity or service purchased.

8.4.1.1 Purchasing Activity

Purchasing is responsible for the following actions:

a) Identifying the need and risk associated in the selection process of a new supplier of products or services

b) Requesting potential new supplier(s) be evaluated and qualified

c) Assuring the scope of work for the selected supplier falls within the limitations and/or restrictions defined by the Approved Supplier Listing (ASL)

d) Providing needed assistance for maintaining and updating the ASL

e) Providing technical support and input to the evaluation process

f) Measuring and reporting supplier performance

g) Identifying supplier performance problems and initiating corrective or preventive actions

8.4.1.2 Quality Assurance Activity

Quality Assurance is responsible for the following actions:

a) Establishing, publishing and maintaining Supplier quality requirements

b) Evaluating and qualifying suppliers based upon their ability to meet Company quality requirements

c) Identifying and coordinating technical support activities necessary to assess supplier capabilities

d) Performing Source, First Article, and Receiving Inspection, when required

e) Measuring and reporting supplier quality performance

f) Maintaining and publishing the ASL

g) Identifying supplier quality performance problems and initiating corrective or preventive actions.

8.4.1.3 Suppliers may be evaluated and selected for inclusion on the ASL based on one or more of the following considerations:

a) Third party accreditation such as ISO, NIAC, ASME, EASA, A2LA, ACLASS, NVLAP, etc.

b) On-site audit

c) References from other customers or users

d) Historical performance

e) Survey Questionnaire which provides evidence demonstrating capability

f) Sole source of a specific commodity or item

g) Established nationally or internationally accepted provider of a product or service, i.e., US Post Office, Federal Express, etc.

Suppliers of nuclear-related products are audited to the requirements of 8.4.3 and 10CFR50 Appendix B. Products which must be procured from suppliers who are not qualified per 10CFR50 Appendix B are dedicated for use in accordance with the appropriate Commercial Dedication Instruction (CDI).

Suppliers of nuclear-related services, i.e., calibration, consultance, etc., may be evaluated and approved for inclusion on the ASL based on above requirements or:

- The supplier's history is evaluated to ensure that identical or similar product that has been previously supplied performs satisfactorily in actual use. Supplier's history shall reflect current capability.
- The supplier's current quality records are supported by documented qualitative and quantitative information which can be objectively evaluated.

Suppliers of products for Government contracts are evaluated and approved based on the requirements defined in Appendix 8.4.3. Products which must be procured from suppliers who are not qualified per Appendix 8.4.3 receive additional instruction through purchase order review.

Detailed procedures for selection, evaluation and re-evaluation are defined in department work instructions.

8.4.2 Type and Extent of Control

TWMC ensures that externally provided processes, products and services do not adversely affect our ability to consistently deliver conforming products and services the customers. TWMC shall:

a) Ensure that externally provided processes remain within the control of its quality management system

b) Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output

c) Take into consideration:

   1) The potential impact of the externally provided processes, products and services on our ability to consistently meet customer and applicable statutory and regulatory requirements

   2) The effectiveness of the controls applied by the external provider

d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

The Company retains the right to verify compliance of purchased product, services, or outsourced process. This right may be exercised at the source or upon receipt by the Company, its customer, or a representative of either. By accepting the Company's contract, the supplier affirms his obligation to observe these rights.

When the Company requires verification of purchased product at the supplier's site, the Company purchase or change order shall specify how verification arrangements are to be made and the method of product release.

When specified in the contract, the Company's customer will be afforded the right to verify that purchased products conform to specified requirements. This does not absolve the Company or its supplier of the responsibility to provide acceptable product or services, nor does it preclude subsequent rejection by the customer.

All purchased products are subject to visual verification by Receiving and Stores personnel for identification, completeness, and condition. Receiving processes the necessary documents and routes product to Receiving Inspection, as required. Appendix 8.4.2-1 identifies product which requires Receiving Inspection.

Quality Assurance maintains a designated Receiving Inspection area to permit organized, efficient, and controlled handling of materials requiring inspection. Purchased products awaiting Quality Assurance verification are identified and, when practical, segregated. Rejected products are documented, clearly identified, and when practical, placed in a segregated area. Product which is not inspected upon receipt is subject to "point of use" inspection by the applicable operator. Products not covered by Appendix 8.4.2-1 are also subject to point of use inspection.

In the event an emergency production need arises, material may be Urgent Released. This release is documented to provide for positive recall should a problem subsequently arise. Planning is responsible for establishing the need for, requesting, and tracking the urgent release of product.

Exception - product designated for Nuclear applications, Government contracts, or Customer Supplied Product shall not be Urgent Released under the provisions of this section.

Product expedited under this urgent release provision is subject to point of use inspection by the using organization or Quality Assurance.

When product is shipped directly to the customer, neither TWMC nor its supplier is absolved of the responsibility to provide acceptable product/services, nor does it preclude subsequent rejection by the customer.

Detailed procedures for accomplishing this quality process are defined in department work instructions.

8.4.3 Information for External Providers

Purchasing documents are reviewed and approved to ensure the adequacy of requirements prior to their communication to the external provider to ensure that technical and quality requirements are specified. Purchasing information shall describe the product to be purchased, including, where appropriate, our requirements for:

a) The processes, products and services to be provided;

b) The approval of:

   1) Products and services

   2) Methods, processes, and equipment

   3) Release of products and services

c) Competence, including any required qualification of persons or procedure

d) External providers' interactions with TWMC or other interested parties

e) Control and monitoring of the external providers' performance to be applied by TWMC

f) Verification or validation activities that TWMC, or our customer, intends to perform at the external providers' premises.

Additionally, the purchasing document, process audit, source and/or receiving inspection are used to ensure control over all processes affecting product conformity that are outsourced. These requirements can include drawing specifications, codes, standards, regulations, procedures, or instructions. Amendments to the purchase order are processed per department work instructions.

Buyers receive and process purchase requests as described in department work instructions. All requests, whether manual or automated, are reviewed by the Buyer. Non-standard, complex, and first-time buys of a commodity or service may require the Buyer to request input and review by Engineering, Production, Quality Assurance, or other departments, as appropriate.

Quality Assurance reviews and/or approves purchase orders for products, services, and outsourced processes on designated commercial and government orders and all nuclear orders.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

TWMC has implemented controlled conditions for production and service provision.

Drawings, Process Specifications, Project Control Plans, and Work Instructions are the forms of documented information available for use. The information defines the characteristics of the products to be produced, the services to be provided, or the activities to be performed, and provides the criteria, tolerances, and dimensions appropriate to determine the results to be achieved.

Product is identified and production is scheduled based on product and delivery requirements.

Planning supports product realization from start to finish. With assistance from Project Management, they determine the manufacture or purchase decision for product.

Product that is determined to be manufactured is produced in stages which are typically performed in the same order and by the same methods. Job Orders and Job Operations specify the sequence of production activities and provide a record that all required activities were performed. Contracts with special requirements are identified during contract review.

Planning department provides the connection between design output, Purchasing, and product and service provision. The following processes are conducted to ensure an orderly production flow:

a) Publishing monthly pre-manufacturing status reports (when required)

b) Conducting regularly scheduled meetings to review materials, capacity, scheduling, and delivery issues

c) Generating and delivering manufacturing information packets to production areas which provide the necessary job order, drawing, and record documents

Manufacturing/Industrial Engineering is responsible for the generation and oversight of the required documentation that will satisfy the manufacturing requirements to produce the component based on product design documents.

Conformity to product requirements is achieved and maintained by those who have been assigned responsibility for performing the work.

Availability and use of suitable monitoring and measuring resources is provided to Production and Quality Assurance for the purpose of accepting or verifying activities at appropriate stages. This ensures that criteria for control of processes or outputs, and acceptance criteria for products and services have been met.

Personnel are responsible for reporting damaged equipment or equipment that is known to have an out-of-tolerance condition to Quality Assurance.

Controlled conditions for suitable infrastructure and environment for the operation of processes are covered in 7.1.3 Infrastructure and 7.1.4 Environment.

8.5.1.1 Inspection and Test

Production and Quality Assurance are responsible for inspection and test activities. Inspection and testing are conducted in accordance with documented procedures upon receipt of product, at significant stages of production, prior to shipping finished products, release for shipment, delivery, and post-delivery activities.

Each person who verifies conformance of work activities for the purpose of acceptance will be qualified to perform the assigned inspection or test activity. Additionally, final test results shall be documented and evaluated by authorized personnel to assure that requirements have been met.

Test procedures shall include or reference test objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained.

Inspection and Test records shall, as a minimum, identify: item inspected or tested, date inspected or tested, equipment used (if applicable), type of observation, identification of person evaluating test result, results and/or acceptability, and action or reference to information on action taken in connection with any deviations/nonconformance.

Quality Assurance is responsible for control of the stamps, tags, and stickers which are used to indicate the status of product. Inspection and test status may be identified by one or more of the following methods depending on type of product or step in the manufacturing process.

a) Inspection acceptance sticker (white circle, orange square for Nuclear)

b) Quality approved sticker (green circle)

c) Nonconforming material sticker (red circle)

d) Signature/employee #/stamp and date on quality checklist or quality record forms

e) Stamp and date on the receiving slip

f) Job operations transactions

g) Signed and/or computer released Test Reports or Blue tag (Blue Circle)

8.5.1.2 Special Processes

Processes for production and service provision must be validated, and periodically revalidation, when the resulting output cannot be verified by subsequent monitoring or measurement.

Particular skills and knowledge required for these processes are identified, appropriate process control methods are detailed, records are maintained, and responsibilities are assigned for these activities. Methods used to control processes and prevent human error include operator training, operator certification, process qualification, and process monitoring.

Production, Manufacturing Engineering, Engineering Lab, and Quality Assurance are responsible for the control of Special Processes.

The following special processes are used in the manufacture or service of TWMC products or services:

a) Welding

b) Brazing

c) Heat Treating

d) Painting

e) Vacuum Pressure Impregnation (VPI)

f) Varnishing

g) Nondestructive Testing (NDT)

h) Soldering, Electrical

i) Tinning

It is the responsibility of the individual/department performing the special process to adhere to the approved procedures and processes.

Conditions necessary for accomplishment of the process shall be included in the procedures or instructions. These conditions will include proper equipment, controlled parameters of the process, and calibration requirements.

The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in the procedures or instructions.

For special processes not covered by existing codes and standards, or where conformity to product requirements specified for an item exceed those of existing codes or standards, the necessary requirement for qualification of personnel, procedures, or equipment will be specified or referenced in the procedures or instructions.

Detailed procedures for accomplishing these quality processes are defined in department work instructions.

8.5.2 Identification and Traceability

Procedures are established and maintained which provide for materials, components, and subassemblies to be identified to drawing, part, material specification, job, and/or shop order number from receipt through warranty, and provide for the traceability of pre-defined materials.

The following is a description of the method used to identify outputs when it is necessary to ensure the conformity of products and services.

a) National Sales, Projects, and Aftermarket Services are responsible for assigning product identification numbers which shall be used to establish job order, service order, or shop order identification during design, manufacture, delivery, installation and warranty. Additionally, they are responsible for identifying and communicating customer material traceability requirements to all affected operations.

b) Engineering is responsible for assigning a unique number to all parts and materials for product identification.

c) Purchasing is responsible for including material traceability requirements in supplier purchase orders.

d) Production, Planning, and Quality Assurance are responsible for identifying the status of outputs with respect to monitoring and measurement.

e) All product Warehouses and Shipping & Logistics are responsible for the receipt and transmittal of traceability documentation required by purchase orders to the Customer, Quality Assurance, Projects, and Aftermarket Services, if required.

Procedures are established and maintained which govern the Company's standard practice of requiring material certifications on critical commodities which could affect final product. Appendix 8.5.2 identifies products which require material traceability.

In the event the contract indicates that a customer requirement for material certification is more stringent than the Company's standard practice, the customer's instructions shall take precedence. Additionally, markings used for identification and

traceability shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted.

Quality Assurance is responsible for review and retention of the documented information necessary to enable traceability.

8.5.3 Property Belonging to Customers or External Providers

TWMC exercises care with property belonging to customers or external providers while it is under our control or being used by the organization. Customer property can include materials, components, tools, equipment, premises, intellectual property, and personal data.

National Sales, Stock Product, Projects, and Aftermarket Services are responsible for coordination between the Company and the customer to ensure timely and efficient receipt and processing.

Logistics is responsible for the receipt, handling, storage, and control of customer supplied product. Customer supplied product is identified, verified, stored, and maintained as other purchased products unless a contract indicates special handling is required. In that event, the customer's instructions will take precedence over standard procedures.

Customer supplied product is inspected to assure conformance to defined product and documentation requirements.

Any property of a customer or external provider which is lost, damaged, or is otherwise unsuitable for use is documented and reported immediately to the customer or external provider and a record is maintained.

Detailed procedures for accomplishing this quality process are defined in department work instructions.

8.5.4 Preservation

Methods and means of handling product to prevent damage or deterioration are determined. This effort preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

National Sales, Projects, and Aftermarket Services are responsible for identifying and communicating special customer requirements. Customer specific requirements for handling, storage, packaging, marking, preservation, and delivery are identified during the order entry and contract review process.

Manufacturing Engineering identifies any non-standard handling requirements and any special fixtures or procedures as part of process planning activities.

Equipment requiring maintenance is regularly checked and records maintained. When equipment operation requires operator qualification, operators are qualified to use the equipment and qualification records are maintained. Instructions for the use of equipment are available in the manufacturing areas where they are needed.

Department supervisors and/or team leaders, with oversight from Health, Safety, and Environmental (HS&E), assure that overhead cranes and associated slings and chains are inspected to assure safety and proper operating condition. Additionally, HS&E provides training on overhead cranes, fork trucks, and the handling of hazardous materials.

Department supervisors and/or team leaders instruct operators on the proper handling of materials and product as part of job training and departmental

orientation. Included are acceptable practices for the use of pallets, blocks, baskets, and other handling devices when moving and storing items.

Items used to transport or handle materials and products are monitored by Production, all product Warehouses, and Shipping & Logistics operators and supervisors. Potentially defective items are replaced, repaired, or cleaned, as necessary.

Material stockrooms are controlled by all product Warehouses and Shipping & Logistics. In-process and floor stock is controlled by Production.

Storage procedures provide for receipt of product into and dispatch of product out of storage areas. Provision is made for special product characteristics such as age-sensitive materials. Limited shelf-life items are stored using "first-in-first-out" inventory methods. Limited shelf-life items are identified in Engineering Material Specifications (EM Specs). Affected materials come labeled by the manufacturer or are labeled when received per Appendix 8.5.4-2.

Area supervisors monitor material storage to assure that materials and product are placed only in designated areas and are clearly identified. Storage locations are selected for each item based on that item's required storage need, such as temperature, humidity, or contamination.

All storage locations are evaluated periodically to assess the condition of materials and validate quantity on hand. Damaged, obsolete, expired, and unidentified material is addressed during this evaluation.

Appendix 8.5.4-2 identifies storage areas requiring periodic inspection. This document also defines actions and responsibilities of Quality Assurance, Production, all product Warehouses, and Shipping & Logistics.

Final product preservation and packaging are performed using suitable materials selected per appropriate process specification. In the event that contractual requirements differ from standard methods, customer requirements shall take precedence.

8.5.5 Post-Delivery Activities

TWMC has processes in place to meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities required, we consider:

a) Statutory and regulatory requirements

b) Potential undesired consequences associated with the products and services

c) Nature, use and intended lifetime of the products and services

d) Customer requirements

e) Customer feedback.

All customer-requested post-shipment activities are governed by the policies and procedures documented in this manual and in supporting department procedures.

All product Warehouses and Shipping & Logistics oversee product loading to assure that the carrier properly loads and protects shipments.

Hazardous and limited shelf-life items are marked prior to shipment. Bills of lading and packing lists reference internal and customer identification numbers and list all items.

Unless contractually arranged by the customer, delivery is subcontracted. When contractually required, the traffic specialist arranges for delivery of product to the customer using shipping instructions found in the order database. If a shipping location specified is a different Customer location (i.e., drop ship to the Customer or a third party) TWMC shall supply proof of shipment (packing list, signed bill of lading, quality documentation package, if required) to the Customer at the time of shipment.

Carriers are selected using approved transport service suppliers.

Instruction books which address storage, preservation, installation, operation, and normal maintenance of the product are provided to the customer. Engineering has the responsibility to ensure that the content of the books is current.

Aftermarket Services and Stock Product Customer Service are responsible for responding to customers' technical support, service, or warranty requests to include customer feedback and compliance with customer requirements. The SAP Customer Service (CS) module and Returned Material Authorization (RMA) system are used to administer warranty issues.

Quality Assurance is responsible for reviewing customers' service or warranty request information. When appropriate, Corrective Action dockets are issued to the responsible department or supplier.

Records are maintained to verify that the service has been completed in accordance with a documented plan and/or that the results of the service comply with the terms of the agreement with the customer.

Department work instructions provide procedures for after-sale communications, parts ordering, installation, servicing and/or repair, performance monitoring, and recommendation for corrective action.

8.5.6 Control of Changes

Changes throughout product realization for production or service provision are reviewed, controlled, and carried out in a planned manner which includes:

a) Correctly communicating any changes to the appropriate departments

b) Retaining documented information describing the results of the review of changes, the person(s) authorizing the changes, and any necessary actions arising from the review.

Planning provides the connection between design output, Purchasing, and production and service provision. Planning, Production, and Quality Assurance are responsible for identifying the status of outputs with respect to changes that affect monitoring and measurement.

8.6 Release of Products and Services

TWMC has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

Production and Quality Assurance are responsible for conducting inspection and testing activities.

Source, receiving, in-process, and final inspections and tests are conducted as a standard practice. Quality checklists, quality plans, project control plans, process specifications, and other types of department work instructions establish the responsibility, type, and point in the manufacturing process when in-process inspections and/or tests shall be performed. The required inspections and tests are documented in accordance with department work

instructions and records are retained. The documented information includes evidence of conformity with the acceptance criteria and traceability to the person(s) authorizing the release.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. The authorization to release final products is a Quality Assurance responsibility. The release of product and delivery of service to the customer may require customer approval.

Detailed procedures for accomplishing this quality process are defined in department work instructions.

8.7 Control of Nonconforming Outputs

8.7.1 TWMC has controls in place to ensure that outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

Nonconforming outputs are dealt with in one or more of the following ways as appropriate:

a) Correction

b) Segregation, containment, return, or suspension of provision of products and services

c) Informing the customer

d) Obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

Procedures for identification, evaluation and reporting of defects and noncompliance as required by 10CFR21 are described in Appendix 8.2.1.

8.7.1.1 Internal Nonconforming Output

Nonconforming product is identified and segregated (where practical) to prevent inadvertent use or delivery. Nonconforming product is documented on an Error Appraisal Notice (EAN).

All TWMC employees are responsible for reporting nonconforming conditions to Quality Assurance. Quality Assurance is responsible for issuing, routing, reviewing, approving, coding, and closing EANs, except as otherwise defined in department work instructions.

The EAN system is an on-line business application which provides input forms, coding tables, data control, administration, and reporting capabilities.

8.7.1.2 External Nonconforming Output

Nonconforming product is documented using either the Supplier Deviation Request (SDR), RMA, or CS Order.

Suppliers of products are responsible for reporting nonconforming conditions identified during product manufacture using an SDR. The supplier prepares and transmits the SDR to Quality Assurance in accordance with the procedures specified in Appendix 8.4.3. Quality Assurance reviews, routes,

approves, codes, closes, and returns the dispositioned copy of the SDR to the supplier. Upon receipt of an SDR, Quality Assurance initiates an EAN record to document the SDR.

Product identified and returned from the customer as nonconforming is processed using the RMA or CS Order. Department work instructions provide guidance for issuing and administering the RMA and CS module processes.

8.7.2 TWMC retains documented information that describes the nonconformity, the disposition, actions taken, and any concessions obtained, and identifies the decision-making authority.

All actions to be taken on nonconforming product shall be in accordance with documented instructions.

When a concurrence is required for a given disposition, the name of the planner and project administrator or the engineer should be recorded as part of the EAN record.

The following represent authorized disposition categories for nonconforming product.

USE **Use As Is** - Deviation from the drawing or specification does not affect the design intent of the product. Condition is acceptable for use and does not adversely affect form, fit, or function. If deemed necessary, Design Center reviews and determines the condition is not detrimental and the product meets the design intent with the stated nonconforming condition(s). This disposition shall include an explanation.
For Nuclear and Government orders, Design Center concurrence is required.

RWK **Rework -** Deviation from drawing or specification may be corrected by standard manufacturing practices. Part will conform to drawing or specification requirements.

REP **Repair -** Deviation will require special processing to render product usable for its intended function. Part does not meet specific drawing or specification criteria. Repaired condition satisfies the original design intent.
For Nuclear and Government orders, Design Center concurrence is required.

SAL **Salvage Materials -** Product is not suitable for intended use. Repair is not feasible or cost effective. Material may be re-used in another application.

SCR **Scrap -** Product is not suitable for intended use. Repair is not feasible or cost effective. Any authorized individual can disposition a part as scrap, but only the President, Director of Operations, or Chief Financial Officer are permitted to perform the scrap authorization transaction in our business system.

RTV **Return to Vendor -** Purchased product does not meet Purchase Order requirements. Product is returned for action by the vendor. Specific actions may include: rework, repair, or replacement of product.

SSI **Ship Short Item -** Final product is missing a part or component at time of shipment but customer desires product as is to meet their needs. Part or component will be shipped at a later date.
Documented concurrence from Planning, Projects, and Customer is required.

CON **Conditionally Use as Is -** Product is subject to further processing which should correct the nonconforming condition and therefore the product is judged acceptable at the point of discovery.

Special Use Codes
In addition to the product disposition codes defined above, two special codes are available for use. The special codes are REC for Record Only and CNX for Cancelled.

REC **Record Only** - all use requires QA concurrence and should be used when a record of the originally defined condition is desired. Additionally, this code can be used when a deviation or material substitution that does not affect the design intent of the product and does not fit the requirements of a Material Authorization Change, i.e., use on current shop order only.

CNX **Cancelled** - used by QA only when it is determined that processing the EAN is not required.

Where required by the contract, the proposed USE or REP of product which does not conform to specified requirements is reported to the customer for review, approval, and/or concession. When accepted by the customer, a record of the nonconformity, its disposition, and the resulting product condition is retained.

Repaired and/or reworked product is re-inspected in accordance with the original criteria and/or the disposition instructions.

Detailed procedures for accomplishing this quality process are defined in department work instructions.

9.0 PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

TWMC has determined what needs to be monitored and measured in QMS processes to demonstrate the ability of the system to achieve planned and valid results. This is accomplished by reviewing, monitoring, measuring, analyzing, and evaluating quality objectives. These objectives include results of internal audits, analysis of data, root cause of nonconforming product, and performance of suppliers. Management review is used to evaluate the performance and the effectiveness of the QMS and appropriate documented information is retained as evidence of the results.

9.1.2 Customer Satisfaction

TWMC is committed to fulfilling customer requirements by monitoring customers' perceptions of the degree to which their needs and expectations have been fulfilled. Methods that may be used to measure customer satisfaction include:

a) Customer satisfaction surveys

b) Customer data on conformity of delivered product to product requirements

c) Percent of business through long-term agreement/supply contract

d) Market-share or lost business analysis

e) Customer complaints and warranty claims

f) Measuring rates of returned product.

National Sales, Commercial Sales, Stock Product Group, Projects, Aftermarket Services, and Quality Assurance are responsible for monitoring information received from the customer on quality concerns and field problems. This information may be

entered into the Customer Quality Concerns database or the CS Module. This information is reviewed and analyzed by appropriate departments to continually improve the QMS and to resolve recurring problems. Recurring problems may be entered into the Corrective Action system and are reviewed by executive management.

9.1.3 Analysis and Evaluation

TWMC collects, analyzes, and evaluates data to demonstrate the performance and effectiveness of the QMS.

The analysis of data is performed by Management and Quality Assurance as specified in departmental procedures on the following:

a) Degree of customer satisfaction

b) Conformity of products and services to requirements

c) Effectiveness of actions taken to address risks and opportunities

c) Characteristics and trends of processes and products including opportunities for improvements

d) Determine if planning has been implemented effectively

e) Supplier performance.

Quality Assurance is responsible for establishing statistical techniques for use in the inspection and testing of product. Statistical techniques can be used for acceptance sampling and measurement systems analysis.

Acceptance sampling plans, based on documented procedure, are used to evaluate supplier performance at Receiving Inspection. TWMC uses an Average Outgoing Quality Limit (AOQL) plan for acceptance sampling inspection of supplier products.

Measurement Systems Analysis is accomplished in accordance with standard industrial practices.

9.2 Internal Audit

9.2.1 Internal audits are conduct at planned intervals to provide information on whether the QMS:

a) Conforms to:

1) Quality policies, QA manual, and department work instructions

2) Requirements of ISO 9001 and other standards, as required

b) Is effectively implemented and maintained.

9.2.2 TWMC:

a) Plans, establishes, implements, and maintains an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, that take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits

b) Defines the audit criteria and scope for each audit

c) Ensures audits are performed by qualified personnel who are not directly responsible for the process being audited

d) Ensures that the results of the audits are reported to relevant management

e) Takes appropriate correction and corrective actions without undue delay

Note: Findings are documented and reviewed with the responsible manager at the conclusion of the audit. The management responsible for an audited area takes action necessary to correct deficiencies identified during the audit.

f) Ensures deficient areas are re-audited to ensure the corrective action taken has been effective. Records of audit results and follow-up activities are maintained.

g) Retains documented information of audit results and follow-up activities as evidence of the implementation of the audit program.

Detailed procedures for accomplishing this quality process are defined in department work instructions.

9.3 Management Review

9.3.1 General

Executive management reviews the company's quality management system to include Policy and Objectives, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, to identify opportunities for improvement and alignment with the strategic direction of the organization.

The Quality Management System will be reviewed annually. Documented information is retained as evidence of the results.

9.3.2 Management Review Inputs

Management reviews are planned and carried out taking the following inputs into consideration:

a) Status of actions from previous management reviews

b) Changes in external and internal issues that are relevant to the QMS

c) Information on the performance and effectiveness of the QMS, including trends in:

1) Customer satisfaction and feedback from relevant interested parties

2) The extent to which quality objectives have been met

3) Process performance and conformity of products and services

4) Nonconformities and corrective actions

5) Monitoring and measurement results

6) Audit results

7) Performance of external providers

d) Adequacy of resources

e) Effectiveness of actions taken to address risks and opportunities

f) Opportunities for improvement.

9.3.3 Management Review Outputs

Management review outputs include decisions and actions related to:

a) Opportunities for improvement

b) Any need for changes to the QMS

c) Resource needs.

Minutes of the review meetings are recorded, distributed, and maintained. The appropriate Department Manager is responsible for follow-up on the action items defined in the meeting.

10.0 IMPROVEMENT

10.1 General

The Quality Policy, quality objectives, risk mitigation, audit results, analysis of data, corrective action, and management review all assist in determining and selecting opportunities for improving and implementing any necessary actions needed to meet customer requirements and enhance customer satisfaction.

Items included are:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing, or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, TWMC:

a) Reacts to the nonconformity and, as applicable:

1) Takes action to contain, control and correct it

2) Deals with the consequences

b) Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) Reviewing and analyzing the nonconformity

2) Determining the causes of the nonconformity

3) Determining if similar nonconformities exist, or could potentially occur

c) Implements any action needed

d) Reviews the effectiveness of any corrective action taken

e) Updates risks and opportunities determined during planning, if necessary

f) Makes changes to the QMS, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 Documented information is retained as evidence of:

a) The nature of the nonconformities and any subsequent actions taken

b) The results of any corrective action.

10.3 Continual Improvement

Executive management works to continually improve the suitability, adequacy, and effectiveness of the QMS. The results of analysis and evaluation, and the outputs from

management review, are considered to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

11.0 MANUAL REVISION HISTORY

Rev. 0, 7/18/02	The original of this manual. This manual supersedes a previous manual (Rev. 4, 6/5/2000). This manual was formatted to conform with the requirements of ISO 9001:2000. Because the changes were extensive, this manual returned to Rev. 0, original. Approved by: M. Kuo
Rev. 1, 7/31/02	Manual updated to meet requirements of NQA-1-1994. Approved by: M. Kuo
Rev. 2, 10/31/02	Manual updated to satisfy SQE-2002-35 and CA0883. Approved by: M. Kuo
Rev. 3, 4/4/03	Manual updated to satisfy requirements of internal audit QS0880. Approved by: M. Kuo
Rev. 4, 7/2/04	Manual updated to satisfy requirements of CA0982. Approved by: M. Kuo
Rev. 5, 7/6/07	Manual updated to include Wind Energy Division. Approved by: H.C. Meng
Rev. 6, 5/27/09	Manual updated to include ISO 9001:2008 and MV Drives product line. Approved by: Vincent Tang
Rev. 7, 9/29/10	Manual updated to correct nonconformances identified on the EBARA External Audit Report EAR-10-05 dated Aug. 24 to 27, 2010: CAR-10-0066/CA1177, CAR-10-0068/CA1179, CAR-10-0071/CA1181. Approved by: Vincent Tang, President
2/20/15	Reviewed and approved by Pat Rogers, President.
Rev. 8, 3/16/18	Manual revised to comply with ISO 9001:2015. Changes throughout. Approved by: Pat Rogers, President.
7/1/19	Reviewed and approved by Dr. Clarence King, President.
5/23/23	Reviewed and approved by Climent Wang, President.