QUALITY MANAGEMENT SYSTEM MANUAL

Power Engineering & Manufacturing Inc.

1463 94th Lane NE
Blaine
Minnesota
MN 55449

Certificate No: US2556
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Q01 Document Control

Document

Certificate Number: **US2556**

Copy Number: **2**

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Authorization

Authorized By: Thomas Kerrick

Position: Operations Manager

Authorized Date: 02/13/2018

Distribution

Number of copies printed = **2**

Copy 1 = Quality Manager

Copy 2 = Computer Network (Quality Manager)

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Q02 Document Amendments

All copies of this Quality Management Systems Manual (QMSM) must be kept under strict control to prevent the system from becoming unreliable. The following controls will ensure that the system remains current and valid.

1. All copies of the manual will be clearly numbered and the Holder recorded.

2. Each page in the manual will carry its own number.

3. The Quality Manager will be responsible for all revisions and additions being recorded.

4. Changes can be suggested by any Employee but must receive signed approval before being entered into the QMSM.

5. All changes must be recorded on the Amendments Table below and appropriate pages in each QMSM changed. Significant changes will be shaded to make them easy to identify. (Where existing text is reworded or reorganized in the document, these changes will not be shaded.)

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<td>Initial Issue</td>
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Q03 Company Organization Chart

Organization Structure

President & CEO
- Product Design
- Sales - New Products
- Purchasing

VP of Engineering
- Product Design
- Sales - New Products, Purchasing

Office Administrator
- Administration, Accounting, Customer Service, Purchasing

Operations Manager
- Purchasing Project Management

Quality Manager
- Quality Representative, Quality Control, Internal Auditor

Engineering Department
- Maintenance Product Design and Test Internal Auditor

Production Manager
- Manufacture Inspection Purchasing

Manufacturing Team
- Receiving, Manufacture, Shipping, Internal Auditor
Q04 Quality Management System

4. Context of the organization

4.1 Understanding the Organization and its Context

We have determined the relevant external and internal issues that affect our ability to achieve the intended outcomes of our management system. We have considered the full business environment, the key drivers and trends having impact on the objectives of the organization and the relationship and values of external stakeholders. Details of the context of our organization are given below:

Power Engineering & Manufacturing, Inc. (PEM) is a design and manufacturing Corporation established in 1994 by the merger of Power Engineering, a five-year-old mechanical design company and System Design Engineering, a two-year-old electronic design company. The combination of these two companies yielded a new entity with capabilities for design of rugged, remote, low maintenance electromechanical products for the industrial and commercial markets. Currently, PEM is located within a 16,000-Sq Ft facility located in Blaine, MN.

Continual partnering with customers to provide a full range of product solutions has led PEM into the manufacturing of mission kits used throughout the US Army, hydraulic controls used in oil wells and actuators for heating, ventilation and valve control. Since 1994 PEM has established its design and manufacturing capabilities in its target markets and has a leading reputation with its US and international customers.

The Corporation has a wide-ranging portfolio including:

- Industrial Control Equipment
- Linear Actuators
- Rotary Actuators
- Automated Manufacturing Systems
4.2 Understanding the Needs and Expectations of Interested Parties

We have identified the interested parties and their requirements with the emphasis being on quality. We have included a process to determine any legal requirements relating to activities, products and services that are relevant to the scope of our management system.

**Interested Parties (Stakeholders)**

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<th>No.</th>
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<th>Internal or External</th>
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<td>1</td>
<td>Customers / End Users</td>
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<td>I</td>
<td>Product Quality Assurance &amp; Quality Control</td>
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<td>Auditors</td>
<td>I/E</td>
<td>Compliance to policies &amp; procedures</td>
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<td>Meeting customers’ expectations, efficiency &amp; effectiveness of the processes</td>
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<tr>
<td>5</td>
<td>Suppliers</td>
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<td>Provide supporting service or material</td>
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4.3 Determining the Scope of the Quality Management System

We have determined the boundaries and applicability of our management system and have taken into account the issues identified in Clause 4.1 and 4.2 (above) as well as those that relate to our product and service when establishing the scope. This scope covers all aspects of the organization, here and abroad.

Located in Blaine Minnesota, Power Engineering & Manufacturing implements the design, engineering and manufacture of specialized products for the Industrial and Commercial sectors.

See QMS Procedures Manual section – M01 Scope of QMS
4.4 Quality Management System and its processes (QMS)

We have established and implemented, and will look to maintain and continually improve our quality management system, including the processes and their interactions needed to meet the requirements of the international standard.

In order to deliver the requirements, we have identified:

- the processes needed for the implementation, operation and maintenance of the management system along with opportunities for its improvement and their application throughout the organization;
- the inputs required and outputs expected from these processes;
- the sequence and interaction of these processes;
- criteria and methods needed to ensure that both the operation and control of these processes are effective;
- the availability of resources and information necessary to support the operation and monitoring of these processes;
- the risks and opportunities within the management system and how to plan to address them;
- the monitoring, measuring and analysing of these processes, and implement actions necessary to achieve planned results and continual improvement.

Appropriate documented information is maintained to support these processes and is retained as records to demonstrate that all processes are working as planned.
QMS Process Diagram

Main work process (Summary)

Customer Enquiry/Order

Plan Work/Purchase Materials

Carry Out and Check Work

Handover

Full details are shown in the Procedures Manual and where applicable other Work Instructions/Technical Manuals etc.

Customer

Sales and Marketing

Company Management Planning
Policy and objectives
Regulations and Standards

Resources and Training

Sub-contractors and Suppliers

Performance Measurement
Internal Audit
Non-conformance
Corrective Action
Collection and Analysis of data
Process Performance

Customer Satisfaction

Management Review Meeting
5. Leadership

5.1 Leadership and Commitment

5.1.1 General

Our Top management have demonstrated leadership and commitment with respect to our QMS by taking accountability of the effectiveness of the QMS; by establishing a quality policy and quality objectives that are compatible with the direction of the organization; that both policy and objectives are communicated, understood and applied within the organization; ensuring integration of QMS requirements into the organization’s business processes and by promoting awareness of a process approach and risk based thinking.

In addition, our Top Management have provided the necessary resources for the QMS; communicated the importance of effective quality management and of conforming to QMS requirements; ensuring that the QMS achieves intended results; engaging with, directing and supporting persons to contribute to the effectiveness of the QMS; promote improvement and support other members of the management team to demonstrate their leadership as it applies to their area of responsibility.

5.1.2 Customer Focus

As an organization we strive to meet our clients’ expectations; top management at PEM have demonstrated their leadership and commitment by ensuring that clients’ requirements and applicable regulatory and statutory requirements are met; that risks and opportunities that could affect our products and services have been addressed; that our focus is on consistently providing client satisfaction.

5.2 Policy

Our Top Management have developed a quality policy that is in line with the requirements of the standard. The Policy is available as documented information, is communicated throughout the organization and is also available to interested parties, as appropriate.

See document— M02 Quality Policy

5.3 Organizational Roles, Responsibilities and Authorities

Our Top management will ensure that the responsibilities and authorities for relevant roles are assigned and communicated throughout the organization. The organization has identified,
documented and communicated the roles, responsibilities and authorities of those involved in the management system and their interrelationships within the organization.

6. Planning

6.1 Actions to Address Risks and Opportunities

We have considered the issues detailed in clause 4.1 and 4.2 of this document and have determined the risks and opportunities that need to be addressed to assure the QMS can achieve its intended outcomes; that we prevent or reduce undesired effects and achieve continual improvement.

We have put a plan in place to address these risks and opportunities and also a plan to integrate and implement these actions in the QMS and evaluate their effectiveness. We have produced a risk assessment register to show what has been achieved.

See QMS Procedures Manual section – M03 Risk Assessment Procedure
PD-0596 Risk & Improvement Workbook

6.2 Quality Objectives and Planning to achieve them

We have established quality objectives at various levels throughout the organization in line with the requirements of ISO9001:2015 Clauses 6.2.1 and 6.2.2; a document has been produced detailing these objectives and the procedure around establishing them.

See QMS Procedures Manual section – M04 Planning to Achieve Quality Objectives
PD-0595 Quality Objectives

6.3 Planning of Changes

If we make changes to our QMS they would be carried out in a planned and systematic manner. We will consider the purpose of any change, their potential consequences, the integrity of the QMS, the availability of resources and the allocation or reallocation of responsibilities and authorities.
7. Support

7.1 Resources

7.1.1 General

We have determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of our QMS. We have considered the capabilities of our existing resources and what we need to obtain from external providers.

7.1.2 People

Those resources include people who have the necessary skills and competencies to effectively operate our QMS and to meet and exceed our clients’ expectations. Also see Clause 7.2.

7.1.3 Infrastructure

We have provided the infrastructure determined necessary for the provision of our processes and conformity of our products and services.

7.1.4 Environment for the Operation of Processes

We have provided the environment determined necessary for the provision of our processes and conformity of our products and services.

7.1.5 Monitoring and Measuring Resources

We have determined that we need to use measuring and monitoring resources for evidence of conformity for our products and services and have created specific documented information detailing how we have approached this requirement.

See QMS Procedures Manual section – M05 Monitoring and Measuring Resources

PD-0013 Calibration Record
PD-0014 Measurement Equipment List

7.1.6 Organizational Knowledge

We have determined the knowledge necessary to operate our processes when achieving conformity of our products and services. We have systems in place to address any changes to our needs and possible trends that come up from time to time. The knowledge is in the form of documented information and is available to those who require it.
7.2 Competence

We have determined the competence of people doing work under our control that affects performance to ensure that these people are competent on the basis of appropriate education, training or experience and where applicable, take actions to acquire the necessary competence and evaluate the effectiveness of the actions taken.

See – PD-0005 Training Details & Needs

7.3 Awareness

We have ensured that people doing work under our control are aware of our policies; our quality objectives relevant to them; their contribution to the effectiveness of the system and the implications of not conforming to the QMS requirements.

See – PD-0005 Training Details & Needs

7.4 Communication

We have determined the need for internal and external communications relevant to the system including on what, when, with whom, how and who would communicate.

7.5 Documented Information

We have written policies and procedures as appropriate to meet the requirements of our QMS and the ISO9001:2015 standard. Details of how we produce and control our documented information are detailed in M06.

See QMS Procedures Manual section – M06 Document Control & Records
8. Operation

8.1 Operational Planning and Control

We have planned, implemented and controlled processes needed to meet requirements for the provision of our products and services, and to implement the actions determined in clause 6.1 of this document by determining the requirements of our products and services; establishing criteria for those processes and for the acceptance of our products and services. We have also determined the resources needed to achieve conformity of our products and services and by implementing control of the processes in accordance with the detailed criteria.

We keep documented information to the extent necessary to have confidence that the processes have been carried out as planned and that demonstrate the conformity of our products and services.

We shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects as necessary. We shall ensure that outsourced processes are also controlled.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

We communicate with clients where necessary in relation to information related to our products and services, enquiries, contracts or order handling including changes, customer property, obtaining their feedback, including complaints and specific contingency actions where appropriate.

8.2.2 Determination of Requirements Related to Products and Services

When determining the requirements for our products and services offered to potential clients; we have ensured that applicable regulatory and statutory requirements have been defined and that we have the ability to meet those requirements and that we can substantiate any claim made for our products and services.
8.2.3 Review of Requirements Related to Products and Services

We review our Clients’ requirements including those for delivery and post-delivery activities; any statutory and regulatory requirement applicable to the product and service being provided. We also review those requirements not stated by the client, when known, plus any contract or order requirements that are different from the original request.

We conduct this review prior to our commitment to supply our products and services; we always provide a documented confirmation of the order, even if the client has not; details of all orders are recorded.

Where requirements change we ensure that all relevant documentation is amended and that personnel are made aware prior to delivery.

8.2.4 Changes to requirements for products and services

We will ensure that when changes are made to our products and services relevant persons are made aware and relevant documentation is amended to reflect those changes made.

8.3 Design and Development of Products and Services

We have determined that we need to use design and development resources for evidence of conformity for our products and services and have created specific documented information detailing how we have approached this requirement.

See QMS Procedures Manual section – M07 Design and Development

8.4 Control of Externally Provided Processes, Products and Services

We have produced a procedure (M08) which details how our organization would deal with the control of externally provided products and services.

See QMS Procedures Manual section – M08 Control of External Providers
8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

We have implemented controlled conditions for the production and service provision, including delivery and post-delivery activities in line with the requirements of Clause 8.5.1 of the ISO9001:2015 quality management system standard.

8.5.2 Identification and Traceability

Where necessary we have introduced a system to uniquely identify our products and services for the purposes of traceability. We identify the status of our processed outputs with respect to monitoring and measurement requirements throughout the provision of our products and services. We retain documented information appropriate to maintaining identification and traceability.

8.5.3 Property belonging to Customers or External Providers

We exercise due care and attention when dealing with property belonging to external providers (including clients). We report any defect, damage or loss to the external provider as soon as it has been identified by our personnel.

8.5.4 Preservation

We ensure the preservation of our products and services to the extent necessary to maintain their conformity throughout the production process.

8.5.5 Post-delivery Activities

We ensure that where applicable we meet the requirements for post-delivery activities associated with our products and services to the extent that we have considered the risks associated with the products and services, the nature of use and lifetime of the products and services, customer feedback and statutory and regulatory requirements.

8.5.6 Control of Changes

We review and control changes necessary for the production and service provision to ensure continued conformity of our products and services. We keep documented records of any such changes.

See QMS Procedures Manual section – M09 Production and Service Provision
8.6 Release of Products and Services

We have implemented arrangements at appropriate stages of production or service provision to verify that product and service requirements have been met; evidence of such acceptance criteria are recorded.

Products and services will not be released to our clients until the verification arrangements have been met; the exception is when authorized by the president or by the client themselves. Appropriate records of who authorized the release are recorded.

8.7 Control of Nonconforming Outputs

We have produced a procedure (M10) which details how our organization would deal with the control of nonconforming process outputs, products and services.

See QMS Procedures Manual section – M10 Control of Nonconforming Product and Service
9. Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

We have determined what needs to be monitored and measured; the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results; when the monitoring and measuring shall be performed and when the results from monitoring and measurement shall be analysed and evaluated.

We retain documented information on the results of such monitoring and measurement to enable us to evaluate the effectiveness of our QMS.

See QMS Procedures Manual section – M11 Monitoring and Measurement Results

9.1.2 Customer Satisfaction

We have determined the methods for obtaining information regarding our clients’ perception of our organization in terms of meeting or exceeding their requirements in the provision of our products and services. The information gathered is reviewed as part of the Management Review process.

See QMS Procedures Manual section – M11 Monitoring and Measurement Results

9.1.3 Analysis and Evaluation

We analyse and evaluate data gathered as part of our monitoring and measuring activities and the results are used as part of our Management Review process.

See QMS Procedures Manual section – M11 Monitoring and Measurement Results
9.2 Internal Audit

We conduct internal audits at planned intervals to provide information on whether our QMS conforms to our requirements, to the requirements of ISO9001:2015 Quality Management System standard and is effectively implemented and maintained; it also takes into consideration the importance of the processes concerned. We have implemented a procedure (M12) that covers in detail the process surrounding the internal audit process.

See QMS Procedures Manual section – M12 Internal Audit

9.3 Management Review

Our Top management reviews the organization’s QMS at planned intervals, at least once annually, to ensure its continuing suitability, adequacy and effectiveness. Each review will take into consideration the status of actions from any previous meetings and any changes in internal or external issues relevant to our QMS and performance information, including trends and indicators as detailed in ISO9001: 2015 Clause 9.3.1 and 9.3.2. Information relating to each of these meetings is recorded.

See QMS Procedures Manual section – M13 Management Review
10 Improvements

10.1 General

We have determined and shall select such opportunities as necessary for improving our clients’ requirements and satisfaction. This will include improving our products and services; correcting, preventing or reducing undesired effects improving the performance and effectiveness of our QMS.

10.2 Nonconformity and Corrective Action

When non-conformity occurs, we shall react to the nonconformity and take action to control and correct it and then deal with the consequences. We will evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere in the organization. We will implement the actions required and review the effectiveness of any corrective action taken, update risks and opportunities determined during planning (if necessary) and make changes to the QMS, where necessary.

We record all nonconformities, actions taken and the results of any corrective action using the appropriate documentation.

See QMS Procedures Manual section – M10 Control of Nonconforming Product and Service

10.3 Continual Improvement

We shall continually improve the suitability, adequacy and effectiveness of our QMS. We consider the results of analysis and evaluation and the outputs from management review to determine if there are needs or opportunities that could be addressed as part of our continual improvement.
Q05 Document Register

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