

*Technical
Manufacturing
Corporation*
(TMC)



Quality Manual

15 Centennial Drive · Peabody · MA 01960

<i>Technical Manufacturing Corporation</i>		Title: Quality Manual
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2. About Our Quality Manual

2.1 Purpose

The purpose of this manual is to identify the Quality System and policies of Technical Manufacturing Corporation, hereafter known as TMC or “the company”.

2.2 Scope

This Quality Manual and policies described herein have been modeled after the ISO 9001:2008, the internationally accepted standard for Quality Management Systems Requirements. It is applicable to all TMC employees. TMC scope of registration for the ISO 9001 system is for the design, manufacture and delivery of vibration isolation systems and related equipment. Servicing is excluded from the TMC quality system as it is not a specified customer requirement and is not applicable to TMC operations.

2.3 Responsibility

The Quality Leader (Management Representative) is responsible for ensuring that this Quality Manual conforms to the requirements of the ISO 9001 standard.

2.4 Distribution and Control

The Quality Manual will be distributed according to its document register held at TMC. Authorization and control of changes to this manual will follow the normal Document Control Procedure. Any copies distributed outside of the company will be considered uncontrolled.

3. Introduction to Our Business

Technical Manufacturing Corporation is a quality minded, leading designer and manufacturer of vibration isolation systems including desktop isolated microscope bases, STACIS[®] active vibration cancellation systems, STACIS[®] iX SEM-Base[™] floor platforms, STACIS[®] iX LaserTable-Base[™] hybrid piezoelectric/air active vibration cancellation systems, and Mag-NetX[™] magnetic field cancellation systems. Products include active and passive vibration isolation systems, optical tops, optical table systems, and breadboards, laboratory tables and table top platforms, floor platforms, electric field shielding systems, and acoustic enclosures. TMC products are everywhere precision research or production is taking place. Our customers fall into a number of categories such as researchers, chipmakers, and OEM suppliers. At TMC we will continue to provide innovative responses to extraordinary challenges.

TMC is a unit of AMETEK Ultra Precision Technologies, a pioneer in the development of ultra precision measurement instruments and a global leader in ultra precise machine tools and manufacturing systems for the semiconductor, photovoltaic, nanotechnology, military, defense and ophthalmic lens markets. AMETEK, Inc. is a leading global manufacturer of electronic instruments and electro-mechanical devices.

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4. Quality Management System Elements

4.1 General Requirements

TMC maintains a documented quality management system. This system creates a framework for controlling our processes and enhancing customer satisfaction. TMC strives to continually improve the effectiveness of this quality management system. TMC ensures that the required resources are available, that relevant processes are monitored, measured, analyzed, and that appropriate continuous improvements are made. Outsourced processes that affect product conformity are controlled via the purchasing and supplier control process.

Documentation References:

Purchasing and Supplier Control procedure

4.2 Documentation Requirements

Quality System documentation is developed to meet the requirements of ISO 9001:2008. The quality system documents include:

Level	Type	Description
1	Quality Manual	TMC policies towards the requirements of the ISO 9001 standard.
2	Procedures	Process oriented documents that will reflect TMC's working practice and the standard's requirements.
3	Work Instructions	Product/task specific documents that will include detailed instructions on how to complete a particular activity.
4	Quality Records	Records resulting from following instructions/processes and documenting the status and results of those activities.

A more detailed list linking TMC's Quality System Documentation (quality manual, procedures, and work instructions) to the sections of the ISO 9001 standard is documented in Appendix A of this Quality Manual. Quality system documents are controlled. Depending on the document and as detailed in the appropriate procedure, the documentation change process will be controlled using the Engineering Change Order (ECO) process or Document Register (DR) process. Quality system records are controlled and retained. TMC Process Flowchart (Appendix B) provides an overview of the key quality system processes.

Documentation References:

Document Control procedure

Drawings and Material Lists Control procedure

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5. Management Responsibility

5.1 Management Commitment

TMC Management is responsible for establishing, implementing, and maintaining the quality management system. Specific responsibilities include: formulating the quality policy statement, establishing quality objectives, communicating to employees the importance of meeting requirements, defining the organizational structure, assigning authorities and responsibilities, appointing the management representative, periodically reviewing the quality system, and making available the resources and personnel necessary to maintain the system.

5.2 Customer Focus

TMC Management ensures that customer requirements are understood prior to acceptance of a customer order. The quality management system processes ensure that customer requirements are fulfilled. TMC will proactively communicate any potential issues with customers. Additionally, TMC monitors customer feedback to assess consumer satisfaction.

Documentation References:

Order Processing procedure

Management Review procedure

5.3 Quality Policy

“Our goal is to consistently meet or exceed customer expectations.”

Every employee at TMC is trained to ensure that the Quality Policy is understood, implemented, and maintained. Everyone at TMC participates in achieving the policy objectives which focus on the continual improvement of our Quality System. The quality policy is reviewed at management reviews for continuing suitability.

5.4 Planning

5.4.1 Quality Objectives

TMC Management ensures that Quality Objectives are established. These quality objectives will be measurable and will be consistent with the quality policy statement.

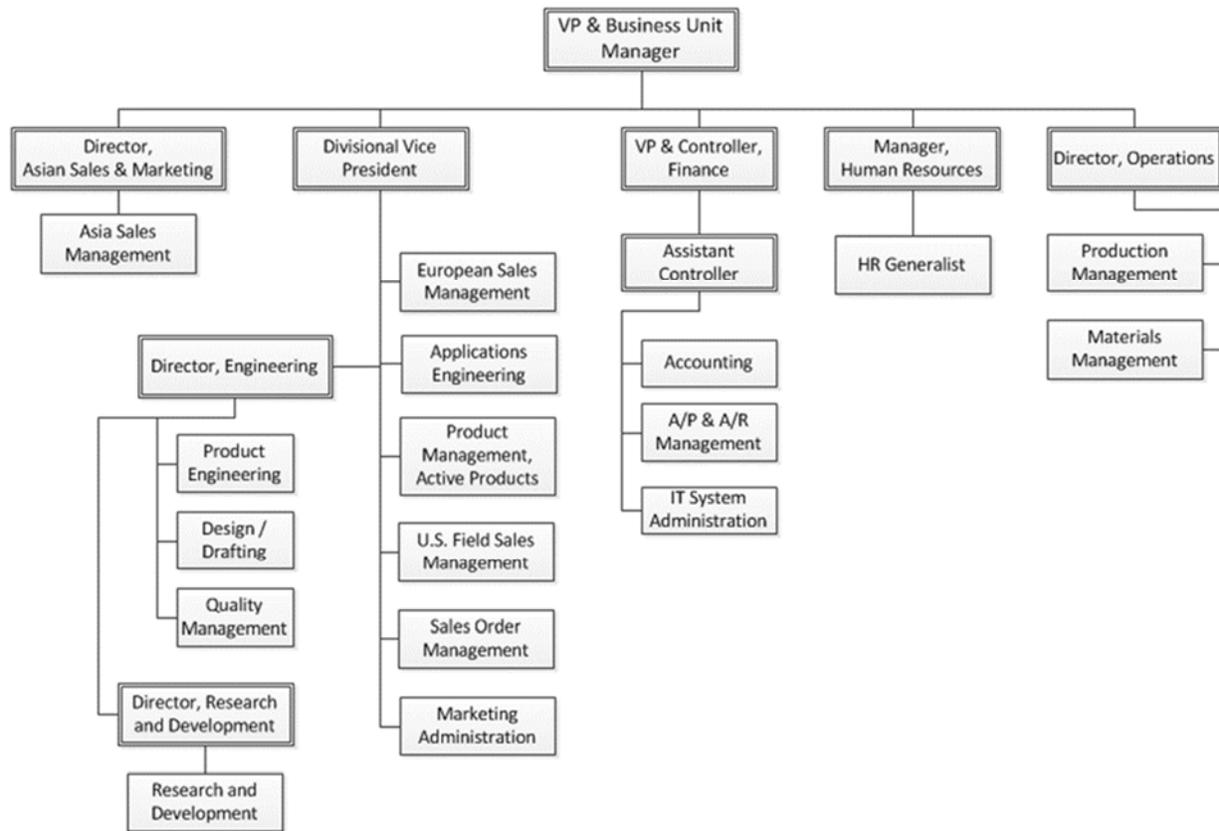
5.4.2 Quality Management System Planning

TMC Management defines the processes needed to meet the requirements and objectives of the quality system. TMC ensures it has the required resources, personnel, documented processes, capabilities, etc. in order to consistently meet requirements. TMC Management ensures that any planned organization or process changes do not adversely impact the integrity of the system.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

This organization chart shows TMC’s department interrelationships and the overall authority structure.



Responsibilities and authorities of all staff involved in quality related activities are defined in pertinent Procedures. Our employees have sufficient authority and organizational freedom to help them in fulfilling their job requirements. At TMC we encourage our employees to recommend suggestions. We assess these suggestions and, if necessary, implement appropriate action. Every department manager is responsible for ensuring that their staff is following assigned procedures. This includes the assistance of all staff in preventing nonconformities from occurring and managing and documenting them if they occur. TMC Management is responsible for determining and instituting various measurement techniques to demonstrate the effectiveness of the quality system. In addition to ensuring that the quality system is effectively implemented within their department, the following top-level duties apply:

Senior Management

- Vice President and Business Unit Manager has overall, general responsibility for all business aspects at TMC. The quality system within TMC has been maintained at the direction of the VP, Business Unit Manager.
- Director of Operations has overall responsibility for the manufacturing operation at TMC, which includes the production, and purchasing functions.

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- Divisional Vice President - TMC Business Segment is responsible for all aspects of Sales and Marketing at TMC including marketing promotion, product management, bids, customer orders, customer complaints, and requests for returns. The Divisional Vice President is also responsible for Engineering and Research and Development.
- Director of Engineering provides overall leadership for engineering and R&D efforts, as well as the quality function. The Director of Engineering manages engineering and R&D resources to effectively support Sales, and Production.
- Director of Research and Development (R&D) develops and introduces new ideas and products to TMC's product line following provided guidelines established for the research and development system.
- Vice President and Controller, Finance has overall responsibility for TMC's strategic financial plan and financial compliance, provides guidance on budgeting and working capital optimization.
- Human Resources Manager handles all personnel issues and is also responsible for ensuring that the training function is properly implemented and maintained

5.5.2 *Management Representative*

The Vice President and Business Unit Manager has appointed the Quality Leader to fulfill TMC's Management Representative's responsibilities. In this capacity, the Quality Leader has been assigned the responsibility and authority for:

- Ensuring that the Quality System is established, implemented, and maintained in accordance with the ISO 9001 requirements.
- Reporting to members of the management team on the performance of the quality system and any improvements needed.
- Ensuring that awareness of customer requirements is promoted within the company.

The Quality Leader has the organizational freedom and authority to initiate action to prevent the occurrence of nonconformities, identify and record problems, initiate corrective actions, verify solutions, and if necessary, stop those processes until such time as they fully comply.

The Quality Leader will also act as the primary communications point with reference to any outside bodies affecting the quality system.

In the absence of the Quality Leader, the Vice President & Business Unit Manager will fulfill all duties related to the Quality System.

5.5.3 *Internal Communication*

TMC Management ensures that appropriate communication processes exist and that necessary internal communication takes place regarding the effectiveness of the quality system.

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5.6 Management Review

TMC Management reviews the performance of quality system periodically. The reviews assess the effectiveness, adequacy and continuing suitability of the quality system. As required, action items are specified for completion. Management Review Records are retained.

Documentation References:

Management Review procedure

6. RESOURCE MANAGEMENT

6.1 Provision of Resources

TMC Management ensures the availability of resources necessary for the effective implementation of, and improvement of the quality system. These resources include adequate buildings, equipment, tools, people, and supporting services. These resources allow TMC to meet customer requirements, maintain and improve the Quality System effectiveness and help enhance customer satisfaction.

6.2 Human Resources

TMC employees are suitably qualified to perform their job function. TMC determines the competency needed for each job function. TMC provides the necessary training to satisfy competency needs. Training records are maintained.

Documentation References:

Training procedure

6.3 Infrastructure

TMC Management determines and ensures that the infrastructure necessary for the realization of products is available and adequate to meet customer requirements and the objectives of the quality system. The infrastructure includes buildings, equipment, workspace, tools, information technology, and supporting services.

6.4 Work Environment

TMC ensures that the work environment is suitable for production and safe for personnel by implementing efficient workflow, adequate work conditions, adequate lighting, proper maintenance of equipment, and good housekeeping.

7 PRODUCT REALIZATION

7.1 Planning of Product Realization

TMC plans and develops processes to meet product and customer requirements. TMC documents the processes to the extent necessary to ensure the ability to consistently meet requirements. TMC considers the following when planning:

- Specific product quality objectives and requirements;
- New resources, processes or documents necessary;

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- Criteria for product acceptance, inspection requirements, verification, validation and monitoring activities;
- Records needed to provide evidence that processes and product meet requirements.

7.2 Customer Related Processes

Inquiries, quotes, contracts and orders are reviewed to confirm that the customer's requirements are adequately defined, and that TMC has the capacity and capability to meet the requirements. Any issues are resolved prior to acceptance of an order. TMC ensures that there are effective communication arrangements with customers in relation to inquiries, requests, orders, feedback and complaints. If an amendment or a revision to a contract is made, TMC assures that the amendment is correctly transferred or communicated to the affected areas within the company.

Documentation References:
Order Processing procedure

7.3 Design/Development

TMC plans and controls the product design activity. TMC Management ensures that design input requirements are clearly defined and that interfaces and communication processes are suitably managed. The resulting design outputs are suitably documented. The design is reviewed at appropriate stages in accordance with the design plan. Verification and validation is performed to ensure the design meets the input requirements and that the resulting design meets the specified application or intended use. TMC controls design changes by ensuring they are reviewed, verified and validated as appropriate. Design Records are retained.

Documentation References:
Research and Development procedure

7.4 Purchasing

TMC ensures that purchased products/materials conform to specified requirements and that suppliers are meeting TMC requirements and specifications. TMC evaluates and selects subcontractors based on their ability to meet assigned specifications and quality requirements. Records of supplier and subcontractor approval and performance are maintained. Purchasing documents clearly describe product/service being ordered and are reviewed prior to release. Where TMC or a customer requires verification at the supplier/subcontractor premises, the verification arrangements and product release process will be defined in the purchasing documents. TMC performs receiving verification to accept purchased product. Receiving Inspection will only be performed, if applicable.

Documentation References:
Purchasing and Supplier Control procedure

7.5 Production & Service Provision

7.5.1 Production Control

TMC carries out production processes that directly affect quality under controlled conditions that include the following:

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- a) Drawings, specifications, documented procedures, work instructions, forms, and production orders describing the process for production;
- b) Use of suitable production and inspection equipment in a suitable environment;
- c) Monitoring and measurement of processes and product characteristics during production;
- d) Use of criteria for workmanship stated in the clearest manner;
- e) Provision of proper maintenance to ensure continuous operation;
- f) Product release and delivery activities;
- g) Maintenance of production and inspection records.

Documentation References:

Production and Quality Control procedure

7.5.2 Validation of Processes

Special processes are those that cannot be fully verified by subsequent inspection and testing. If a special process is identified, it will be validated and will be performed by only specifically trained personnel using assigned equipment. Detailed drawings and/or instructions will also be provided to ensure product conformance.

Documentation References:

Production and Quality Control procedure

7.5.3 Identification & Traceability

Each TMC product will be identified by the assigned part number. Complete detailed traceability of the components types, supplier name, and purchase order number will not be maintained and is typically not required by TMC customers. If specified by the customer, more detailed traceability will be maintained and documented. Inspection status of a product is identified to assure that only product that has passed inspection is available for use. All products will carry an identification of their inspection status that indicates conformance or nonconformance of the product with regards to the inspection conducted. These identifications include stamps, signatures, tickets, and comments on relevant production documents.

Documentation References:

Production and Quality Control procedure
 Nonconformance Control procedure
 Receiving and Shipping procedure
 Customer Complaints and Returns procedure

7.5.4 Customer Property

TMC exercises care with customer property (including intellectual property) while under TMC control. TMC ensures that any customer-supplied products, customer returns or labels are identified, verified, handled, and stored appropriately. TMC recognizes that even with the verification process, the customer is still responsible for providing acceptable products. Any customer-supplied property that is lost, damaged, or unsuitable for use will be recorded and reported to the customer immediately.

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Documentation References:

Production and Quality Control procedure
 Nonconformance Control procedure
 Receiving and Shipping procedure
 Drawings and Material Lists Control procedure
 Customer Complaints & Returns procedure

7.5.5 Preservation of Product

TMC will preserve the conformity of materials, components and product while at TMC and during delivery. Methods of identification, handling, packaging, storage, protection, preservation and shipment will be suitable to meet requirements.

Documentation References:

Receiving and Shipping procedure
 Production and Quality Control procedure

7.6 Control of Monitoring and Measuring Equipment

TMC will determine inspection requirements and the measuring/inspection equipment to be used. TMC will control, calibrate, and maintain specified measuring, and inspection equipment. Calibration requirements will be tailored to the required measurement capability. Calibration will be conducted either internally by trained staff or externally by appropriate calibration organizations. Calibration records will be retained.

Documentation References:

Calibration procedure

8 MEASUREMENT, ANALYSIS & IMPROVEMENT

8.1 General

TMC will plan and implement suitable monitoring, measurement, analysis and improvement processes. These activities will be performed to ensure product conformity, quality system conformity and continuous improvement of the quality system. Where applicable, statistical techniques will be identified and implemented.

8.2 Monitoring & Measurement

8.2.1 Customer Satisfaction

TMC will assess customer perception of the product/service provided. The monitoring process includes data from customer complaints, returns and customer feedback. Additionally, TMC may decide to actively solicit customer satisfaction information from customers. Customer Satisfaction information obtained is reviewed as part of the Management Review activity.

Documentation References:

Customer Complaints & Returns procedure
 Management Review procedure

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8.2.2 *Internal Audit*

TMC will establish an audit program to determine if the quality system conforms to requirements and to determine whether it is effectively implemented and maintained. Audits are planned and carried out periodically by personnel independent of the activity being audited. Department Management reviews the results of audits. Timely action is taken, where appropriate. Follow-up activities verify and record the implementation and effectiveness of the action taken. Audit results are reported at management review.

Documentation References

Internal Auditing procedure

8.2.3 *Monitoring and Measurement of Processes*

TMC will implement suitable methods for monitoring the Quality System. These include the internal audit, corrective action, preventive action, management review processes, statistics, etc. TMC will identify and implement any product or process specific measurements deemed appropriate.

Documentation References

Internal Auditing procedure

Nonconformance Control procedure

Management Review procedure

8.2.4 *Monitoring and Measurement of Product*

TMC conducts inspection and testing activities at appropriate stages to verify product to specifications. Monitoring and measurement is planned according to TMC and customer requirements. Inspection records are retained which show that product was inspected to requirements and identifies the inspection authority responsible for release of the product for shipment. Finished products are not released for packaging and shipping until all required activities have been completed satisfactorily and all required authorizations have been obtained.

Documentation References:

Production and Quality Control

Receiving and Shipping

8.3 *Control of Nonconforming Product*

TMC will ensure that any product that does not conform to requirements is identified and controlled and prevented from unintended use or delivery. TMC personnel are encouraged to be vigilant in identifying nonconforming product. Nonconforming product is reviewed and assigned a disposition in an appropriate manner. If product is reworked or repaired it will be re-inspected to requirements. If it is determined that TMC has inadvertently shipped nonconforming product, then suitable action will be taken. Records of nonconforming products and their dispositions are retained.

Documentation References:

Nonconformance Control procedure

Customer Complaints and Returns procedure

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8.4 Analysis of Data

TMC will review and analyze data to demonstrate the effectiveness of the quality system and to evaluate continuous improvement opportunities. The data reviewed will include, but is not limited to: customer satisfaction, product conformity, product and process trends, preventive action opportunities, and supplier performance information.

Documentation References:

Management Review procedure

8.5 Improvement

8.5.1 Continual Improvement

TMC will use the management review, corrective action, preventive action, internal audit, quality policy, quality objectives and analysis of data to continually improve the effectiveness of the quality system.

Documentation References:

Internal Auditing procedure

Nonconformance Control procedure

Management Review procedure

8.5.2 Corrective Action

The TMC corrective action system includes:

- Processing, documenting, and solving customer complaints and returns including reporting of any nonconforming product.
- Investigating the cause of the nonconformity related to TMC products, processes, and overall quality system.
- Identifying problem cause and implementing appropriate corrective action that will eliminate cause.
- Recording investigation results, corrective action determined that will eliminate the cause of the nonconformity, person assigned for completion, and completion date.
- Reviewing corrective action taken to ensure that it is effective.

Documentation References:

Customer Complaints and Returns procedure

Nonconformance Control procedure

Internal Auditing procedure

Management Review procedure

8.5.3 Preventive Action

The TMC preventive action system includes:

- Analyzing quantitative data and collected information from customer complaints, internal audits, and nonconforming products to detect and eliminate potential causes of nonconformities.
- Identifying steps to be taken to prevent conditions adverse to quality.

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- Conducting preventive action and conducting periodic reviews to ensure that it is effective.
- Submitting results of action taken to the management review committee.
- Reviewing results for effectiveness and as necessary determine and assign new action items.

Documentation References:

Nonconformance Control procedure
Management Review procedure