

TED Machine

QUALITY MANUAL

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REVISION 01

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TED Machine

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APPROVALS

APPROVED BY:

Ted Clark

April 7, 2010

(NAME), President

Date

Ted Clark

April 7, 2010

(NAME), Quality Manager

Date

(NAME), Production Manager

Date

(NAME), Purchasing Manager

Date

(NAME), Engineering Manager

Date

(NAME), Personnel Manager

Date

Ted Clark

April 7, 2010

(NAME), Sales/Marketing Manager

Date

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1.0 GENERAL

1.1 INTRODUCTION

TED Machine recognizes its responsibility as a manufacturer of quality products/provider of quality services. To this end, TED Machine has developed and documented a quality management system. The quality system complies with the international standard ISO 9001:2008, Quality management systems – Requirements. The quality system also complies with the following standards: [MIL – STD – 810](#).

The purpose of this manual is to provide comprehensive evidence to all customers, suppliers and employees of what specific controls are implemented to ensure product/service quality. This manual also governs the creation of quality related documents. It will be revised, as necessary, to reflect the quality system currently in use. It is issued on a controlled copy basis to all internal functions affected by the quality system and on an uncontrolled copy basis to customers and suppliers. It may be issued to customers on a controlled copy basis upon customer request.

This manual is divided into eight main sections. Sections 4-8 are modeled on the sectional organization of the ISO 9001:2008 standard. Sections are further subdivided into several subsections representing main quality system elements or activities.

Ted Clark

(Name), President

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1.2 EXCLUSIONS

General Policy

The TED Machine quality system is tailored to our operations/processes, including all customer, and applicable statutory and regulatory requirements. Requirements of ISO 9001 that are not applicable to the nature of our business are excluded from the scope of our quality system.

Procedure

1.0 General

1.1 Exclusion of an ISO 9001 requirement is permissible only when both of the following conditions are satisfied:

- The requirement must be limited to ISO 9001 Clause 7, Product Realization and
- Exclusion of the requirement will not affect our ability or responsibility to provide product that meets customer, and applicable statutory and regulatory requirements.

2.0 Responsibilities

2.1 The Quality Manager is responsible for identifying those requirements of ISO 9001 that are not applicable to our business, and to recommend their exclusions from the TED Machine quality system.

2.2 The President has responsibility for evaluation and approval of the exclusions. This evaluation and approval of exclusions are normally conducted during the management review process. The details are explained in the Management Review Procedure.

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3.0 Identification

- 3.1 Any excluded requirements are identified in this section of the quality manual and reference the applicable clauses in the ISO 9001 standard. In each case, there is also an explanation as to why the exclusion is applicable.

List of Exclusions

The TED Machine Quality System satisfies all the requirements of ISO 9001:2008; therefore, no exclusions are claimed.

1. **Exclusion:** ISO 9001:2008 Section 7.3, Design and Development

Explanation: TED Machine does not design or develop products or services. All requirements/specifications for products/services are provided by the customer. TED Machine engineering activities are limited to process control in production, servicing, and/or installation.

1.3 SCOPE

The TED Machine quality system applies to the design/development, production, and service of our products/services. Products/services included in the scope of registration are:

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1.4 QUALITY POLICY STATEMENT

TED Machine accepts responsibility for the complete satisfaction of its customers. We exercise this responsibility through adequate training of our employees, adherence to proven procedures, total commitment to meeting and exceeding customer requirements, and maintaining a company culture that fosters continuous improvement. Our objective is to deliver defect free products/services on time, every time.

Ted Clark

(Name), President

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2.0 COMPANY HISTORY

TED Machine designs/develops, manufactures, distributes, and services ABC products.

Ted Clark founded TED Machine in the hope of profiting from better service and experiences for his customers in the job machine and custom manufacturing industry. He also founded tedmachine.com. Ted began by doing small jobs for local customers and eventually began doing work for his internet clients.

3.0 COMPANY CONTACT INFORMATION

TED Machine is located at:

Phone: (612) 781 - 3978

Fax: (612) 605 - 1536

E-mail ted@tedmachine.com

Web Site: <http://www.tedmachine.com>

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4.0 QUALITY MANAGEMENT SYSTEM

4.1 GENERAL REQUIREMENTS

TED Machine has developed, documented, implemented, and maintains its quality system in accordance with the requirements of ISO 9001:2008, Quality management systems – Requirements. TED Machine’s quality system is based upon a “process approach” to quality management and:

- a) determines the processes needed for the quality system and their application throughout the organization;
- b) determines the sequence and interaction of these processes (see Table 1.);
- c) determines criteria and methods required to ensure the effective operation and control of these processes;
- d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) monitors, measures, and analyzes these processes; and
- f) implements actions necessary to achieve planned results and continual improvement of the processes.

TED Machine continually maintains and improves these processes in accordance with requirements of ISO 9001:2008, Quality management systems – Requirements.

Where TED Machine chooses to outsource processes that affect the conformance of the product to requirements, TED Machine ensures control over these processes. The type and extent of control to be applied to these processes is defined within our quality management system. Ensuring control over the outsourced processes does not absolve TED Machine of the responsibility of conformance to customer, and applicable statutory and regulatory requirements.

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Table 1.
Sequence and Interaction of TED Machine Quality Management System

#	Process	Related Procedures	ISO 9001 Clause
	Customer Need is Identified	- Measuring and Monitoring Customer Satisfaction	8.2
	Product/ Service is Designed/ Developed	- Control of Monitoring and Measuring Devices Procedure - Control of Nonconforming Product Procedure - Design and Development Control Procedure	7.6 8.3 7.3
	Quotations are Sent and Orders are Received	- Contract Review Procedure	7.2.2
	Production/ Service Planning	- Facility Management Procedure - Product Realization Planning Procedure	6.3 7.1
	Materials are Purchased	- Control of Nonconforming Product Procedure - Identification and Traceability Procedure - Purchasing Procedure	8.3 7.5.3 7.4
	Production, Verification, Shipment	- Control of Customer-Supplied Product Procedure - Control of Monitoring and Measuring Devices Procedure - Control of Nonconforming Product Procedure - Facility Management Procedure - Process Control Procedure - Process Validation Procedure - Statistical Techniques Procedure - Handling, Storage, Packaging, Preservation, And Delivery - Inspection and Test Procedure - Inspection and Test Status Procedure	7.5.3 7.6 8.3 6.3 7.5.1 7.5.2 8.4 7.5.5 8.2.4 8.2.4
	Customer Service	- Measuring and Monitoring Customer Satisfaction	8.2
	Servicing	- Measuring and Monitoring Customer Satisfaction - Process Control Procedure - Process Validation Procedure - Servicing Procedure - Statistical Techniques Procedure	8.2 7.5.1 7.5.2 7.5.1 8.4

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Continual Improvement of TED Machine Quality Management System

PDCA	Related Procedures	ISO 9001 Clause
Plan	<ul style="list-style-type: none">- Control of Documents Procedure- Statistical Techniques Procedure- Product Realization Planning Procedure- Training Procedure	4.2.3 8.4 7.1 6.2.2
Do	<ul style="list-style-type: none">- Control of Quality Records Procedure- Statistical Techniques Procedure- Training Procedure	4.2.4 8.4 6.2.2
Check	<ul style="list-style-type: none">- Control of Quality Records Procedure- Measuring and Monitoring Customer Satisfaction- Inspection and Test Procedure- Internal Audits Procedure- Management Review Procedure- Process Validation Procedure- Statistical Techniques Procedure- Training Procedure	4.2.4 8.2 8.2.4 8.2.2 5.6 7.5.2 8.4 6.2.2
Act	<ul style="list-style-type: none">- Continual Improvement Procedure- Corrective and Preventive Action Procedure- Statistical Techniques Procedure- Internal Communication Procedure	8.5.1 8.5.2 8.4 5.5.3

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4.2 DOCUMENTATION REQUIREMENTS

4.2.1 GENERAL

TED Machine's quality system documentation is comprised of:

- a) documented statements of quality policy and quality objectives;
- b) this Quality Manual, which includes all the procedures required by the ISO 9001 standard;
- c) documented procedures required by applicable standards and regulations;
- d) documents, including records, needed to ensure the effective operation and management of the processes (i.e., where applicable, process maps, quality plans, work instructions, samples, drawings, and bills of materials);
- e) records required by TED Machine, the ISO 9001 standard, and any other applicable standards and regulations.

The extent of TED Machine's documentation depends on the:

- a) organizational needs;
- b) complexity and interaction of the processes;
- c) competence of personnel performing the tasks.

Documents are maintained on various media such as paper, electronic, video, etc.

4.2.2 QUALITY MANUAL

The Quality Manual is the principal document that defines the quality system at TED Machine. It includes:

- a) the scope of the quality system, including details of, and justification for, any exclusions;
- b) documented procedures;
- c) references to documented procedures and external documents not included in the quality manual;
- d) a description of the sequence and interaction of the processes included in the quality system.

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4.2.3 CONTROL OF DOCUMENTS

TED Machine identifies and controls documents required by the quality system according to the Control of Documents Procedure. It ensures that documents:

- a) are reviewed and approved for adequacy prior to issue;
- b) are updated, reviewed, re-approved, and re-issued as necessary;
- c) are identified with their current revision status;
- d) are available at point of use;
- e) remain legible, readily identifiable, and retrievable;
- f) of external origin are identified and their distribution is managed;
- g) that are obsolete are prevented from unintended use and are suitably identified if they are retained for any purpose.

Documents defined as quality records are managed per the Control of Quality Records Procedure.

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4.2.3.1 Control of Documents Procedure

General Policy

All documents and data are reviewed and approved by authorized personnel prior to issue. Each department issues and maintains its own documents. Current revisions of appropriate documents are available at locations where they are used. Obsolete documents are removed from points of use.

Procedure

1.0 General

1.1 The following types of documents are controlled by the document control procedure:

- Quality Manual, procedures and forms, Quality Plans, Project Plans, Test Plans and Service Plans
- Work instructions (i.e., configuration instructions, production control plans/routings, installation instructions, inspection/test instructions, etc.)
- Standards and other reference material
- Product requirements, codes, specifications, drawings, and Bills of Material (BOMs)

2.0 Document and Data Identification, Approval, and Issue

2.1 All documents are identified with a title, revision level (if required) and where applicable, a code or part number. Certain work instructions (i.e., directions posted in work areas or displayed by other means) do not have to have a revision level. Only original forms, which are stored on file, are identified with the issuing authority. All documents are reviewed and approved (signed and dated) prior to issue.

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- 2.2 Prior to issue and release, documents are reviewed for correctness and compliance to quality requirements. A document is considered to be formally issued when it is authorized and approved by the issuing authority. Documents that require more than one approval signature indicate how many and which signatures are required for approval and issue.
- 2.3 For electronic documents, only approved documents may be posted on the company network. The system administrator is responsible for reviewing all the required approval signatures.
- 2.4 The Quality Manager is responsible for ensuring that the Quality Manual is reviewed, approved, and distributed as required. Copies of this manual will be serialized and issued on a controlled distribution basis. Uncontrolled copies will be marked “uncontrolled” and will be provided for use outside of the company, although a controlled copy can be issued to customers upon customer request.
- 2.5 Customer engineering documents (i.e., standards, specifications, drawings, samples, etc.) and external documents (i.e., changes received from customers) are reviewed by Engineering, the Production Manager and the Quality Manager. If any ambiguities or errors are detected, the customer is notified. Only documents approved by the designated TED Machine personnel may be used for engineering/production/service operations.
- 2.6 Each department issues and maintains its own documents and a Master Index of all applicable documents and their current revision. Current revisions of appropriate documents are available at locations where they are used.
- 3.0 Document and Data Changes
- 3.1 Any employee can request a change to a document, but the review and re-approval must be performed by the same functions that performed the original review and approval. Revised portions of documents are distributed with a Change Brief, and obsolete documents are removed. Work instructions that are not marked with a revision level are destroyed and replaced with new, approved instructions.

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4.0 Obsolete Documents

- 4.1 Obsolete documents that are retained for reference or legal obligations are marked "OBSOLETE" and are kept separate from active documents. Filing cabinets containing obsolete documents are segregated and labeled "OBSOLETE". Obsolete electronic documents are removed from the network and are stored in media that are only accessible to authorized personnel. Any obsolete documents that need to be reactivated (i.e., for spare parts), must be reviewed, approved, and released in the same manner as newly established documents.

5.0 Uncontrolled Documents

- 5.1 Copies of documents issued to TED Machine personnel and outside parties for information only (are not affected by the documents) are stamped "UNCONTROLLED" across the front page. Such documents are not under revision control. Uncontrolled copies of documents may not be issued to personnel or outside parties who manage, perform, or verify work that is directly affected by the document.

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4.2.4 CONTROL OF QUALITY RECORDS

TED Machine has established and maintains quality records to provide evidence of conformance to requirements and of effective operation of the quality system. The Control of Quality Records Procedure ensures proper identification, storage, retrieval, protection, retention time, and disposition of quality records.

All records are adequately maintained to ensure they remain legible, identifiable, and retrievable.

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4.2.4.1 Control of Quality Records Procedure

General Policy

To demonstrate the implementation of the quality system, TED Machine adheres to strict control of quality records. All records are maintained by the department that is responsible for the activity on record and are stored in a secure and easily accessible location to prevent loss or damage. The retention period and disposition process for records are defined.

Procedure

1.0 General

- 1.1 Quality records are maintained to attest to the full implementation of the quality system. The records are stored as secured computer files or in designated filing cabinets to prevent deterioration and damage. Such records are easily accessible for use and are made available for review upon customer, internal, or external auditor request.
- 1.2 The following documents are acceptable records: forms, reports, minutes of meetings, signed or stamped documents, computer files, or databases.

2.0 Responsibility

- 2.1 Quality records are generated and maintained by the departments responsible for their creation. All records must contain sufficient data to attest to satisfactory completion of the recorded activity and at minimum, must be signed and dated by the individual responsible for completing the record.
- 2.2 For computerized records, appropriate back up procedures are established. Engineering is responsible for backing up computer files.

3.0 Storage, Location, and Retention Time

- 3.1 All record cabinets, containers, and devices are clearly marked/labeled to identify their contents. Records are indexed and grouped for expedient retrieval. Records must not be stored in employees' personal filing devices/locations.

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- 3.2 The retention period for quality records is determined by contractual requirements, warranty periods, product life cycles, legal considerations, etc. The following are quality records that are stored at TED Machine, at the designated locations for the specified retention time:

Title	Storage Location	Retention Period
Audit Reports		# Years
Calibration		# Years
Contract/Order Reviews		# Years
Corrective Action Reports		# Years
Customer Complaints		# Years
Design and Development Reviews, Verification, & Validation		# Years
Inspection and Test Reports		# Years
Management Reviews		# Years
Nonconformance Reports		# Years
Product Identification/Traceability		# Years
Production Control Plans/Routings		# Years
Servicing		# Years
Special Processes Qualification		# Years
Supplier Qualification/Purchasing		# Years
Training		# Years

4.0 Disposition

- 4.1 The Quality Manager is responsible for the disposition of quality records that exceed their specified retention time.

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5.0 MANAGEMENT RESPONSIBILITY

5.1 MANAGEMENT COMMITMENT

TED Machine's management provides evidence of its commitment to the development, implementation, and continual improvement of the effectiveness of the quality system by:

- a) communicating to the organization the importance of meeting customer, regulatory, and legal requirements;
- b) establishing and documenting the quality policy and quality objectives as described in the Management Review Procedure;
- c) conducting management reviews as described in the Management Review Procedure;
- d) ensuring the availability of necessary resources.

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5.2 CUSTOMER FOCUS

The management of TED Machine will ensure that customer needs and expectations are identified, transformed into requirements, and fulfilled with the intent of achieving and exceeding customer satisfaction. Customer needs and expectations are identified via the Measuring and Monitoring Customer Satisfaction Procedure, and Contract Review Procedure, and translated via the Design and Development Control Procedure. TED Machine complies with all relevant regulatory and legal requirements.

5.3 QUALITY POLICY

The quality policy is established by top management and is approved by the President. The management of TED Machine ensures that the documented quality policy:

- a) is appropriate to the purpose of TED Machine;
- b) includes a commitment to meeting requirements and to continuing improvement of the quality system per the Continual Improvement Procedure;
- c) provides a framework for establishing and reviewing quality objectives;
- d) is communicated and understood at appropriate levels of the organization per the Training Procedure, and in addition it is posted throughout visible areas of the company;
- e) is reviewed for continuing suitability per the Management Review Procedure.

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5.4 PLANNING

5.4.1 Quality Objectives

The management of TED Machine establishes annual key initiatives, which include quality objectives. The objectives are established via the Management Review Procedure and communicated to all levels of the organization for use in establishing each function's and employee's annual key objectives. Quality objectives are measurable, include business performance indicators reflecting requirements for products/services, and are consistent with the quality policy including the commitment to continuous improvement. The use of quality objectives for facilitating continual improvement is explained in the Continual Improvement Procedure.

5.4.1.1 Classification of Quality Objectives

Quality objectives are classified into the following four categories:

- **Policy objectives:** Are principal, strategic objectives that apply to the entire organization. They are normally included in the quality policy itself; if not, they are communicated via memorandum. Policy objectives are developed by top management and approved by the President.
- **Quality performance objectives:** Are objectives that set specific targets for measuring and improving performance to ensure product quality and customer satisfaction. They apply to all functions that have direct responsibility for product/service quality.
- **Product quality objectives:** Are objectives that pertain to the improvement of product and service associated with the product. The President and top executive managers responsible for marketing and product development establish these objectives. They can be documented in product briefs, memoranda, or minutes of meetings and apply to functions responsible for research, design, and development of products and services.
- **Quality system objectives:** Are objectives that pertain to the improvement of quality system processes and performance.

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5.4.2 Quality Management System Planning

The management of TED Machine ensures that quality management system planning is executed to meet the requirements provided in Section 5.4.1, as well as the quality objectives. Quality planning includes:

- a) the processes of the quality system, including permissible exclusions;
- b) the resources needed;
- c) continual improvement of the quality system.

Table 1 in Section 4.1 depicts the quality management system planning process output at TED Machine and describes the sequence and interaction of the processes of the quality management system. TED Machine's quality system is based upon a "process approach" to quality management. For each instance of quality management system planning, the output is documented accordingly, and changes are conducted in a controlled manner.

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5.5 RESPONSIBILITY, AUTHORITY, AND COMMUNICATION

5.5.1 Responsibility and Authority

TED Machine has defined all functions and their responsibilities within the organization. Responsibilities and authorities are defined and communicated in order to facilitate effective quality management.

5.5.1.1 Organization

TED Machine Organization Chart

Sole Proprietorship: TED Machine
Mr. Ted Clark: owner

5.5.1.2 Management Responsibilities

- The President formulates the quality policy, initiates the quality system, provides the necessary resources to maintain the quality system, and conducts annual management reviews of the quality system.
- Marketing/Sales conducts market research and analysis to define market demand as to the grade, price range and potential quantities; establishes the desired quality characteristics of products/services including unstated expectations; establishes specifications for products and associated services, communicates all customer requirements and expectations clearly and accurately within the company, advertises and promotes company's products, monitors the quality of competitors' products and services, carries out contract and order reviews, processes contracts and orders, provides customer liaison and service, and handles customer complaints.

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- Engineering prepares product functional specifications from Marketing specifications or customer-specified requirements, designs/develops products/services, initiates design and development reviews and assures that design and development output meets the design and development input, verifies and tests the designs, and collects field performance and reliability data, and participates in the disposition of nonconforming products.
- Production determines production personnel and equipment requirements, controls and monitors processes, defines workmanship standards, maintains production equipment, administers storage areas, performs production engineering, prepares production plans, prepares quality plans, and participates in the disposition of nonconforming products.
- Purchasing selects qualified suppliers and subcontractors, prepares and approves purchasing documents, monitors and assesses supplier performance and participates in the disposition of nonconforming products.
- Service processes servicing orders, performs servicing, and collects field performance and reliability data.
- Personnel defines personnel qualification requirements, implements employee incentive programs, implements training programs, and maintains training records.
- Quality establishes and maintains the quality management system, audits implementation of the quality system, initiates requests for, and follows up on, corrective actions, maintains and calibrates measuring and test equipment, carries out supplier quality surveys and audits, determines statistical techniques, performs inspections and testing in accordance with the quality plans, handles and participates in the disposition of nonconforming products, coordinates document control activities, and maintains inspection records.

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5.5.2 Management Representative

TED Machine designates the Quality Manager as the Management Representative. She or he, is a member of TED Machine management, and irrespective of other responsibilities, has the authority and responsibility for:

- a) ensuring that the processes of the quality system are established, implemented, and maintained;
- b) reporting to top management on the performance of the quality system, including any needs for improvement;
- c) ensuring promotion of awareness of customer requirements throughout the organization;
- d) acting as liaison with external parties on matters relating to the quality system.

5.5.3 Internal Communication

TED Machine management ensures that communication regarding the effectiveness of the quality management system is facilitated throughout the organization via the Internal Communication Procedure.

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5.5.3.1 Internal Communication Procedure

General Policy

TED Machine communicates all matters regarding the effectiveness of the quality systems to the entire organization. This includes quality requirements, objectives, and achievements as well as product and process performance.

Procedure

1.0 Continual Communication

- 1.1 Internal information pertaining to the TED Machine quality systems is communicated via user and product manuals, procedures, work instructions, drawings, specifications, quality records reports; and through on-the-job training, formal instruction, and quality related meetings.
- 1.2 The Quality Manager has the overall responsibility for ensuring that information and data about quality performance and the effectiveness of the quality system are reported to management. This includes the distribution of all applicable documents, reports, and records to appropriate functions.
- 1.3 Internal communication flows two ways:
 - a) Management's direction on quality is communicated to the organization through: the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions on how to implement and use the quality system.
 - b) The organization reports data and information relative to customer satisfaction, quality expectations of products and services, quality performance of products and processes, opportunities for improvement and the effectiveness of the quality system to management on a continual basis.

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2.0 Communication Meetings

- 2.1 Formal communication/review meetings serve an important role in ensuring proper communication between management and the organization. Management conducts quarterly communication meetings for the entire organization. In addition, management reviews provide the framework for the organization to report on the status of quality-related issues and activities, and for the management to formulate policies and directives to change and/or improve the quality system. The Quality Manager has the overall responsibility for coordinating structured communication meetings. For details, refer to the Management Reviews Procedure.

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5.6 MANAGEMENT REVIEW

5.6.1 General

The management of TED Machine conducts reviews of the quality system each October, as described in the Management Review Procedure. The reviews evaluate the system's continuing suitability, adequacy, effectiveness, and the need for any potential changes, including the quality policy and quality objectives.

5.6.2 Review Input

Inputs to management reviews may include, but not be limited to, current performance data and potential improvement opportunities related to:

- a) audit results;
- b) customer feedback;
- c) process performance and product conformance;
- d) status of corrective and preventive actions;
- e) follow-up actions from previous management reviews;
- f) changes that may affect the quality system, and
- g) recommendations for improvement

5.6.3 Review Output

Outputs from management review include conclusions reached and action items related to:

- a) improvement of the quality system and its processes;
- b) improvement of product to customer requirements; and
- c) necessary resources.

Results of management reviews are recorded as described in the Management Review Procedure and maintained per the Control of Quality Records Procedure.

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5.6.4 Management Review Procedure

General Policy

Management reviews of the quality system are conducted annually. The purpose of the reviews is to determine the continuing suitability and effectiveness of the system, including the quality policy and objectives.

Procedure

1.0 Scheduling and Attendance

- 1.1 The company's President, with support from the Quality Manager, conducts annual reviews of the quality system each October. In response to changing business conditions or performance data, the President may, at his or her discretion, call for unscheduled reviews.
- 1.2 Attendance is mandatory for all department managers. In the event a manager cannot attend, he or she must send a representative. After reviewing the minutes of the meeting, the absent manager must submit written input within two weeks of receiving the meeting minutes. Only one manager per meeting may be absent.

2.0 Meeting Inputs and Outputs

- 2.1 The Quality Manager is responsible for preparing the meeting agenda. The President is responsible for approving the agenda and distributing it to all department managers no less than two weeks prior to the meeting.
- 2.2 The inputs for reviews include the following information:
 - **ACTION ITEMS FROM LAST MEETING:** The Quality Manager opens the meeting by reporting on the status of action items from the last meeting. Issues that were not completed remain on the list as open action items, and are recorded as such in the minutes of the meeting.

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- **PROCESS PERFORMANCE AND PRODUCT CONFORMANCE:** The Quality Manager presents quality performance data. These include process performance and product conformance/nonconformance, supplier quality performance, on-time delivery performance, and productivity data.
- **INTERNAL QUALITY AUDITS:** The Quality Manager presents the results of internal quality audits. This includes quality systems audits, process audits and product audits, including summaries of important findings.
- **CORRECTIVE AND PREVENTIVE ACTIONS:** The Quality Manager presents the overall status of important corrective and preventive actions implemented, and the status and importance of open issues.
- **CUSTOMER FEEDBACK AND COMPLAINTS:** Marketing/Sales presents summaries of customer complaints, including analysis of trends for particular categories.
- **CUSTOMER NEEDS, EXPECTATIONS, AND SATISFACTION:** Marketing presents customer feedback, customer needs and expectations based on customer satisfaction data, and discusses developing trends in this area.
- **TRAINING:** The Personnel Manager reports on the status of training programs and the effectiveness of training provided.
- **CONTINUAL IMPROVEMENT:** The Quality Manager presents the status of current and completed improvement projects, and presents data supporting the progress made toward achieving continual improvement goals.
- **CHANGES THAT COULD AFFECT THE QUALITY SYSTEM:** The Quality Manager presents information on the changes in quality activities, products, processes, capacity, or any other operational or organizational changes that will have an impact on the quality system; and proposes specific actions to revise the system in response to these changes.

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2.3 The outputs from reviews include defined improvement actions that will have a positive effect on continuous improvement of products, services, and the quality system. These improvement actions are formulated into quality objectives as needed, with specific measurable targets, completion dates, assignments of responsibilities, and the required resources for their successful implementation. Objectives that have been achieved may either be upgraded to a higher performance level, or be closed out. Objectives that were not achieved will be investigated to determine the causes for the failure.

3.0 Records

3.1 The results of the reviews are documented in meeting minutes by the Quality Manager, distributed to company management for appropriate action, and maintained per the Control of Quality Records Procedure.

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6.0 RESOURCE MANAGEMENT

6.1 PROVISION OF RESOURCES

TED Machine management is committed to provide adequate resources to:

- a) implement and improve the processes of the quality system and continually improve its effectiveness, and
- b) promote customer satisfaction by meeting customer requirements.

6.1.1 General

The required resources for implementation and improvement of the quality system, and for addressing customer satisfaction, may include any of the following: suppliers, information, infrastructure, work environment, and financial funds. The principal means for determining and communicating resource requirements are management reviews of the quality system. For details, refer to the Management Review Procedure.

6.1.2 Responsibilities for Determination of Required Resources

The Quality Manager and all management personnel affected by the quality system are responsible for determining resource requirements for the implementation and improvement of the system.

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6.1.3 Provision of Resources

- Top management has the responsibility and authority for provision of resources.
- Resources for designated activities are integrated with the process of defining and initiating the activity. They may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.
- Allocation of resources may be documented in the quality manual, operational procedures, and minutes of meetings, memoranda, or any other form. Approvals of resource allocations may also be communicated verbally.

6.2 HUMAN RESOURCES

6.2.1 General

TED Machine selects and assigns qualified personnel to ensure that those who have responsibilities defined in the quality system are competent on the basis of applicable education, training, skills and experience.

Any personnel working within the quality management system may directly or indirectly affect the conformance of the product to quality requirements.

6.2.2 Competence, Awareness and Training

TED Machine has established and maintains a Training Procedure to:

- a) identify competency needs for personnel who perform tasks affecting quality /conformance to product requirements;
- b) provide training to address these needs or take other actions achieve the necessary competence;
- c) assess the effectiveness of the training provided and ensure the achievement of necessary competence;

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- d) ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and
- e) maintain appropriate records of education, training, skills, experience, and qualifications per the Control of Quality Records Procedure.

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6.2.3 Training Procedure

General Policy

TED Machine regards employees as its greatest asset. To this end, the company maintains an established employee qualification/training program. All personnel are classified on the basis of appropriate education, training, skills, or experience. Records of all training activities are kept in each employee's file.

Procedure

1.0 Training Requirements Review

- 1.1 The responsibility for identifying employee-training requirements lies with each department manager/supervisor. The purpose for the review is to identify competency needs for all personnel performing activities affecting quality. Job requirements, internal audit reports, and corrective action activities determine employee-training needs. In addition, an annual review is conducted with each employee, at which time the employee's training needs, as well as the effectiveness of the previous training are discussed. Each employee is made aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

2.0 Formal and Informal Training

- 2.1 All employees receive informal "on-the-job" training by the responsible area supervisor. After a 60-day trial period, all new/transferred employees are evaluated against the position requirements and if performance is found to be satisfactory, qualification for the applicable position is awarded.
- 2.2 New employees receive indoctrination into the quality system from the Quality Manager.
- 2.3 Designated employees may receive formal off-site/on-site training/seminars in various job-related disciplines/topics, as determined by the responsible supervisor/manager. This includes certification in specialized skills such as welding and soldering.

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2.4 TED Machine supports continuing education programs by reimbursing tuition for job related courses.

3.0 Qualification/Training Records

3.1 The Personnel Manager maintains records of education, experience, skills, training, and qualifications for each employee.

6.3 INFRASTRUCTURE

To ensure that our infrastructure is suitable for achieving conformance to product requirements, TED Machine has established and maintains a Facility Management Procedure. Assessment and maintenance of infrastructure includes:

- a) workspace, associated facilities and utilities;
- b) process equipment, hardware, and software; and
- c) supporting services (i.e. transport, communication, information systems, etc.).

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6.3.1 Facility Management Procedure

General Policy

Suitable facilities and work environment are provided as required to assure product quality. This includes planning, provision, and maintenance of employee facilities, workspaces, equipment, software, and supporting services.

Procedure

1.0 Facility Management Planning

- 1.1 Planning for new and/or modification of existing facilities is normally conducted with capacity or work force expansions and product or process changes. Facilities may also be expanded or modified to improve productivity, quality, and the work environment.
- 1.2 Each functional manager is responsible for identifying the need and requirements for new, or modification of existing, facilities in their areas. All requests for modifications or expansions of facilities must be reviewed and approved by the Production Manager and Quality Manager at a minimum. Requests for significant modifications or expansions must also be reviewed and approved by the President.

2.0 Maintenance of Equipment, Facilities, and Supporting Services

- 2.1 Maintenance of equipment, buildings, and facilities is performed by the Maintenance Function, or external contractors. This includes regularly scheduled maintenance of production equipment, lighting systems, information systems, communication systems, air conditioning and heating systems, landscaping, and cleaning. Repairs of buildings and other such facilities are contracted as needed. Purchasing is responsible for coordinating and managing maintenance contracts.

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2.2 All maintenance is performed per the recommendations provided by the equipment's manufacturers and is recorded on the Equipment Maintenance/Service Record for each piece of equipment. The accuracy and performance of the equipment is continuously monitored. Special attention is given to equipment features that contribute to key product quality characteristics.

3.0 Work Environment

3.1 The Personnel Manager and departmental managers are responsible for ensuring suitable working environment for personnel. This includes human as well as physical factors.

3.2 The Production Manager and the Quality Manager are responsible for identifying operations with extreme environmental conditions that have a potential for impacting quality performance of personnel and product/process quality. Where applicable, limits of exposure (i.e., extremely low or high temperature, excessive noise, etc.) or mitigating measures (i.e., limiting exposure time, increasing the frequency of breaks, supplying protective gear, automating processes, etc.) shall be defined and implemented for affected operations.

6.4 WORK ENVIRONMENT

TED Machine has implemented and maintains a Facility Management Procedure to manage the human and physical factors of the work environment that are necessary for achieving conforming product. Such factors include, but are not limited to:

- a) safety and ergonomics;
- b) light;
- c) noise;
- d) cleanliness;
- e) heat and humidity;
- f) space, and
- g) language

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7.0 PRODUCT REALIZATION

7.1 PLANNING OF PRODUCT REALIZATION

TED Machine has established and maintains a documented Product Realization Planning Procedure to ensure that processes and sub-processes are conducted under controlled conditions. Planning of the realization processes is consistent with the other requirements of the organization's quality system. Product realization plans determine the following:

- a) quality objectives for the product, project, or contract;
- b) the need to establish processes and documentation, and provide resources, infrastructure, and work environment necessary to produce conforming product;
- c) required verification, validation activities, monitoring, measuring, inspection, test and the criteria for the determination of acceptable product;
- d) the records that are needed to provide evidence that the realization processes and resulting product conform to specified requirements.

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7.1.1 Product Realization Planning Procedure

General Policy

Product realization planning encompasses determination of product/process quality objectives, development of required processes, and process documentation and records.

Procedure

1.0 Product Quality Objectives

- 1.1 Product quality objectives are defined in drawings and specifications, contracts, standards, samples, workmanship standards, and applicable legal and regulatory requirements.
- 1.2 The Quality Manager is responsible for identifying product quality objectives and requirements. This may be included in the process of determining customer and product requirements.

2.0 Product Realization Planning

- 2.1 Product realization planning includes the following:
 - Quality objectives and product requirements
 - Definition and evaluation of production/service processes
 - Development of suitable and capable processes
 - Identification of special processes and consideration of associated risks and consequences
 - Development and implementation of appropriate process control measures
 - Development and implementation of required verification, validation, monitoring, measuring, inspection, and test methods.
 - Development of instructions (where applicable) and training for process personnel

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- Identification of the records required to demonstrate product/process quality

2.2 Product realization plans are generated collectively by the Production/Service, Engineering, and Quality Functions. The plans are defined in associated production/service documents (i.e., process flowcharts, production/service work orders, process control plans, operator/installation instructions, process validation reports, etc.).

7.2 CUSTOMER-RELATED PROCESSES

7.2.1 Determination of Requirements Related to the Product

TED Machine has established a Design and Development Control Procedure and a Contract Review Procedure for identifying customer requirements. These processes determine:

- a) product requirements specified by the customer, including the requirements for availability, delivery, and post-delivery support;
- b) product requirements not specified by the customer but necessary for intended or specified use, where known;
- c) obligations related to product, including regulatory and legal requirements;
- d) any additional requirements determined by TED Machine.

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7.2.2 Review of Requirements Related to the Product

TED Machine reviews the identified customer requirements together with additional requirements that are not specified but necessary for fitness for use, and governed by laws and regulations, and requirements for availability, delivery, and support. This review is conducted prior to commitment to supply a product to the customer per the Contract Review Procedure. The review process ensures that:

- a) product requirements are defined;
- b) contract or order requirements differing from those previously expressed in a tender or quotation are resolved;
- c) TED Machine has the ability to meet the customer requirements;
- d) in situations where the customer provides no documented statement of requirements, or where customer requirements are changed, customer requirements are confirmed before acceptance;
- e) the results of the reviews, pertinent related correspondence, and necessary follow-up actions are documented by TED Machine order number and customer name.

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7.2.2.1 Contract Review Procedure

General Policy

Contract/order review is an integral part of the quality system at TED Machine. All contracts/orders are reviewed and accepted only if the requirements are clear and understood, and the company has the capability and capacity to assure full customer expectations.

Procedure

1.0 General

1.1 Order Entry/Sales receives and processes all customer Requests for Quotations (RFQs)/orders. All RFQs/orders are stamped with the date received. Phone orders are accepted providing the customer follows up in writing within 24 hours. Orders for catalog products/services are reviewed and processed without further involvement from supporting departments/functions. RFQs for customized products/services are also reviewed by Engineering, Production, and Quality before an offer is made to the customer.

2.0 Review

2.1 Review of RFQs/orders for products/services consists of a verification that the customer's requirements, including requirements not stated by the customer (where known), are adequately defined and documented and have been fully understood. Should the RFQ/order require clarification, it will not be accepted until the missing information is obtained from the customer. Consideration is given as to whether our capability and capacity are adequate to satisfy the customer's needs.

3.0 Order Acceptance

3.1 Once all issues are resolved, the order is marked "ACCEPTED", dated, and initialed by all reviewing parties.

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4.0 Amendment to Contracts/Orders

4.1 Change Orders are received and processed through the same channels as the original order. The Change Order form is completed and distributed to all affected functions within the company, and where a conflict may exist, the customer is immediately notified.

5.0 Records

5.1 Records of contract/order review are stored on file. For catalog products/services, the actual order is signed and a copy is stored on file. For custom products/services, a copy of the quotation, signed by authorized representatives of all participating functions, in addition to a copy of the order, is filed.

7.2.3 Customer Communication

TED Machine has implemented and maintains processes for communication with the customers. Customer communications includes:

- a) product/process information as described in the Customer Satisfaction Procedure, Continual Improvement Procedure, and Servicing Procedure;
- b) addressing inquiries, contracts or order handling, including amendments as described in the Contract Review Procedure;
- c) customer feedback, including customer complaints as described in the Corrective and Preventive Action Procedure;

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7.3 DESIGN AND DEVELOPMENT

7.3.1 Design and Development Planning

TED Machine plans and manages the design and development of its product/service in accordance with the Design and Development Control Procedure. Design and development is viewed as a creative activity involving conceptual elements. It is not viewed as encompassing minor modifications to standard products, or the specification of details from standard data tables or equivalent.

The design and development process determines:

- a) stages of the design and development process;
- b) review, verification, and validation activities appropriate to each design and development stage;
- c) responsibilities and authorities for design and development activities.

Organizational interfaces between the different groups involved in design and development are managed as described in the Design and Development Control Procedure to ensure effective communication and clarity of responsibilities. Planning output is updated at appropriate stages as design and development progresses.

Design and development reviews, verification and validation are conducted in series, or in parallel, as determined by the design and development team.

7.3.2 Design and Development Inputs

Inputs relating to product/service requirements are defined per the Design and Development Control Procedure. These include:

- a) functional and performance requirements;
- b) applicable regulatory and legal requirements;
- c) applicable information derived from previous similar designs;
- d) any other requirements essential for design and development.

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These inputs are reviewed for adequacy. Incomplete, ambiguous, or conflicting requirements are resolved.

7.3.3 Design and Development Outputs

The outputs of the design and development process are recorded and expressed in terms of requirements, calculations, analysis, or other means that can be verified against input requirements as described in the Design and Development Control Procedure. This process ensures that design and development outputs:

- a) meet the design and development input requirements;
- b) provide adequate information, which may include instructions for product preservation, to purchasing, production and service operations;
- c) contain or reference product acceptance criteria;
- d) define the characteristics of the product that are essential for its safe and proper use.

All design and development output documents are reviewed and approved before release per the Control of Documents Procedure.

7.3.4 Design and Development Review

Systematic reviews are planned, conducted, and documented at suitable stages of design and development per the Design and Development Control Procedure to:

- a) evaluate the ability to fulfill requirements;
- b) identify problems and propose necessary follow-up actions.

Participants in the design and development review include representatives of functions concerned with the design and development stage under review. Records of reviews and necessary follow-up actions are maintained in accordance with the Control of Quality Records Procedure.

7.3.5 Design and Development Verification

Design and Development verification are defined, planned, executed, and recorded by competent personnel to ensure that the design and development output meets the inputs. The results of the verification and subsequent necessary follow-up actions are recorded per the Control of Quality Records Procedure.

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7.3.6 Design and Development Validation

Design and development validation is performed per the Design and Development Control Procedure to ensure that resultant products are capable of meeting the requirements for the specified application or intended use, where known, prior to release for delivery or implementation. Where it is impossible to perform full validation prior to delivery or implementation, partial validation is performed to the extent applicable.

The results of the validation and subsequent necessary follow-up actions are recorded per the Control of Quality Records Procedure.

7.3.7 Control of Design and Development Changes

Design and development changes are documented and controlled in accordance with the Design and Development Control Procedure and Control of Documents Procedure. This process includes evaluation of the impact of the changes on constituent parts and delivered products. The changes are verified, reviewed, validated, and approved before implementation, as appropriate.

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7.3.8 Design and Development Control Procedure

General Policy

The design and development process is carried out under controlled conditions. All activities are planned and documented. Designs are reviewed at appropriate stages and where applicable, validated. The design and development output is verified before it is released to production.

Procedure

1.0 General

- 1.1 Engineering will adhere to this documented procedure that assures all designed/developed solutions (hardware, software, service, etc.) meet market requirements and performance standards.

2.0 Design and Development Input

- 2.1 Marketing/Sales will identify and document the market's needs for new solutions in a Market Requirements Statement (MRS), which will serve as the input for design and development work. The MRS shall include the following:
 - What is required (features/functions, etc.)
 - Why it is needed (customer demand)
 - When it is needed
 - Market Segment
 - Detailed product requirements (performance standards, including customer requirements, reliability, statutory and regulatory requirements, and products' life needs)
 - Pricing Targets

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- 2.2 When a product/service is to be designed or modified to meet specific customer requirements, Engineering receives from Marketing/Sales a design order with customer requirements and specifications. The MRS and design order contain the same type of information, and both provide Engineering with design and development input.
 - 2.3 Design and development input is documented. Design and development input can be in any form, including data sheets, customer drawings and specifications, photographs, samples, references to standards, etc. All documents constituting design and development input are recorded in the project book.
 - 2.4 Marketing/Sales, Engineering, and the Quality Function review and approve all design MRS and design order documents prior to issue and release. Production and Purchasing also take part in the review as required.
 - 2.5 When it's more practical to do so, design and development input review may be conducted at the contract review phase.
- 3.0 Design and Development Activities
- 3.1 Engineering will translate the needs and expectations from the MRS to technical specifications for materials, products, and processes. The design is geared towards meeting customer requirements, while providing a product cost, which will enable TED Machine to have a satisfactory return on investment. Engineering is responsible for providing a design, which is producible, verifiable, and controllable under the specified production, installation, and operational conditions.
 - 3.2 Project management tools and methodologies are used to manage the development process in order to deliver timely, profitable solutions.
 - 3.3 Each design and development activity is planned, divided into phases, and tasks are assigned to qualified personnel equipped with adequate resources. Plans are documented and updated as the design evolves.
 - 3.4 Organizational and technical interfaces between different functions that contribute to the design and development process are defined and the necessary information documented, transmitted, and regularly reviewed.

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- 3.5 Designs and design changes are documented, revision controlled, and approved by authorized personnel. Design and development documentation addresses all design and development intent requirements (performance, safety, reliability, regulatory, customer satisfaction, etc.), highlights changes from the last revision, and includes but is not limited to:
- Release notes for software
 - Critical dimensions for parts
 - Critical relationships for assemblies
 - Critical relationships and performance criteria for product and system solutions.
- 3.6 Formal, documented design and development reviews are held at appropriate stages of the design and development activity and include representatives from all concerned functions. The following elements are considered during design and development reviews:
- Customer needs versus technical specifications
 - Ability to perform under expected conditions of use and environment
 - Safety and potential liability during unintended use and misuse
 - Safety and environmental considerations
 - Compliance with applicable regulatory requirements, national and international standards
 - Comparison with competitor's design
 - Comparison with similar designs for analysis of previous quality problems and possible recurrence
 - Reliability, serviceability, and maintainability
 - Tolerances compared to process capabilities
 - Product acceptance/rejection criteria

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- Ease of assembly, installation, and safety factors
- Packaging, handling, storage, shelf life, and disposability
- Esthetic specifications and acceptance criteria
- Failure modes and effects analysis
- Ability to diagnose and correct problems
- Identification, warnings, labeling, traceability, and user instructions
- Manufacturability, including special processes
- Capability to inspect and test
- Materials and components specifications
- Review and use of standard parts

Records of design and development reviews, including corrective action plans and those in attendance are maintained.

- 3.7 Design and development verification and validation are performed and approved as appropriate before designs are released to assure each product conforms to all specified design requirements. This includes alternative calculations to verify correctness of the original calculations and analysis, and periodic evaluation of sample production models. The amount and degree of testing is related to the risk factor identified in the design and development plan. The test will include evaluation of performance, durability, safety, reliability, and maintainability under expected storage and operational conditions and where applicable, defect and failure analysis. All results of tests, evaluation, and inspection are documented throughout the product qualification cycle. The Quality Function verifies that all design features meet requirements and that all authorized design and development changes have been implemented. Records of verification and validation activities are filed.

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4.0 Design and Development Changes

- 4.1 Design and development input changes may be requested during design and development projects by Marketing/Sales, Service, Production, or Engineering itself. The changes are verified, reviewed, validated, and approved before implementation, as appropriate. Once approved by Marketing/Sales, Engineering incorporates the new requirements into the design and adjusts activities and schedules to accommodate the revised design and development input.
- 4.2 Design and development changes to released products are submitted on an Engineering Change Request form (ECR). Engineering logs all ECRs in the Engineering Change Request Log, performs an evaluation, and either approves or denies the request. Major changes are also evaluated by Marketing, Quality, and Production.
- 4.3 All ECRs serve as design and development inputs for design and development change projects.

5.0 Design and Development Tools and Techniques

- 5.1 All software that is used in calculations and other design and development activities is validated and approved. Software developed in-house is validated and approved prior to release. Software documentation includes validation specifications approved by the Chief Engineer and validation records attesting to acceptable performance. Standard/commercial software is accepted without validation. Software that has been successfully used in design and development prior to implementation of this procedure, and has proven to demonstrate successful performance for at least one year, may be used without validation testing.
- 5.2 Design and development reference materials (i.e., standards, catalogs, etc.) are available and maintained by the Engineering Function. Only current issues and revisions of reference material are used. Standards and reference materials are controlled by the Control of Documents Procedure.

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6.0 Design and Development Output

- 6.1 Design and development output is in the form of documents that define the product, including characteristics that affect safety, fitness for use, performance, and reliability and provide instructions for manufacturing (i.e., drawings, specifications, procedures, workmanship standards, inspection procedures, etc.).
- 6.2 Specifications and procedures for product preservation, packaging and labeling are also part of the design and development output.
- 6.3 Support documentation (i.e., calculations, risk analysis, test results, verification and validation reports, etc.) is also part of the design and development output.
- 6.4 All design and development output documentation is reviewed by qualified personnel and approved by the Chief Engineer prior to release. Design and development output documentation is controlled via the Control of Documents Procedure.

7.0 Records

- 7.1 Records are maintained per the Control of Quality Records Procedure

7.4 PURCHASING

7.4.1 Purchasing Process

TED Machine ensures that the purchasing process is controlled such that purchased products and subcontracted services, which affect product quality, conform to specified requirements. The type and extent of methods to manage the purchasing process depends on the effect on subsequent realization processes and their output or the final product. For details, refer to the Purchasing Procedure.

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TED Machine evaluates and selects suppliers as described in the Purchasing Procedure. Selection is based on suppliers' ability to deliver products that satisfy all TED Machine requirements. Criteria for selection, periodic evaluation, and re-evaluation are defined. The results of evaluations and necessary follow-up actions are recorded.

7.4.2 Purchasing Information

Purchasing documents contain data clearly describing the product to be purchased, including the following, where appropriate:

- a) requirements for approval or qualification of product, procedures, processes, and equipment;
- b) requirements for qualification of personnel; and
- c) quality management system requirements.

TED Machine ensures the adequacy of specified requirements contained in the purchasing documents prior to their release to suppliers.

7.4.3 Verification of Purchased Product

TED Machine has identified and implemented verification activities for ensuring that purchased product conforms to specified purchase requirements. Verification activities are defined in the Inspection and Test Procedure. Where TED Machine or its customer requests verification activities at the supplier's facility, TED Machine specifies the required verification arrangements and method of product release in the purchasing documents per the Purchasing Procedure.

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7.4.4 Purchasing Procedure

General Policy

TED Machine maintains a supplier qualification and rating process. Orders are only placed with suppliers that are on the Approved Suppliers List. Purchasing documents are clear and include full product/service descriptions and quality requirements. All purchasing documents are reviewed for accuracy and adequacy, and approved prior to release.

Procedure

1.0 Qualification of Suppliers

- 1.1 Purchasing and Quality share responsibility for the qualification and monitoring of suppliers.
- 1.2 Suppliers' quality capabilities are evaluated through the use of the Supplier Self-Evaluation and where necessary, on-site surveys, before orders for supply of materials and services are placed. The effectiveness of the suppliers' quality system shall be reviewed at intervals consistent with the complexity of the items supplied and the suppliers' performance. TED Machine's Supplier Self-Evaluation is normally the first official contact between TED Machine's Quality Function and a potential supplier. All questions in the evaluation form should be answered as completely as possible, and the form should be returned to TED Machine Purchasing within the requested time period. The Supplier Self-Evaluation is a necessary prerequisite to any award of business from TED Machine. Quality will review the evaluation findings and determine whether a site survey, described next, is required.
- 1.3 Suppliers who have been supplying TED Machine for at least one year prior to implementation of this procedure, and whose performance has proven to be acceptable, are exempted from the requirement for Supplier Self-Evaluation, and may be classified as "APPROVED". In this case, only the cover page of the Supplier Self-Evaluation form is completed, marked approved, dated, and signed by the Quality Manager and Purchasing Manager.

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2.0 Site Surveys

2.1 The Quality Manager is responsible for conducting the Site Survey on potential suppliers. Site Surveys may also be conducted by Quality or by a team. If a team is to make a site survey, the team members are to be selected from Quality (team leader), Purchasing, Materials, and Engineering. Quality is responsible for reporting all results. The Site Survey is an on-site investigation of a supplier's management structure and overall business operations. Site Surveys will be made using the Supplier Self-Evaluation form.

Note: Suppliers registered to ISO 9000 standards may be exempt from Site Surveys.

2.2 The survey will begin with a brief introductory meeting and discussion with appropriate supplier management personnel, and conclude with a verbal briefing on the findings. The review will include a discussion of XYZ Company's Quality philosophy and an assessment of the supplier's physical facilities, manufacturing and technical capabilities, and quality system. A supplier must receive approval to be considered as a potential business supplier to TED Machine. Should concerns be noted during the Site Survey, conditional approval to purchase material from a supplier may be given provided the supplier agrees to take, within the specified time period, any corrective actions requested.

2.3 The Quality Manager will evaluate survey findings and generate a Site Survey Report. All pertinent information will be taken from the applicable survey forms. A summary and recommendation will be made and, if applicable, corrective action requests listed. Official survey results will be communicated by letter within two weeks. Quality will send a copy of the Site Survey Report to the responsible buyer.

2.4 The responsible buyer is responsible for sending a copy of the Site Survey Report to the supplier.

2.5 The Quality Manager is responsible for entering the survey findings, audit date, active or inactive status, and other pertinent information into the Approved Supplier List (ASL). Original Survey Reports will be stored on files.

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3.0 Rating and Classification of Suppliers

- 3.1 A Nonconforming Material Report (NMR) shall be generated for all nonconforming material received from suppliers. For details, refer to the Control of Nonconforming Product Procedure. All NMRs will be incorporated into the Quality Performance Rating System. Suppliers will be issued copies of their respective NMRs.
- 3.2 Quality and delivery performance of all suppliers is continuously monitored via a supplier performance rating system, and a monthly supplier performance report is distributed to all concerned functions. Suppliers whose performance is inadequate are asked to implement corrective actions and submit a written response. Suppliers that demonstrate inadequate performance and show no sign of improvement are removed from the Approved Supplier List and discontinued from use. For suppliers meeting a minimum delivery lot criteria, TED Machine's Quality and Purchasing Functions provide periodic feedback on how well they are doing and where they rank in relation to suppliers providing similar parts/services. The rating system is a method for gauging a supplier's progress toward zero defects and 100% on-time delivery. TED Machine classifies suppliers into one of the following categories:
- APPROVED - An Approved supplier is a supplier that has an approved quality system and is actively displaying acceptable quality and delivery performance. Purchasing may order products or services from this supplier.
 - CONDITIONAL - A Conditional supplier is a supplier that does not have an approved quality system and/or does not meet acceptable quality and delivery requirements as demonstrated over two consecutive quarters. In the event that a supplier obtains a Conditional classification for two consecutive quarters, the TED Machine Purchasing Function may administer any or all of the following actions:
 - 1) Request an immediate meeting with the supplier to discuss, in detail, the current classification and strategies for improvement (resolution approaches).
 - 2) Evaluate short and long-term purchase order volume relative to current business conditions.

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3) Initiate an immediate “freeze” on all purchase order volume in order to assess a supplier’s current capabilities in reference to future performance expectations.

- **DISAPPROVED** - The supplier is not qualified due to major nonconformances or other problems. Purchasing **will not** purchase goods or services from disapproved suppliers.

3.3 A file, which includes all qualification documentation and performance records, is maintained for each supplier.

4.0 Approved Supplier List

4.1 The Quality Manager maintains an Approved Supplier List, which is authorized by the Quality Manager and the Purchasing Manager. This includes all suppliers whose supplies or services affect the quality of the TED Machine products/services, and who have been surveyed/audited and have demonstrated, by performance, their ability to meet the specified quality requirements. Orders may only be placed with suppliers that are on the list. Emergency purchases from suppliers that are not on the list are allowed with written permission from the Purchasing Manager and the Quality Manager (use Request to Deviate from the Approved Supplier List form). An updated Approved Supplier List is printed and distributed monthly to all personnel who are responsible for preparing and approving the company's purchasing documents.

5.0 Purchasing Data

5.1 All purchasing documents are prepared by Purchasing. The documents clearly describe ordered products/services. They include precise identification of the products/services, reference applicable standards and other relevant technical data, and state quality and compliance requirements, quality system requirements; and where appropriate, requirements for qualification of personnel. All purchasing documents are reviewed and approved by the Purchasing Manager prior to release.

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6.0 Request for Deviation

- 6.1 To request a deviation, the supplier must complete the Request for Deviation form (RFD) with the following information as a minimum: date of the request; name, address, phone and fax numbers of the requester; the name of the TED Machine buyer who placed the order for the part in question; part number; part revision level; part description; purchase order number; quantity of parts the deviation will apply to; (preferably in terms of P.O. line item numbers); effective date when applicable; the reason for the request; a description of the deviation; the effect on price and/or delivery (required for a deviation to be granted). Suppliers are required to submit the request to the TED Machine Purchasing Function and attach photographs or samples of characteristics that cannot be quantified (example: surface imperfections, extent of dents, bends, hairline cracks, porosity, etc.).
- 6.2 The TED Machine buyer forwards the RFD to the Quality Manager.
- 6.3 The Quality Manager logs the RFD in the Deviation Log, reviews the request for completeness and conducts a preliminary investigation to determine if the request or a similar one had previously been granted or denied. Quality may deny the request or present it to the engineer with design responsibility for the part.
- 6.4 After the investigation is complete, the RFD is approved or disapproved. If the deviation is denied, the disapproval box is checked with an explanation of why the request was denied. If the deviation is granted, the approval box is checked and any applicable conditions and/or limitations are noted. If applicable, the "corrective action request" and "ECR is required" boxes are checked.
- 6.5 The Quality Manager is responsible for obtaining the appropriate signatures and entering the deviation request into the Deviation Log.
- 6.6 The responsible buyer will return a copy of the completed deviation to the supplier. If the deviation is granted, the supplier must maintain a copy for as long as it is applicable.

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7.0 Verification of Purchased Product

7.1 In the event the Quality Manager determines that a verification of purchased products will be required at the supplier's facility, verification arrangements will be specified on the purchase order.

7.2 Our customers are given the right to verify purchased products at our supplier's premises. In this case, TED Machine is not relieved of the responsibility for products meeting stated quality requirements.

8.0 Settlement of Quality Disputes

8.1 The Quality Manager and Purchasing have the responsibility and authority to settle all disputes with suppliers regarding the quality of their materials/products/services or matters such as inspection and testing methods. Open communication channels with all approved suppliers will be maintained to provide for the quick resolution of quality disputes. In the event the Quality Manager and Purchasing cannot resolve a dispute, they will request the assistance of the General Manager. Disputes involving the rejection of materials/products from a supplier shall be documented.

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7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 Control of Production and Service Provision

Processes that directly affect quality of intermediate and end products are carried out under controlled conditions. To this end, TED Machine has established and maintains a Process Control Procedure, a Process Validation Procedure and a Servicing Procedure. Controlled conditions include the following:

- a) the availability of information that specifies the characteristics of the product;
- b) where necessary, the availability of work instructions;
- c) the use and maintenance of suitable equipment for production and service operations;
- d) the availability and use of measuring and monitoring equipment per the Control of Monitoring and Measuring Equipment Procedure;
- e) the implementation of monitoring and measurement activities;
- f) the implementation of defined processes for release, delivery, and applicable post-delivery activities.

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7.5.1.1 Process Control Procedure

General Policy

All production/installation/servicing shall be planned and conducted under controlled conditions. Controlled conditions shall include work instructions, where applicable, use of suitable production/installation/servicing equipment and working environment. Personnel performing complex or critical operations are provided with work instructions and, when applicable, criteria for workmanship. All equipment is suitably maintained to ensure continuing process capability.

Procedure

1.0 Production Control Plan

- 1.1 A Production Control Plan/Routing is prepared by the Production Manager. This document lists all the required production operations, including verification activities.

2.0 Control of Quality in Production

- 2.1 The Production Manager has primary responsibility for ensuring control of quality during production by selecting appropriate process control methods. Written work instructions are generated for complex and/or critical production operations. When determining the need for work instructions, the following factors are considered:
 - Qualification of personnel
 - Complexity and criticality of the work to be performed
 - Previous quality history
- 2.2 Where necessary, criteria for workmanship (i.e., written standards, work instructions, user manuals, samples, etc.) are utilized. Simple and verifiable processes are not formally controlled.

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- 2.3 The plant environment is monitored, measured, and controlled during production to ensure those factors such as temperature, humidity, and cleanliness that can adversely impact product quality, are within specified limits. Auxiliary materials and utilities such as water, compressed air, electric power, and chemicals used during production are also monitored to ensure a uniform effect on production processes. For details, refer to the Facility Management Procedure.
 - 2.4 All reference standards/codes, quality plans, and/or documented procedures are strictly adhered to.
 - 2.5 Suitable process parameters and/or product characteristics are monitored, measured, and controlled to assure continuing process capability.
 - 2.6 Suitable production equipment is used and its reliability is assured through regular maintenance by the Maintenance Function according to assigned schedules. For details, refer to the Facility Management Procedure.
- 3.0 Records
- 3.1 Records of process control are maintained per the Control of Quality Records Procedure, as appropriate.

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7.5.1.2 Servicing Procedure

General Policy

TED Machine services its products in accordance with the warranties specified in the contracts/current catalogs. If contractually specified, servicing is extended beyond the warranty periods. The Service Function carries out its activities under control of the quality system and complies with all applicable procedures.

Procedure

1.0 General

- 1.1 The Service Department functions independently from order intake, through product shipment.
- 1.2 Servicing is the responsibility of the Service Manager.

2.0 Quality System

- 2.1 The entire quality system of TED Machine, as documented in the Quality Manual, applies to the servicing operations.
- 2.2 Where necessary, the quality system is further documented and maintained in work instructions for assembly and installation, commissioning, operation, spares or parts lists, and servicing of any product.

3.0 Support

- 3.1 Field operations are supported with adequate logistics back-up, technical advice, spares or parts supply, and reliable servicing. Responsibility for all activities is clearly communicated to all suppliers, distributors, and users.

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4.0 Feedback on Performance

- 4.1 A performance feedback system is implemented to monitor and measure the quality characteristics of the products throughout their life cycle. This system is designed to analyze the degree to which the products or services satisfy customer quality, safety, and reliability expectations.
- 4.2 Information is collected from complaints, failures, customer needs and expectations, or any problem encountered in use and is to be made available for design and development reviews and corrective action in the supply and/or use of the items.

7.5.2 Validation of Processes for Production and Service Provision

Any TED Machine production and service processes where the resulting output cannot be verified by subsequent measurement or monitoring are validated in accordance with the Process Validation Procedure. This includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered.

Process validation demonstrates the ability of the processes to achieve planned results. TED Machine has defined arrangements for validation that include the following, as applicable:

- a) qualification of process per the Process Validation Procedure;
- b) qualification of equipment and personnel per the Process Validation Procedure and the Training Procedure;
- c) use of defined methodologies and procedures per the corresponding procedures;
- d) requirements for records per the Control of Quality Records Procedure;
- e) revalidation per the Process Validation Procedure.

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7.5.2.1 Process Validation Procedure

General Policy

Any production and service processes where the resulting output cannot be verified by subsequent measurement or monitoring (special processes) are carried out by qualified personnel and are subject to continuous monitoring and control of process parameters through the establishment of process verification and validation methods.

Procedure

1.0 Product/Process Verification and Validation Planning

1.1 Planning of product verification and validation activities results in the documentation of an inspection and testing plan for each applicable product, and for materials and components incorporated into the product. This includes:

- Criteria for review acceptance of the process
- Identification of inspection and testing points
- Scope, frequency, and methods of inspection and testing
- Approval of required equipment and qualification personnel
- Specific methods and procedures
- The required records to attest to the product quality
- Revalidation.

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1.2 The Quality Manager, Chief Engineer, and Production have responsibility for the development of product verification plans. The plans are defined in various types of documents (i.e., drawings and specifications, production work orders, purchasing documents, inspection and testing procedures, etc.). For critical processes, a formal Control Plan is documented for each applicable product. These plans define the inspection and testing process for a product, including all the required inspection/test equipment. In addition, the Inspection and Test Procedure explains how outputs of product verification and validation planning are used.

2.0 Records

2.1 Records are maintained per the Control of Quality Records Procedure.

7.5.3 Identification and Traceability

TED Machine maintains a documented procedure for identifying the product by suitable means throughout all stages of production, delivery, installation, and service operations. This process identifies the status of the product with respect to measurement and monitoring requirements. Where traceability is a requirement, unique identification of the product is recorded and controlled. Product identification and traceability are maintained and controlled through TED Machine's Identification and Traceability Procedure.

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7.5.3.1 Identification and Traceability Procedure

General Policy

All products are suitably identified by a part number/job number corresponding to applicable drawings, specifications, and other technical documents. Where appropriate, the identification system shall allow for traceability from finished products back to incoming records.

Procedure

1.0 Responsibility

- 1.1 Engineering is responsible for assigning part numbers/job numbers/serial numbers to all material and parts that are used in the company's products, and for maintaining all applicable documentation and records.
- 1.2 Receiving and Production are responsible for appropriate marking of purchased and manufactured products and for all associated records. Preserving of the identification is the responsibility of all personnel handling the products.
- 1.3 Inspection personnel are responsible for ensuring proper labels/markings are applied when required and for associated records.
- 1.4 Stockroom/Inspection personnel ensure that labels are properly stored and identified to prevent mix-ups.

2.0 Product Identification

- 2.1 All parts/products, whether purchased or manufactured, are identified with part numbers/job numbers, and where applicable, serial numbers, which link the parts/products to their documentation.

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3.0 Traceability

- 3.1 When required by the customer, traceability is maintained from receipt of parts to delivery of the final products. Engineering maintains records that trace part numbers to their corresponding drawings, specifications, and any other relevant documentation.
- 3.2 Engineering maintains product configuration records that trace serial numbers of products to their parts lists.

7.5.4 Customer Property

TED Machine exercises care with customer property while it is under TED Machine's control or being used by TED Machine as defined in the Control of Customer Supplied Product Procedure. TED Machine ensures identification, verification against specified requirements, and protection and safeguarding of customer property provided for use or incorporation into the product. Any customer property that is lost, damaged, or otherwise found to be unsuitable for use is recorded and reported to the customer.

Customer property may include intellectual property, such as information provided in confidence.

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7.5.4.1 Control of Customer-Supplied Product Procedure

General Policy

TED Machine does not differentiate between customer-supplied products and those that are purchased for incorporation into the supplies, and unless otherwise specified by the customer, they will be handled through our standard operating procedures. Any such product that is lost, damaged, or unsuitable for use is recorded and reported to the customer.

Procedure

1.0 Responsibility

- 1.1 Marketing/Sales is responsible for all coordination of customer-supplied product with the customer.

2.0 Receiving, Marking, Storage, and Handling

- 2.1 Receiving, inspection, marking, storage, handling, and preservation of customer-supplied product follows the same procedures that generally apply to purchased products, unless otherwise specified by the customer in the contract.
- 2.2 Verification of customer-supplied product by TED Machine does not absolve the customer of the responsibility of providing acceptable product.

3.0 Loss or Damage

- 3.1 Any customer-supplied product that is lost, damaged, or otherwise unsuitable for use shall be recorded and segregated per the Control of Nonconforming Product Procedure, and shall be reported to the customer by the Quality Manager/Sales Manager.

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7.5.5 Preservation of Product

To preserve conformance of product with customer requirements during internal processing and delivery to the intended destination, TED Machine has developed and maintains a documented Handling, Storage, Preservation, and Delivery Procedure. Details for identification of product are described in the Identification and Traceability Procedure. These procedures ensure adequate identification, handling, packaging, storage, and protection and also apply to the constituent parts of the product.

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7.5.6 Handling, Storage, Packaging, Preservation, and Delivery Procedure

General Policy

Suitable handling, storage, packaging, preservation, and delivery methods are established to prevent product damage and deterioration. Product is stored in designated storage areas with appropriate control of inbound receipts and outbound releases. Product in storage is periodically assessed to detect deterioration. Packaging is sufficient to ensure product quality. Protection of the product's quality is extended to include delivery to the customer.

Procedure

1.0 Handling

- 1.1 The Production Manager is responsible for establishing and enforcing suitable handling methods to assure preservation of product quality. All containers utilized for storing products are adequate and in good condition. All equipment that is used for internal transportation of products is regularly maintained and all operators receive the required level of training to assure efficient and safe operation.
- 1.2 Any items that are sensitive and require special handling (i.e. protection from electro-static discharge) are identified and handled with extreme care.

2.0 Storage and Preservation

- 2.1 The Production Manager is responsible for operating and maintaining the stockroom and storage areas. Only products with the proper identification and inspection status are accepted into and released from storage by authorized stockroom personnel. For details, refer to the Inspection and Test Status Procedure and Identification and Traceability Procedure.
- 2.2 Limited shelf life items are issued on a "first in, first out" basis. Products are preserved with appropriate rust preventative chemicals, where applicable, and are suitably wrapped/packaged. The condition of material in stock is assessed every three months to prevent product deterioration.

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2.3 Completed products awaiting packaging and shipping will be protected so as to prevent damage from vibration, shock, abrasion, corrosion, humidity, temperature, or any other conditions occurring during handling and storage.

3.0 Packaging

3.1 Product being prepared for shipment will have indication of having passed a final inspection test. All products are packaged in a manner that will prevent damage during storage and delivery. Unless otherwise specified by the customer, Engineering has responsibility for establishing packaging requirements.

3.2 Where special requirements are contractually specified, standard procedures are modified as required to satisfy those requirements.

4.0 Delivery

4.1 TED Machine utilizes company owned/leased and operated vehicles for local deliveries.

4.2 All goods are transported utilizing only common carriers from the Approved Supplier List. Air Ride vans will be specified where required. Shipping activities will comply with all applicable shipping and packaging regulations to assure safe arrival at destination.

Note: Where the customer specifies a specific carrier in the contract, the responsibility for delivery will remain with the customer.

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7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

TED Machine ensures that the monitoring and measurement activities are identified, and that the necessary monitoring and measuring equipment is available to assure conformance of the product to specified requirements. TED Machine's Control of Monitoring and Measuring Equipment Procedure is used to control measuring and monitoring equipment so that measurement capability is consistent with the measurement requirements. Measuring and monitoring equipment:

- is calibrated and adjusted periodically or prior to use against standards traceable to the international or national standards
- is safeguarded from adjustments that would invalidate the calibration
- is protected from damage and deterioration during handling, maintenance, and storage
- has the results of its calibration recorded
- has the validity of previous results re-assessed if it is subsequently found to be out of calibration and corrective action is taken per the Control of Nonconforming Product Procedure.

Software used for monitoring of specified requirements is validated according to defined guidelines prior to release for use in production, installation, and servicing.

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7.6.1 Control of Monitoring and Measuring Equipment Procedure

General Policy

All inspection, measuring, and test equipment, which are used in all phases of product/process verification, are controlled and calibrated against nationally traceable standards at specified intervals. Software used to control processes shall also be verified for proper functioning. All equipment/instruments in the calibration system are identified with stickers that indicate the calibration status. Where applicable, calibration certificates are maintained.

Procedure

1.0 Scope of Calibration

- 1.1 The Quality Manager has responsibility for control and calibration activities. All measuring, test equipment, and test software used for controlling production/servicing processes are calibrated at prescribed intervals. The calibration system also extends to manufacturing jigs, fixtures, tooling, and process instrumentation that can affect product quality, or is used to measure specified characteristics. Equipment that is used for reference only (not verification) is not included in the calibration system and is labeled with "DO NOT USE FOR VERIFICATION" stickers warning that it is not calibrated.
- 1.2 All employee-owned measuring instruments used for verification of products are registered with Quality and subject to all controls of the calibration system. Employees shall not, under any circumstances, use their measurement instruments if they are not registered and calibrated.

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2.0 Equipment Accuracy and Precision

2.1 Appropriate inspection, measuring, and test equipment is selected to satisfy the accuracy and precision of the required characteristics. Quality is responsible for selecting suitable equipment to perform the measurements.

3.0 Identification and Maintenance

3.1 All active equipment is entered on a controlled list, indicating the calibration interval. All inspection, measuring, and test equipment used for verification purposes are calibrated to nationally or internationally traceable standards and are labeled with a calibration sticker. Where practical, the instruments are sealed with tamper proof seals to prevent unauthorized repair or adjustment.

3.2 Calibration is either performed by external calibration laboratories or internally. When external services are utilized, they are incorporated into the Approved Supplier List and are monitored via the company's supplier rating system to prevent the use of labs that fail to meet quality and performance requirements. All internal calibration is performed in accordance with written instructions.

4.0 Environment

4.1 All equipment is calibrated in a suitable environment and is handled with care to assure damage is not sustained and the calibration is not affected.

5.0 Calibration Records

5.1 Certificates of calibration are maintained on file for all instruments that were calibrated by calibration laboratories. Each instrument is traceable to its own Calibration History Record which contains its identification number, storage location, make or type, frequency of calibration, reference standards used, actual calibration findings including date, and actions to be taken in case of unsatisfactory results.

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6.0 Software

6.1 Test software (developed or purchased) that is used for inspection and testing and/or monitoring of process performance is validated before it is used for verification of products. Standard software purchased from commercial sources is ordered with validation certificates. Software that is developed in-house is validated and approved in accordance with its documentation, which contains instructions for validation of proper functioning. Software is re-validated at prescribed intervals or whenever a change from the original release is introduced.

7.0 Supplier Measurement Control

7.1 The Quality Manager is responsible for extending the control of measuring and test equipment to all approved suppliers.

8.0 Nonconforming Equipment

8.1 If it is confirmed that the equipment is out of calibration, the Quality Manager investigates the validity of measurements for which the equipment was previously used and assesses the acceptance status of all the affected product. If applicable, all nonconforming product is identified and dispositioned as described in the Control of Nonconforming Product Procedure. In the event nonconforming product has been shipped, the customer is immediately notified.

8.2 Any measuring or test equipment that appears to give inaccurate readings is checked and calibrated.

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8.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.1 GENERAL

Measurement and analysis activities that are required to assure product quality and contribute to continual improvement are planned, and defined statistical techniques are used for analyzing measurement data.

8.1.1 Planning

Measurement and analysis activities to verify and assure product quality are defined in engineering specifications and drawings, production work orders, inspection and testing procedures, and process control procedures.

8.2 MONITORING AND MEASUREMENT

8.2.1 Customer Satisfaction

A key measure of TED Machine's quality system performance is the information obtained on customer satisfaction. The methodologies for obtaining and using customer satisfaction data are documented in the Monitoring and Measuring Customer Satisfaction Procedure.

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8.2.1.1 Measuring and Monitoring Customer Satisfaction

General Policy

TED Machine collects and analyzes information on the needs and expectations of its customers. This information is utilized to maintain and/or improve customer satisfaction. Customer satisfaction information is also considered when specific requirements for improving our products and services are developed.

Procedure

1.0 General

- 1.1 The overall methodology for collecting customer satisfaction data and information is defined in this procedure. However, the overall approach may be periodically adjusted in response to the status and importance of customer satisfaction with respect to particular aspects; or in response to new product or service launches, and changing priorities.

2.0 Information and Data Collection Points

- 2.1 Customer satisfaction information is obtained from customer feedback and by analyzing customer responses to:
- Customer satisfaction surveys
 - Complaints
 - Recognition and awards from customers, associations, and consumer groups
 - Product returns
 - Warranty claims
 - Repeat customers
 - Market share

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3.0 Unsolicited Customer Feedback

- 3.1 Customer complaints, spontaneous feedback on satisfaction, and other unsolicited customer feedback are collected and processed by the Sales/Marketing Function.
- 3.2 Customer complaints and feedback are grouped by selected categories to aid with statistical analysis of the data for assessing customer satisfaction.
- 3.3 The customer satisfaction data is compiled and analyzed by the Sales/Marketing Manager and reviewed and approved by the Quality Manager. The findings are reported to management quarterly and presented and discussed at management review meetings.

4.0 Returns and Warranty Claims

- 4.1 Sales/Marketing is responsible for coordinating product return authorization requests and warranty claims. The reason for each return request or claim is recorded. Product returns are categorized and the data is analyzed by the Sales/Marketing Manager and reviewed and approved by the Quality Manager.

5.0 Recognition and Awards

- 5.1 TED Machine seeks to participate in customer's award and recognition programs, and also encourages customers to provide feedback on its performance. This type of recognition and performance rating is considered to be the most valuable feedback on customer satisfaction or dissatisfaction and is considered to be one of the most important inputs for determining customer satisfaction.
- 5.2 Customer ratings and/or awards and recognition are analyzed and used in the same way as other customer feedback. Sales/Marketing analyzes which aspects of products and/or services are most responsible for achievement of the recognition. The results are presented at management reviews.

6.0 Repeat Customers, Referrals, and Market Share

- 6.1 Sales/Marketing periodically analyzes sales data to track repeat customers and identify their ordering patterns. Wherever possible, sales information is also analyzed for customer referrals.

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- 6.2 Marketing is responsible for collecting and analyzing data regarding competition, competitive products, and market share.
- 6.3 The results of the analysis (i.e., repeat customers, referrals, and market share) are presented and discussed at management reviews.

- 7.0 Customer Satisfaction Surveys
 - 7.1 Sales/Marketing conducts annual customer satisfaction surveys. A survey form is sent to customers for this purpose. OR [Sales/Marketing conducts customer satisfaction surveys. A Customer Satisfaction Survey is sent to customers with each product or, at the completion of the service.] If a customer does not respond within four weeks, a follow-up telephone call is made and a verbal survey is conducted.

 - 7.2 Sales/Marketing compiles and analyzes customer satisfaction surveys, and combines the results with other customer satisfaction data to draw conclusions on the quality of products and services. The results are presented and discussed at management review meetings.

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8.2.2 Internal Audit

TED Machine conducts periodic internal audits, in accordance with the Internal Audits Procedure to ensure that the quality system:

- a) conforms to the requirements of the applicable standards and regulations;
- b) has been effectively implemented and maintained.

TED Machine plans, conducts, and reports on internal audits in accordance with the Internal Audits Procedure. The audit scope, frequency, and methodologies are defined. Audit plans take into consideration the status and importance of the activities and areas to be audited as well as the results of previous audits. The audits are conducted by personnel independent of the activities being audited. Timely corrective action is taken on deficiencies found during the audits. Follow-up actions include the verification of the implementation of the corrective actions and the reporting of verification results per the Corrective and Preventive Action Procedure.

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8.2.2.1 Internal Audits Procedure

General Policy

Internal quality audits are planned and implemented by personnel independent of audited activities/areas. The purpose of the audits is to determine internal compliance with all stated quality objectives and procedures, as defined in the quality manual and associated documentation. All nonconformances noted during the audits are brought to the attention of the responsible managers/supervisors and formal corrective action is requested.

Procedure

1.0 General

- 1.1 Every activity and area is subject to an internal quality audit at least once a year. Where importance of product/service quality and deteriorating quality performance warrants more frequent verification, the Internal Quality Audit Schedule is adjusted to ensure that audits are performed as required. A documented Internal Quality Audit Plan is prepared before each audit.

2.0 Responsibility

- 2.1 The Quality Manager is responsible for planning, coordinating, and implementing internal quality audits. He or she is normally the team leader (if a team is used), except when auditing quality activities. In this case, the Production Manager conducts the audit.
- 2.2 All personnel conducting internal quality audits are qualified and independent of the areas/activities being audited.

3.0 Internal Quality Audit Plan

- 3.1 The Internal Quality Audit Plan covers the following items:
 - a) specific areas and activities to be audited;
 - b) the dates and times of the audits;
 - c) auditors responsible for each audited activity/area;

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d) type of audit (routine or special).

4.0 Audit Preparation, Implementation, and Reporting

- 4.1 In preparation for the audit, auditors review all applicable standards/specifications, Quality Manual and related work instructions, previous audit reports, and any other pertinent documents/data.
- 4.2 In executing the audit, auditors review quality records, observe pertinent activities, and interview applicable personnel. The auditors must verify through objective evidence that the requirements of the documented quality system are implemented.
- 4.3 In the event nonconformances are detected, they are immediately brought to the attention of the responsible supervisor/manager.
- 4.4 In reporting the results of the audits, auditors will complete the following information on a separate Internal Audit Nonconformance Record for each area/activity audited: responsible manager/supervisor, duration of the audit and completion date, findings, nonconformances noted, requests for corrective action and recommendations.
- 4.5 An Internal Quality Audit Report will be prepared by the Quality Manager and distributed to the company president and all affected department managers/supervisors.

5.0 Audit Follow-up

- 5.1 In all areas where an Internal Audit Nonconformance Record was issued, the responsible manager/supervisor will concur with the findings, identify the corrective action to be taken, and set a completion date.
- 5.2 All corrective actions will be re-audited to verify compliance, at which time they will be closed out. Where the corrective actions are found to be unsatisfactory, they will be re-issued.

6.0 Records

- 6.1 Records of Internal Quality Audits are maintained per the Control of Quality Records Procedure.

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8.2.3 Monitoring and Measurement of Processes

TED Machine applies suitable methods for measurement and monitoring of those realization processes that are required to meet customer requirements. These methods are applied in accordance with the Statistical Techniques Procedure and assure the continuing ability of each process to satisfy the intended purpose. When planned results are not achieved, action is taken to correct the immediate problem as specified in the Corrective and Preventive Action Procedure.

In the determination of suitable methods, TED Machine takes into consideration the type and extent of measurement or monitoring that are appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.4 Monitoring and Measurement of Product and/or Service

TED Machine measures and monitors the characteristics of the product to verify that requirements for the product are met. This is carried out at appropriate stages of the product realization process in accordance with the Inspection and Test Procedure. Products are not released/service delivery does not proceed until all planned monitoring and measuring activities have been satisfactorily completed. Evidence of conformance to the acceptance criteria is documented as described in the Inspection and Test Procedure and Inspection and Test Status Procedure. Records include the authority responsible for release of the product.

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8.2.4.1 Inspection and Test Procedure

General Policy

Incoming, in-process, and final inspection/testing are conducted to verify that products conform to specified requirements. Materials, components, subassemblies, and finished products are prevented from use, assembly, and dispatch until the required inspections are completed. Modified products shall be fully re-inspected and re-tested. The required records of inspections/tests are established and maintained.

Procedure

1.0 Receiving Inspection and Test

- 1.1 All purchased material which influences the manufacture of, or is intended for use as part of, deliverable products is subject to inspection and/or testing by Receiving Inspection. Upon receipt of products, receiving personnel verify the quantity of delivered units, check marking and identification of packages, and inspect all packages for any signs of tampering or damage. If all these checks and inspections are satisfactory, receiving personnel signs the delivery receipt. If not, any shortages or damages are noted on all copies of the delivery receipts.
- 1.2 The received containers are then moved to the designated inspection area, a copy of the purchase order is retrieved, and the packing slips are removed from the containers. Upon opening the containers, the goods are verified against the purchase order and the packing slip, and are examined visually for any signs of damage. The purchase order is stamped "RECEIVED" and is signed and dated by the receiving inspector. All receiving inspections are logged in the Receiving Inspection Log.
- 1.3 On critical parts and components, as determined by the Quality Manager, a precision inspection/test is performed. This type of inspection includes:
 - Review of material certificates, supplier inspection records, compliance certificates, and any other relevant documentation delivered with the product

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- Random sampling based on statistical technique specified
 - Visual inspection to detect any damage or other visible problems
 - Performing measurements and testing against specified requirements as required
 - Recording the sample size, actual measurements, and inspection test results on the Inspection/Test & Audit Report
- 1.4 Where it is not practical to perform receiving inspection upon receipt, provisions are made to perform source inspection at the supplier's facility.
- 1.5 The Quality Manager determines the extent and scope of receiving inspection based on the importance of the item and the suppliers' control methods and performance. The Quality Manager may request that suppliers provide objective evidence of conformance (i.e., material certifications, certificates of conformance, test data, first article inspection and SPC data). Objective evidence provided by suppliers may be used as the basis for reducing/waiving receiving and source inspection.
- 1.6 Upon acceptance, products are identified with an "ACCEPT" tag [green sticker] and moved to stock. In the event that product which is designated for receiving inspection is released to production due to urgency, it shall be positively identified and recorded in receiving inspection records.
- 2.0 In-process Inspection and Test
- 2.1 In-process inspection/testing is conducted to ensure that the product/process conforms to specified requirements. The inspection/testing is normally carried out by production personnel. Random audits of the in-process inspection/testing process are conducted by quality control personnel.
- 2.2 The Quality Manager determines the extent and scope of in-process inspection/testing based on the importance of the item, control methods, and previous performance.

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3.0 Final Inspection and Test

3.1 For acceptance of completed products, final inspection/testing is utilized. This includes a verification of satisfactory receiving and in-process inspections/tests, as well as completion of the remaining inspections/tests to assure that the finished products/processes conform to specified requirements. Products are not released, processes are not approved until all inspection/test activities have been satisfactorily completed and the appropriate documentation is available and authorized. All final inspections are logged in the Final Inspection Log. On critical parts and components, as determined by the Quality Manager, a Final Inspection/Test & Audit Report is completed.

3.2 The Quality Manager determines the extent and scope of final inspection/testing based on the importance of the item, control methods, and previous performance.

4.0 Inspection and Test Records

4.1 Inspection/test records, which show clearly whether the product/process has passed or failed the defined acceptance criteria, are established and maintained per the Control of Quality Records Procedure.

5.0 Nonconforming Material/Products

5.1 All material/products that are found to be nonconforming are identified and segregated and/or quarantined, and appropriately dispositioned per the Control of Nonconforming Product Procedure.

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8.2.4.2 Inspection and Test Status Procedure

General Policy

The inspection and test status of all products is clearly visible throughout all stages of production, installation, and servicing. Only product that has passed the required inspections/tests is released for further processing.

Procedure

1.0 Responsibility and Authority

1.1 All personnel authorized to carry out inspections and testing are responsible for identifying the inspection status of products and for the release of products to the next operation. Quality has authority for release of products for shipment after completion of the required final inspections/tests. All personnel who come in contact with the products are responsible for preserving the identification.

2.0 Conforming Status

2.1 Products that pass the required inspections/tests are identified as conforming with an "ACCEPT" tag and by the appropriate inspection signature or initials on the accompanying paperwork (travelers, job cards, process sheets, inspection/test reports, etc.). Only products that have passed the required inspections/tests are released for further processing.

3.0 Nonconforming Status

3.1 All material that is found to be nonconforming is identified and where practical, segregated and/or quarantined per the Control of Nonconforming Product Procedure.

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8.3 CONTROL OF NONCONFORMING PRODUCT

To ensure that product that does not conform to specified requirements is properly identified and managed, to prevent unintended use or delivery, TED Machine has established and maintains a documented Control of Nonconforming Product Procedure. Nonconforming product is corrected, where applicable, and subject to verification after correction to demonstrate conformance. In the event nonconforming product is detected after delivery or after it started being used, it is appropriately identified and managed.

Where product is accepted under concession, it is authorized for use by a relevant authority such as the customer, the end user, regulatory body, or other applicable authority.

Records of the nature of nonconformances and any subsequent actions taken, including authorized concessions are maintained.

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8.3.1 Control of Nonconforming Product Procedure

General Policy

Material/product that does not conform to specified requirements is identified, segregated, and prevented from use. The responsibility for review and disposition of nonconforming material/product is defined. Records of nonconformances are analyzed and forwarded to functions concerned.

Procedure

1.0 Identification and Segregation

- 1.1 All personnel at TED Machine shall immediately notify their supervisors when materials, components, assemblies, or completed product fails to meet the specified requirements during receiving, in-process, and final inspection and testing. All nonconforming material/product is identified with a Reject Tag and/or a Nonconforming Material Report (NMR).
- 1.2 The nonconforming material/product is then segregated from production and where practical, moved to an isolated storage area. All NMRs are logged in the Nonconforming Material Report Log. All Reject Tags/NMRs are evaluated for responsibility and defect trends. Corrective actions are initiated as necessary.
- 1.3 In the event nonconformances are detected after delivery or when use has started, they are classified as customer complaints and handled as described in the Corrective and Preventive Action Procedure.
- 1.4 The Quality Manager will determine nature and seriousness of the nonconformance and determine if previous production lots should be re-inspected, customers should be notified, and determine if a recall or stock purge is in order.

2.0 Disposition

- 2.1 Nonconforming material/product is dispositioned as follows:

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ACC = Accept (nonconformance could not be validated)

or

RTO = Return To Originator

or

RTS = Return to Supplier

or

RWK = Rework

or

UAI = Use As Is

or

Scrap

and

H = Responsibility House

or

S = Responsibility Supplier

- 2.2 When the disposition of nonconforming material/product is evident (scrap, RTO or RTS), the Production Manager may make the appropriate disposition and forward a copy of the applicable NMR/Reject Tag to the Quality Manager. All other NMRs/Reject Tags are dispositioned by the Material Review Board (MRB) and where required, by the customer. The MRB is comprised of the Quality Manager, the Production Manager, Purchasing and a representative from Engineering.
- 2.3 Suppliers are issued copies of all NMRs that are dispositioned as responsibility S and RTS or UAI.
- 2.4 Upon completion of the necessary corrective measures, all material/product is re-inspected. The Quality Manager will isolate the root cause of the problem and take appropriate action to prevent recurrence.
- 3.0 Records
- 3.1 All dispositioned Reject Tags and NMRs shall be filed and maintained per the Control of Quality Records Procedure.

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8.4 ANALYSIS OF DATA

TED Machine has established and maintains a documented Statistical Techniques Procedure to collect and analyze appropriate data to determine the suitability and effectiveness of the quality system and to identify improvements that can be made. This includes data generated by measuring and monitoring activities and other relevant sources.

TED Machine analyzes this data to provide information on:

- a) customer satisfaction per the Customer Satisfaction Procedure;
- b) conformance to customer requirements per the Design and Development Control Procedure and the Corrective and Preventive Action Procedure;
- c) process characteristics;
- d) supplier performance per the Purchasing Procedure.

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8.4.1 Statistical Techniques Procedure

General Policy

Effective data analysis is an essential part of the quality management system at TED Machine. Statistical techniques are utilized, where appropriate, and the data is analyzed by designated personnel and utilized for continuous product and process improvement.

Procedure

1.0 General

- 1.1 Where appropriate, statistical techniques are utilized to monitor and improve product quality and process capability.
- 1.2 Statistical techniques may include, but are not limited to, data analysis, defect analysis, process performance, sampling the quality of product, supplier performance, product performance, and customer satisfaction.

2.0 Responsibility and Application

- 2.1 The Quality Manager determines the need for statistical techniques.
- 2.2 When required, statistical techniques are employed under the direction of Quality. All personnel involved in the application of statistical techniques are trained in their use and are provided with the necessary tools.

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8.5 IMPROVEMENT

8.5.1 Continual Improvement

It is the overall responsibility of top management at TED Machine to continually improve the effectiveness of the quality management system in accordance the Continual Improvement Procedure. This process describes facilitation of the continual improvement of the quality system through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive action, and management review. Each manager/supervisor is responsible for the continual improvement of the quality management system in his or her respective areas. Effectiveness of continual improvement activity is assessed during the Management Review Process as described in the Management Review Procedure.

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8.5.1.1 Continual Improvement Procedure

General Policy

TED Machine has implemented a continual improvement philosophy throughout the entire organization, which is driven by goals documented in the quality objectives and quality policy. Opportunities for improvement are identified and translated in improvement projects. Causes of nonconformance are identified, investigated, and where appropriate, corrective actions are implemented to ensure there is no recurrence. Preventive actions are implemented to eliminate the causes of potential nonconformances.

Procedure

1.0 General

- 1.1 TED Machine has implemented a continual improvement philosophy throughout the entire organization. This philosophy is inherent in the TED Machine quality system. Every employee in the organization is encouraged to suggest new ideas for improving products, processes, systems, productivity, and the working environment.
- 1.2 Opportunities for improvement of operations and processes are identified by functional managers on a continual basis from daily feedback on operations and periodic management reviews. Opportunities for improvement of products and services are identified mainly by Sales/Marketing and Engineering.

2.0 Sources for Improvement Opportunities

- 2.1 Inputs for improvement opportunities are obtained from the following sources:
 - Customer satisfaction and any other customer feedback
 - Market research and analysis
 - Inputs from employees, suppliers, and other interested parties
 - Internal and external audits of the quality system
 - Records of product nonconformances

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- Data from process and product characteristics and their trends
- 2.2 Opportunities for improvement may also be identified on a special project basis. The following are examples of such projects:
- Non value-added use of floor space
 - Excessive inspection/testing
 - Excessive handling and storage
 - Excessive failure quality costs
 - Machine set-up changeover times
- 3.0 Evaluation, Prioritization, and Implementation
- 3.1 Opportunities for improvement from daily feedback on operational performance (i.e., disposition of nonconforming product, internal audits, customer complaints, etc.) are evaluated by the Quality Manager. Typically, they are implemented through the corrective and preventive action system.
- 3.2 Opportunities for improvement from analysis of longer-term data and trends are evaluated and implemented through the management review process. They are prioritized with respect to their relevance for achieving quality objectives. When opportunities for improvement are no longer supported by the current policy and objectives, management will establish new quality objectives, and possibly change the policy. The process for this evaluation and prioritizing is described in the Management Review Procedure. Longer-term improvement projects are initiated through the management review process, as well as the corrective and preventive action system.
- 3.3 Product improvement opportunities are evaluated by Sales/Marketing, Engineering, and the top management. They are implemented through the Market Requirements statements or Engineering Change Orders.

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8.5.2 Corrective Action

TED Machine has established and maintains a documented Corrective and Preventive Action (CAPA) Procedure for eliminating the causes of nonconformance in order to prevent recurrence. Corrective actions taken are appropriate to the impact of the problems encountered. The Corrective and Preventive Action Procedure defines requirements for:

- a) identification of nonconformities, including customer complaints;
- b) determination of the causes of nonconformities;
- c) evaluation of the need for actions to ensure that nonconformities do not recur;
- d) determination and implementation of corrective actions needed;
- e) recording the results of actions taken;
- f) reviewing the effectiveness of the corrective action taken.

8.5.3 Preventive Action

TED Machine has established and maintains documented quality plans, a Design and Development Control Procedure and a CAPA Procedure for eliminating the causes of potential nonconformities to prevent occurrence. Preventive actions taken are appropriate to the impact of the potential problems. Quality plans and the procedures define requirements for:

- a) identification of potential nonconformities and their causes;
- b) determination and implementation of preventive action needed;
- c) recording results of action taken;
- d) reviewing the effectiveness of the preventive action taken.

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8.5.3.1 Corrective and Preventive Action Procedure

General Policy

The quality system at TED Machine is geared toward the prevention of defects. To this end, a formal corrective and preventive action system is utilized. Root causes of nonconforming product, services, and quality system nonconformances are investigated, and corrective and preventive actions are implemented to prevent their recurrence.

Procedure

1.0 Initiation of Corrective/Preventive Actions

- 1.1 Corrective actions may be requested when a condition, which is adverse to quality or which has the potential for product/process improvement is identified. This includes nonconforming material received from a supplier.
- 1.2 Preventive actions may be requested when potential product/process problems are identified.
- 1.3 Any employee of the company can initiate a corrective/preventive action request by completing the top portion of the Corrective Action Request (CAR) form, but only the Quality Manager can issue a Supplier Corrective Action Request (SCAR). The Quality Manager records all CARs in the Corrective Action Status Log and SCARs in the Supplier Corrective Action Status Log.

2.0 Customer Complaints

- 2.1 Marketing/Sales is responsible for receiving, processing, and responding to customer complaints. This includes nonconformances detected after delivery or when use has started.
- 2.2 All received customer complaints are recorded in the Customer Complaints Status Log.
- 2.3 The Quality Manager evaluates every complaint and when relevant, requests implementation of corrective actions from the responsible function. The Quality Manager, in conjunction with the President and Sales, determines the appropriate customer response.

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3.0 Preventive Actions

3.1 When corrective actions are implemented or when a potentially serious nonconformance is identified, similar parts, products, and processes are analyzed to determine the required steps for effective implementation of preventive actions.

4.0 Analysis and Approvals

4.1 A thorough analysis of all related processes, operations, quality records and specifications, which may have contributed to the deficiency, is conducted by the responsible function. The investigation and analysis of the root cause and preventive measures shall be fully documented by the group or individual assigned to the problem. The analysis shall include review of all applicable data and examination of product scrapped or reworked to determine the extent and cause of the problem and analysis of trends in processes or performance of work to prevent nonconformances.

4.2 All problems are evaluated in terms of potential impact on production costs, quality costs, performance, reliability, safety, and customer satisfaction. All problems are classified either minor or major. Resolutions to all corrective and preventive actions are reviewed and approved by the Quality Manager. Where the response is unsatisfactory, the corrective action request is re-issued. The Quality Manager conducts periodic reviews/follow up to determine if the corrective and preventive actions have been implemented and are effective.