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## **Quality Policy**

It is the policy of XYZ. to engineer and manufacture proprietary products that meet the highest quality requirements, following the company and personal principle of "Continuous Improvement". XYZ strives to continuously improve products, processes, and the quality management system by establishing, monitoring, reviewing and acting upon quality objectives.

## **Quality Strategies**

Quality is the responsibility of all employees and must be intrinsic in the products and services that we provide. We are committed to continuous improvement by employee education, reducing defects, reducing variation, and controlling our processes with measurable results.

Customers are critical to our success in driving continuous improvement. We welcome all feedback from customers in order to achieve our mutual objectives and profitable growth over time.

We acknowledge that our suppliers are an integral part of meeting our customer needs and expectations. Only through a continually improving customer-supplier relationship can we expect to maintain the success that we have experienced.

## **Manual Scope and Purpose:**

The policies contained within this manual are written to conform to ISO 9001 (2000). This manual is intended as a working document that describes, as a minimum, the quality management systems to be deployed at XYZ, Incorporated. QUALITY MANAGEMENT SYSTEM (QMS). This manual supports XYZ scope which is "blah blah"

### **1.1 General Requirements**

- 1.1.1 XYZ has established and maintains a documented quality management system. XYZ continuously monitors and improves the effectiveness of the system in accordance to ISO 9001 (2000) standard.
- 1.1.2 XYZ shall:
  - 1.1.2.1 Identify all processes needed for the QMS and their application throughout the standard.
  - 1.1.2.2 Determine the interaction and sequence of these processes
  - 1.1.2.3 Determine the criteria and methods needed to ensure that both the operation and control of these processes are effective
  - 1.1.2.4 Ensure the availability of resources and information necessary to support the operation and monitoring of these processes
  - 1.1.2.5 Monitor, measure and analysis these processes and
  - 1.1.2.6 Implement actions necessary to achieve planned results and continual improvement of these processes.
- 1.1.3 XYZ shall manage the processes in accordance with ISO 9001 (2000) standard.
- 1.1.4 If XYZ decides to outsource any process that affects product conformance with requirements, XYZ shall assure control over such processes. These processes will be identified within the QMS.

### **1.2 Documentation Requirements**

- 1.2.1 The QMS documentation includes
  - 1.2.1.1 Documented statements of the Quality Policy and Quality Objectives
  - 1.2.1.2 This Quality Manual
  - 1.2.1.3 Documented procedures required by ISO 9001 (2000).
  - 1.2.1.4 Documents needed by the organization to ensure the effective planning, operation and control of its processes.
  - 1.2.1.5 Records required by ISO 9001 (2000).
- 1.2.2 Quality Manual

The organization established and maintains this Quality Manual which includes

  - 1.2.2.1 The scope of the QMS and justification of any exclusions.
  - 1.2.2.2 The documented procedures established for the QMS and or reference to them (
  - 1.2.2.3 A description of the interaction between the processes of the QMS is included in the back of this Manual.
- 1.2.3 Control of Documents

XYZ ensures that all documents required by the QMS are controlled. Records are controlled per section 1.2.4. XYZ has established a documented procedure () which defines the controls needed to

  - 1.2.3.1 Approve documents for adequacy prior to use.
  - 1.2.3.2 Review and update as necessary and re-approve documents
  - 1.2.3.3 Ensure that changes and the current revision of documents is identified.

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- 1.2.3.4 Ensure that relevant versions of the document are available at point of use.
- 1.2.3.5 Ensure that documents remain legible and readily identifiable.
- 1.2.3.6 Ensure that documents of external origin and their distribution are identifiable and controlled.
- 1.2.3.7 Prevent unintended use of obsolete documents and apply suitable identification to them if they are retained for any purpose.
- 1.2.4 Control of Records
  - 1.2.4.1 XYZ establishes and maintains records to provide evidence of conformity to requirements and of the effective operation of the quality management system.
  - 1.2.4.2 These records will
    - 1.2.4.2.1 Remain legible
    - 1.2.4.2.2 Be easily identifiable
    - 1.2.4.2.3 Retrievable
  - 1.2.4.3 A documented procedure () defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of the records.

## 2.0 MANAGEMENT RESPONSIBILITY

### 2.1 Management Commitment

XYZ's top management (see organizational chart) is committed to developing and maintaining an efficient and effective quality management system. The quality management system is focused the following eight quality management principles.

- 2.1.1 **Customer Focus:** Customers determine the expectations, standards and requirements. XYZ strives to understand, meet and exceed these requirements.
- 2.1.2 **Leadership:** XYZ top management establishes the vision, goals, measurable objectives and direction for the organization. Top management believes in leading by example and including all employees in establishing the company's objectives.
- 2.1.3 **Involvement of People:** Quality is the responsibility of all employees and must be intrinsic in the products and services that we provide. XYZ can only achieve its visions, goals and measurable objectives by including all employees.
- 2.1.4 **Process Approach:** Top management recognizes, identifies, understands, documents and manages processes that determine final outcome of activities. Processes can be identified as input – process – output and all activities can be broken down as a series of processes.
- 2.1.5 **System Approach to Management:** Top management recognizes, identifies, understands, documents and manages systems. Systems are made from interrelated activities. These activities can be broken down as a series of processes.
- 2.1.6 **Continuous Improvement:** Continuous improvement is the core of XYZ Quality Policy. All employees are trained in the Quality Policy.
- 2.1.7 **Factual Approach to Decision-Making:** Top management is dedicated to making effective and efficient decisions based on data and information.
- 2.1.8 **Mutually Beneficial Supplier Relationships:** Top management realizes that suppliers are an integral part of meeting customer needs and expectations. Improving our supplier performance benefits our suppliers, our customers and ourselves.
- 2.1.9 XYZ is committed to communicating to the organization of meeting internal\external customer requirements as well as statutory and regulatory requirements. Examples include:
  - 2.1.9.1 Continuous training of all employees
  - 2.1.9.2 Extensive documentation of all requirements
  - 2.1.9.3 Understanding external customer needs and expectations and transferring this information to employees through pertinent media
  - 2.1.9.4 Including internal customers in determining requirements
- 2.1.10 XYZ has established a Quality Policy (See page 3). This policy is communicated and taught to all employees. Continuous improvement is the core of XYZ Quality Policy.
- 2.1.11 Top Management ensures quality objectives are established.
  - 2.1.11.1 Objectives will be defined and documented.
  - 2.1.11.2 Objectives will be periodically reviewed on a schedule basis.
  - 2.1.11.3 Objectives will be measurable.
  - 2.1.11.4 Objectives will be tracked.
  - 2.1.11.5 Improvement actions will be implemented based on results of measurements.
- 2.1.12 Objectives include but are not limited to:
  - 2.1.12.1 Financials
  - 2.1.12.2 Process performance

- 2.1.12.3 Yields
- 2.1.12.4 Cycle Time
- 2.1.12.5 Customer Satisfaction
- 2.1.13 Top Management shall conduct quality management reviews. These reviews will include but are not limited to:
  - 2.1.13.1 Review of the quality management system
  - 2.1.13.2 Review of the key measurement objectives and goals
  - 2.1.13.3 Reviewing open corrective action issues
  - 2.1.13.4 Reviewing open items from audits
  - 2.1.13.5 Determining future quality objectives
  - 2.1.13.6 Creating action plans, assigning responsibilities and setting goal dates.
  - 2.1.13.7 Review of the Quality Policy
- 2.1.14 Top Management shall ensure the availability of resources. This includes but are not limited to:
  - 2.1.14.1 Staffing
  - 2.1.14.2 Equipment
  - 2.1.14.3 Facilities
  - 2.1.14.4 Tooling
  - 2.1.14.5 Supplies

## 2.2 Customer Focus

Customers determine the expectations, standards and requirements. XYZ strives to understand, meet and exceed these requirements.

- 2.2.1 **Definition of customers are:**
  - 2.2.1.1 External Customers are product end users.
  - 2.2.1.2 Internal Customers are people in the organization.
  - 2.2.1.3 The public that can be affected by the product.
- 2.2.2 **Expectations include:**
  - 2.2.2.1 Product Safety
  - 2.2.2.2 Product Liability
  - 2.2.2.3 Availability
  - 2.2.2.4 Delivery
  - 2.2.2.5 Packaging and Shipping
  - 2.2.2.6 Conformity
- 2.2.3 **Standards include:**
  - 2.2.3.1 Customer established written requirements
  - 2.2.3.2 Government specifications
  - 2.2.3.3 Regulatory specifications
- 2.2.4 **Requirements include:**
  - 2.2.4.1 Key product characteristics
  - 2.2.4.2 Internal product and process specifications



- 2.2.4.3 Internal process procedures
- 2.2.4.4 Purchase material specifications
- 2.2.4.5 Key supplier selection

## **2.3 Quality Policy**

The quality policy is detailed on the third page of this manual.

- 2.3.1 Top management shall assure that the quality policy is appropriate to XYZ.
- 2.3.2 The quality policy provides a commitment for products to meet the highest quality standards.
- 2.3.3 Continuous improvement is the core of XYZ Quality Policy. In order to improve, 2.1.11 must be met.
- 2.3.4 Review of the quality policy will form part of the Quality Management Review.
- 2.3.5 The Quality policy will be communicated to all employees within XYZ.

## **2.4 Planning**

### **2.4.1 Quality Objectives**

Top Management determines quality objectives. These objectives must meet 2.1.11. These objectives are established at relevant functions and levels within the organization.

### **2.4.2 Quality Management System Planning**

Top Management is responsible for the quality planning throughout the organization. The quality planning focuses on meeting the quality objectives and requirements.

#### **2.4.2.1 Inputs of the Quality planning include:**

- 2.4.2.1.1 Organization strategies
- 2.4.2.1.2 Organization objective
- 2.4.2.1.3 Customer requirements
- 2.4.2.1.4 Regulatory requirements
- 2.4.2.1.5 Product performance data
- 2.4.2.1.6 Process performance data
- 2.4.2.1.7 Lessons learned
- 2.4.2.1.8 Quality Management Review

#### **2.4.2.2 Outputs Needs of Quality planning include:**

- 2.4.2.2.1 Process improvement plans
- 2.4.2.2.2 Necessary skills and knowledge
- 2.4.2.2.3 Necessary resources
- 2.4.2.2.4 Performance metrics
- 2.4.2.2.5 Documentation

#### **2.4.2.3 Documentation of Quality Planning includes:**

- 2.4.2.3.1 Control Charts
- 2.4.2.3.2 Product, Equipment and Process Control (PEP) documentation
- 2.4.2.3.3 Gantt Charts
- 2.4.2.3.4 Travelers
- 2.4.2.3.5 Procedures
- 2.4.2.3.6 Quality System Documentation
- 2.4.2.3.7 Quality Records

2.4.2.4 Top Management shall ensure that changes to the quality management system do not affect the integrity of the quality management system.

## **2.5 Responsibility, Authority and Communication**

### **2.5.1 Responsibility and Authority**

2.5.1.1 The Quality Assurance Manager who reports directly to the company President (See organizational chart within this manual) heads the Quality Assurance Department. The Quality Assurance department is responsible for ensuring the adequacy of the quality system.

- 2.5.1.2 The managers of marketing, manufacturing & production, engineering, facilities, quality and the president form the top management staff. They are the key personnel and are independent of each other. They are jointly responsible for achieving product quality, compliance to the quality system and the operating guidelines within this manual.
- 2.5.1.3 Engineering, Manufacturing and Production, and Quality are jointly responsible for:
  - 2.5.1.3.1 Supporting the Quality Assurance Policy of Continuous Improvement.
  - 2.5.1.3.2 Creation, implementation and review of quality plans and quality objectives.
  - 2.5.1.3.3 Initiation of corrective action to prevent product non-conformance.
  - 2.5.1.3.4 Identification and recording of product quality problems.
  - 2.5.1.3.5 Initiation, recommendation and development of preventive measures and solutions.
  - 2.5.1.3.6 Verification of such preventive measures and solutions.
  - 2.5.1.3.7 Control of further processing and delivery of non-conforming product until appropriate corrective action of the deficiency.
- 2.5.1.4 Operators who are in charge of inspection and testing of products are responsible for:
  - 2.5.1.4.1 Identifying and segregating non-conforming products,
  - 2.5.1.4.2 Monitoring the production process on a scheduled basis, and
  - 2.5.1.4.3 Maintaining SPC charts and following reaction plans for all significant process characteristics and parameters (where appropriate).

**2.5.2 Management Representative**

- 2.5.2.1 The manager of quality assurance is designated by the company as the management representative for the quality system.
- 2.5.2.2 The quality manager is responsible for ensuring that the necessary processes needed for the quality management system are established, implemented, and maintained.
- 2.5.2.3 The quality manager has the necessary authority and responsibility to ensure that the operation of the quality system is in compliance with ISO 9001 requirements.
- 2.5.2.4 The quality manager is responsible for reporting to top management on the performance of the quality management system and any necessary improvements.
- 2.5.2.5** The quality manager is responsible for ensuring the promotion of awareness of customer requirements throughout XYZ.

**2.5.3 Internal Communication**

- 2.5.3.1 Top Management ensures that appropriate communication systems are established within the organization.
- 2.5.3.2 Top Management has defined and implemented an effective and efficient communication with regard to the quality management system.
- 2.5.3.3 Communication parameters of the quality management system include:
  - 2.5.3.3.1 Quality Policy
  - 2.5.3.3.2 Objectives
  - 2.5.3.3.3 Results of objective measurements
  - 2.5.3.3.4 On going improvement projects
  - 2.5.3.3.5 Requirements
  - 2.5.3.3.6 Standards
  - 2.5.3.3.7 Accomplishments
- 2.5.3.4 Methods of communication include:

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- 2.5.3.4.1 Schedule quality reviews
- 2.5.3.4.2 Weekly production meetings
- 2.5.3.4.3 MRB meetings
- 2.5.3.4.4 Performance Boards
- 2.5.3.4.5 Workforce meetings
- 2.5.3.4.6 Gantt charts

## **2.6 Management Review**

### **2.6.1 General**

- 2.6.1.1 Top Management reviews the quality management system every year to ensure its suitability, adequacy and effectiveness.
- 2.6.1.2 The review will include review of the quality objectives, quality policy, and necessary changes and improvement to the quality management system.
- 2.6.1.3 The review scope goes beyond the verification of the quality management system to include processes that extend into the whole organization.
- 2.6.1.4 Records from the review will be maintained.

### **2.6.2 Review Input**

The input to the quality management review shall include:

- 2.6.2.1 Results of Audits
- 2.6.2.2 Customer feedback
- 2.6.2.3 Process performance and product conformity
- 2.6.2.4 Status of preventive and corrective actions
- 2.6.2.5 Review of Quality objectives
- 2.6.2.6 Process Map Review
- 2.6.2.7 Follow-up actions from previous quality management reviews
- 2.6.2.8 Changes that could affect the quality management system
- 2.6.2.9 Recommendations for improvement

### **2.6.3 Review Output**

The output from the quality management review shall include any decisions and actions related to:

- 2.6.3.1 Improvement to the quality management system and its processes
- 2.6.3.2 Improvement of product related to customer requirements
- 2.6.3.3 Resource needs

### **3.0 RESOURCE MANAGEMENT**

#### **3.1 Provision of Resources**

- 3.1.1 Top management shall determine and provide the resources necessary to implement, maintain and improve the quality management system.
- 3.1.2 Top management shall determine and provide resources needed to enhance customer satisfaction by meeting customer requirements.
- 3.1.3 Resources include:
  - 3.1.3.1 People
  - 3.1.3.2 Facilities
  - 3.1.3.3 Suppliers and supplies
  - 3.1.3.4 Infrastructure
  - 3.1.3.5 Work environment
  - 3.1.3.6 Financial
  - 3.1.3.7 Natural resources
  - 3.1.3.8 Equipment

#### **3.2 Human Resources**

- 3.2.1 XYZ shall select personnel based on appropriate education, training, skills and experience to perform work that affects product quality.
- 3.2.2 XYZ encourages the involvement and development of its people by:
  - 3.2.2.1 Ongoing training
  - 3.2.2.2 Establishing responsibilities and authorities
  - 3.2.2.3 Involving them in objective setting and decision making
  - 3.2.2.4 Operator certification
  - 3.2.2.5 Establishing Training needs
- 3.2.3 Competence, Awareness and Training
  - 3.2.3.1 XYZ shall determine the required competence for personnel performing work affecting product quality. Consideration will be given to:
    - 3.2.3.1.1 Future demands
    - 3.2.3.1.2 Cross training
    - 3.2.3.1.3 Audit results
    - 3.2.3.1.4 Statutory and regulatory requirements
  - 3.2.3.2 XYZ shall provide training or take other action to satisfy these needs. The objective is to provide people with skills, knowledge and experience that will improve their competence.
  - 3.2.3.3 XYZ shall evaluate the effectiveness of the actions\training taken.
  - 3.2.3.4 XYZ shall ensure its personnel are aware of the relevance and importance of their activities and how they contribute to the quality objectives.
  - 3.2.3.5 Records of education, training, skills and experience will be maintained.

#### **3.3 Infrastructure**

- 3.3.1 XYZ determines, analyzes, provides and maintains the infrastructure to maintain and continuously improve this quality system and ensure that customer requirements are met. This includes the following:
  - 3.3.1.1 Targeted invested plans for new equipment
  - 3.3.1.2 Product Development Schedule
  - 3.3.1.3 Schedule Preventive Maintenance of equipment
  - 3.3.1.4 Process Capability studies
  - 3.3.1.5 Supplier scores\evaluations

**3.4 Work Environment**

- 3.4.1 XYZ determines, analyses, provides and maintains the work environment to maintain and continuously improve this quality system and ensure that customer requirements are met. This includes the following:
  - 3.4.1.1 Continuous safety training
  - 3.4.1.2 Continuous statutory and regulatory environmental training
  - 3.4.1.3 Safety audits of departments
  - 3.4.1.4 Work environment improvement plans
  - 3.4.1.5 Feedback from employees

## **4.0 PRODUCT REALIZATION**

### **4.1 Planning of Product Realization**

XYZ plans and develops processes for creating and maintaining products. The plans and processes includes:

- 4.1.1 Quality objectives
- 4.1.2 Product requirements
- 4.1.3 Documentation of process and product requirements
- 4.1.4 Operation procedures
- 4.1.5 Determination of necessary processes
- 4.1.6 Product verification
- 4.1.7 Product validation
- 4.1.8 Product and Process monitoring
- 4.1.9 Inspection and Test processes
- 4.1.10 Product acceptance requirements
- 4.1.11 Product reliability requirements
- 4.1.12 Necessary records to provide evidence that product and process meet established requirements.

### **4.2 Customer Related Processes**

#### **4.2.1 Determination of requirements related to the product**

XYZ ensures that all requirements of the product are determined through the contract review system. These include the following:

- 4.2.1.1 Customer specified requirements
- 4.2.1.2 Delivery and Post Delivery requirements
- 4.2.1.3 Requirements not implicitly stated but necessary for intended function and use
- 4.2.1.4 Statutory and regulatory requirements
- 4.2.1.5 Any additional requirements determined by XYZ

#### **4.2.2 Review of requirements related to the product**

XYZ reviews all orders (through contract review system) prior to accepting the order. The review ensures that:

- 4.2.2.1 The product requirements are defined.
- 4.2.2.2 Requirement differences between customer and XYZ are resolved. This includes changes to orders after acceptance of order by XYZ.
- 4.2.2.3 XYZ can meet the requirements.
- 4.2.2.4 Customer orders without requirement documentation are documented and confirmed by XYZ prior to acceptance.
- 4.2.2.5 Accepted changes/amendments to on-going orders are documented and communicated to relevant personnel.
- 4.2.2.6 Documented evidence includes:
  - 4.2.2.6.1 Contract review forms
  - 4.2.2.6.2 Price lists
  - 4.2.2.6.3 Delivery schedules

- 4.2.2.6.4 PEP documentation
- 4.2.2.6.5 Traveler special instructions
- 4.2.2.6.6 HP\Reflection documentation
- 4.2.2.6.7 Special packaging instructions

### 4.2.3 **Customer Communication**

XYZ determines and implements effective arrangements for communicating with customers with relation to the following:

- 4.2.3.1 Product information
- 4.2.3.2 Product inquiries, contracts, order handling, and amendments
- 4.2.3.3 Customer feedback
- 4.2.3.4 Documented evidence includes:
  - 4.2.3.4.1 Catalogs
  - 4.2.3.4.2 Website
  - 4.2.3.4.3 Order confirmation
  - 4.2.3.4.4 Customer visit reports
  - 4.2.3.4.5 Customer complaints
  - 4.2.3.4.6 Goldmine, contact database



## **4.3 Design and Development**

### **4.3.1 Design and Development Planning**

XYZ follows its internal design Control System for the design and development of its products. This system outlines the following:

- 4.3.1.1 The design and development stages
- 4.3.1.2 The review of each stage
- 4.3.1.3 The verification of the product
- 4.3.1.4 The validation of the product
- 4.3.1.5 The responsibilities and authorities
- 4.3.1.6 The methods of managing the interfaces between different groups and ensures effective communication and assignment of responsibility.
- 4.3.1.7 The methods for tracking the output through the design and development progress.

### **4.3.2 Design and Development of Inputs**

Design inputs will be determined for each product design. Records of these inputs will be maintained. Inputs include the following:

- 4.3.2.1 Functional and performance requirements
- 4.3.2.2 Statutory and Regulatory requirements
- 4.3.2.3 Information derived from previous designs
- 4.3.2.4 Other requirements essential for design and development which may include
  - 4.3.2.4.1 Market place needs and expectations
  - 4.3.2.4.2 Industry codes of practice
  - 4.3.2.4.3 Existing process and product data
  - 4.3.2.4.4 Technological development
  - 4.3.2.4.5 Equipment requirements
  - 4.3.2.4.6 Storage, handling, and delivery
  - 4.3.2.4.7 Raw Material performance requirements

### **4.3.3 Design and Development Outputs**

XYZ ensures that the outputs of design and development enables verification against the design inputs and shall be reviewed and approved prior to release. Records of these outputs will be maintained. Design outputs include the following:

- 4.3.3.1 Meeting the input requirements
- 4.3.3.2 Providing appropriate information for purchasing and production
- 4.3.3.3 Developing reference product acceptance criteria
- 4.3.3.4 Specifying the characteristics of the product that are essential for its safe and proper use.

### **4.3.4 Design and Development Review**

Reviews are conducted at each stage of the development cycle. The PEP system determines the representatives and sign-offs required during the review stage. Records of the review are maintained. The review addresses the following issues:

- 4.3.4.1 Evaluate the ability of product to meet the requirements

4.3.4.2 Identify problems and propose necessary actions

**4.3.5 Design and Development Verification**

Verification occurs at the prototype stage prior to the launch stage. Verification ensures that the product is capable of meeting the input requirements and usually is completed prior to submitting product to customer validation. Records of verification are maintained

**4.3.6 Design and Development Validation**

Validation occurs during the prototype stage, after verification and prior to launch. Customer validation assures the product is capable of meeting the requirements for the specified application or intended use. Records of validation are maintained.

**4.3.7 Control of Design and Development Changes**

Design and development changes shall be identified and records maintained. The changes will be reviewed, verified and validated prior to product implementation. The review of the changes shall include evaluation of the effect of the changes on already delivered product.

**4.4 Purchasing**

**4.4.1 Purchasing Process**

The quality and engineering departments shall ensure that all supplies and services procured from suppliers conform to specified requirements.

4.4.1.1 The type and extent of control is dependent upon the effect of the purchased product on the subsequent product realization or the final product.

4.4.1.2 The company shall select suppliers on the basis of their ability to meet and exceed requirements.

4.4.1.3 A controlled list of approved critical material suppliers shall be kept by the company. Critical is defined as material that has been deemed to affect product quality.

4.4.1.4 Records of the results of the evaluations and any necessary actions arising from the evaluation shall be maintained.

**4.4.2 Purchasing Information**

All company purchase orders shall contain data clearly describing the product ordered and where appropriate, the following information:

4.4.2.1 The type, class, style, grade, quality code or other precise identification.

4.4.2.2 The title, document number, and revision level of all relevant technical data or standards.

4.4.2.3 The title number and issue of any quality system standard to be applied.

4.4.2.4 All requirements for approval of the purchased item

4.4.2.5 All requirements for qualification of personnel

4.4.2.6 Quality management system requirements

4.4.2.7 XYZ shall ensure the purchase requirements are adequate and correct prior to placing the order with the supplier.

**4.4.3 Verification of Purchase Products**

XYZ has established and implemented inspection procedures with acceptance criteria for purchase products to assure product meets purchase requirements. This includes the following:

4.4.3.1 Acquisition of objective evidence of the quality of the product from subcontractors (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control )

- 4.4.3.2 Inspection and audit at the source. If inspection is required at source, the verification arrangements and product release information will form part of the purchase order.
- 4.4.3.3 Review of the required documentation
- 4.4.3.4 Inspection of products at delivery

## **4.5 Production and Service Provision**

### **4.5.1 Control of Production and Service**

XYZ management plans and carries out production and service under controlled conditions. This includes but is not limited to:

- 4.5.1.1 Availability of specifications and information that describe the characteristics of the product and process requirements
- 4.5.1.2 Availability of procedures and work instructions for all manufacturing processes and inspections
- 4.5.1.3 The use of suitable equipment including its maintenance and repairs
- 4.5.1.4 The availability of monitoring and measuring devices
- 4.5.1.5 The implementation of measurement and monitoring
- 4.5.1.6 The implementation of release, delivery and post-delivery activities

### **4.5.2 Validation of processes for production and service provisions**

XYZ will validate any process change where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any process where deficiencies become known only after the product has been delivered.

Validation will demonstrate the ability of these processes to achieved planned results. XYZ has established validation processes for appropriate applications using the following:

- 4.5.2.1 Defined criteria for review and approval of the process
- 4.5.2.2 Approval of equipment and qualification of personnel
- 4.5.2.3 Use of specific methods and procedures
- 4.5.2.4 Requirements for records
- 4.5.2.5 Revalidation

### **4.5.3 Identification and Traceability**

All products, including raw material shall be identified with a part number, lot number, or move order number. All final product shall be traceable to all raw material sources for the purposes of investigation. This traceability is documented from receiving to final product and defined in appropriate procedures. According to the level of traceability required by contract, regulatory, or other established requirement, the quality system shall provide for the following:

- 4.5.3.1 identification to be maintained throughout the product life
- 4.5.3.2 all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch
- 4.5.3.3 for a given product, a sequential record of its production to be retrieved
- 4.5.3.4 identification of the product status with regards to monitoring and measurement requirement
- 4.5.3.5 Maintaining the identification of the configuration - via the lot traveler of the product - in order to identify any differences between the actual configuration and the agreed configuration

### 4.5.4 Customer Product

XYZ shall exercise care with customer property while it is under XYZ's control or being used by XYZ. XYZ shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found unsuitable for use, this shall be reported to the customer and records maintained.

**Preservation of Product**

- 4.5.4.1 All product, at whatever stage of production or delivery shall be handled in a manner such as to prevent damage or deterioration to the product. The proper handling method will be documented in the appropriate procedures.
- 4.5.4.2 The receipt and issue of product from stores shall be controlled and undertaken in accordance with written procedures and records shall be maintained.
- 4.5.4.3 Product or critical materials liable to deterioration shall be identified and assessed or tested at defined intervals. Critical materials with limited shelf life shall be identified on receipt to stock or stores at the time it is produced. Final stocked product subject to deterioration shall be identified, and tested in accordance with written procedures.
- 4.5.4.4 Adequate bins, containers, pallets, trays, or bags shall be used to move production in-house.
- 4.5.4.5 The use and configuration of packaging and labeling material shall be defined in written procedures or in accordance with customer requirements. Written procedures shall cover the specific requirements for:
  - 4.5.4.5.1 Cleaning
  - 4.5.4.5.2 Prevention, detection and removal of foreign objects
  - 4.5.4.5.3 Special handling for sensitive products
  - 4.5.4.5.4 Marking and labeling including safety warnings
  - 4.5.4.5.5 Shelf-life control and stock rotation
  - 4.5.4.5.6 Hazardous materials
  - 4.5.4.5.7 Where applicable, accordance with product specifications and/or applicable regulations
- 4.5.4.6 Shipping documentation shall exist to identify product, customer and destination.
- 4.5.4.7 Product shipped from stock shall be processed according to a "First In- First Out" policy.
- 4.5.4.8 The company shall ensure that the accompanying documents for the product are present at delivery as specified in the contract\order and are protected against loss and deterioration.

**4.6 Control of Monitoring and Measuring Devices**

XYZ shall determine the needs for measuring and monitoring processes and determine what devices will be used for such to provide evidence of product conformity to requirements. XYZ has established processes to ensure that monitoring and measurement can be done in such a manner that is consistent with the requirements. Where necessary to ensure valid results, measuring equipment shall be:

- 4.6.1 Calibrated as per the calibration system. Inspection, measuring and test equipment shall be reviewed at specified intervals to assure that it is capable of the accuracy and precision necessary. The review will be traceable to national standards. Where no such standard exist, XYZ will determine the method and standards to be used.
  - 4.6.1.1 Where calibration is performed in-house, documented methods of calibration shall be provided.
  - 4.6.1.2 External Calibration of equipment and standards for in-house calibration, shall be carried out by a suitable, approved house. The test house shall provide a certificate of calibration detailing the standards achieved and traceability to national standards.
  - 4.6.1.3 Frequency of calibration will be dependent upon previous results. Any change to such frequency shall be properly authorized prior to execution.
  - 4.6.1.4 Records of calibration shall be maintained that provide details of results, traceability, and check frequencies.

- 4.6.1.5 The validity of previous inspections and test results shall be assessed and documented when inspection, measuring and test equipment is found to be out of calibration.
  - 4.6.1.5.1 When the assessment indicates that the product may be nonconforming, disposition of the nonconformance shall occur as per section 4.3 Control of non conforming material.
- 4.6.1.6 The calibration system defines the method for recall of measuring devices that require calibration.
- 4.6.2 Adjusted or re-adjusted as necessary.
- 4.6.3 Have the calibration status identified.
  - 4.6.3.1 Status shall be shown on all inspection equipment.
  - 4.6.3.2 A list of all calibrated equipment will be maintained and unique identified with an Asset number.
- 4.6.4 Safeguarded from adjustments that would invalidate the measurement result.
- 4.6.5 Protected from damage and deterioration during handling, maintenance and storage.

## 5.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

### 5.1 General

- 5.1.1 XYZ uses data to improve its products and processes. In order to continuously improve, XYZ plans and implements monitoring, measurement, analysis and improvement processes to assure the following:
  - 5.1.1.1 Demonstration of product conformity.
  - 5.1.1.2 Conformity of the quality management system
  - 5.1.1.3 Continuous improvement of the quality management system.
- 5.1.2 XYZ realizes that measurement data is important for making fact-based decisions. To ensure XYZ performance and customer satisfaction, effective and efficient measurement, collection and validation of data is necessary.
- 5.1.3 Examples of process performance measurables include:
  - 5.1.3.1 Evaluation of products
  - 5.1.3.2 Process capability studies
  - 5.1.3.3 Achievement of project objectives
  - 5.1.3.4 Customer satisfaction
- 5.1.4 A broad range of data is collected and acted upon. This measurement data is converted to information and knowledge that benefits XYZ. Data collection takes two forms and both are used extensively within XYZ.
  - 5.1.4.1 Variable data provides actual numbers which in turn provide for CpK studies, process control, and product measurement data.
  - 5.1.4.2 Attribute data provides go/no-go studies that generates pareto charts and summaries of sample inspection findings.
- 5.1.5 XYZ continually monitors its performance improvement actions and records their implementation. This provides data for future improvements and feedback into management review.
- 5.1.6 Information collected will be current and purpose defined.

### 5.2 Monitoring and Measurement

#### 5.2.1 Customer Satisfaction

XYZ shall monitor information relating to customer perception as to whether the organization has met customer satisfaction. The Customer Satisfaction system documents the methods for obtaining and using this information. Methods include:

- 5.2.1.1 Customer complaints
- 5.2.1.2 Delivery data
- 5.2.1.3 Growth data
- 5.2.1.4 Customer feedback through analysis of internal customer contact and customer feedback

#### 5.2.2 Internal Audit

5.2.2.1 Internal Audits, see procedure (), are conducted at planned intervals to determine whether the quality management system conforms and is effectively implemented and maintained to:

- 5.2.2.1.1 Planned arrangements
- 5.2.2.1.2 Requirements of the ISO Q9001 – 2000 standard
- 5.2.2.1.3 Requirements established by this QA manual

- 5.2.2.2 The audit program is planned and takes into consideration the status, importance, and previous audits of processes and areas.
- 5.2.2.3 The audit program defines the following:
  - 5.2.2.3.1 Criteria
  - 5.2.2.3.2 Scope
  - 5.2.2.3.3 Frequency
  - 5.2.2.3.4 Methods
  - 5.2.2.3.5 Responsibilities
  - 5.2.2.3.6 Planning
  - 5.2.2.3.7 Reporting results
  - 5.2.2.3.8 Maintaining records
- 5.2.2.4 The Management responsible for the audited area shall ensure actions are taken to eliminate deficiencies with undue delay. Follow up activities shall include verification of the actions and reporting of verification results.

5.2.3 **Monitoring and measurement of processes**

- 5.2.3.1 XYZ applies suitable methods for monitoring and measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not met, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.
- 5.2.3.2 Measurements are used for managing and evaluation of daily operations and processes.
- 5.2.3.3 Measurements are used for tracking on-going continuous improvement.
- 5.2.3.4 Examples of measurements of process performance include:
  - 5.2.3.4.1 SPC
  - 5.2.3.4.2 Capability
  - 5.2.3.4.3 Cycle time
  - 5.2.3.4.4 Yield
  - 5.2.3.4.5 Process input characteristics
  - 5.2.3.4.6 Process output characteristics
  - 5.2.3.4.7 Specific process characteristics.
- 5.2.3.5 Evidence of process performance will be maintained.

5.2.4 **Monitoring and Measurement of Product**

- 5.2.4.1 XYZ monitors and measures the characteristic of the product to verify that product requirements have been met. This will be carried out at appropriate stages of product realization in accordance with the planned arrangements.
- 5.2.4.2 Acceptance criteria records will be maintained.
- 5.2.4.3 Records of inspection, including authorizing person of acceptance, will be maintained. This includes:
  - 5.2.4.3.1 Inspection and test reports
  - 5.2.4.3.2 Product acceptance forms
  - 5.2.4.3.3 Certificates of Conformity
- 5.2.4.4 Product release shall not proceed until planned arrangements have been satisfactory completed unless approved by a relevant authority, and where applicable, by the customer



5.2.4.5 When selecting methods for ensuring product conformity, XYZ will consider the following:

- 5.2.4.5.1 The product characteristics
- 5.2.4.5.2 Accuracy and repeatability of the measurement means
- 5.2.4.5.3 Inspector skills needed
- 5.2.4.5.4 Equipment, tools and software required
- 5.2.4.5.5 Location of measurement points within the product realization flow
- 5.2.4.5.6 Customer or Regulatory witness or verification points as necessary.
- 5.2.4.5.7 Third party inspection as necessary
- 5.2.4.5.8 Qualification of people, material, products, processes and the quality management system.

### **5.3 Control of Nonconformity**

XYZ ensures that product that does not meet requirements is identified and controlled to prevent use or delivery of the product. MRB and Control of Non Conforming Material procedure, () defines the responsibilities and authorities for dispositioning the non-conforming material.

- 5.3.1 All non-conforming material is reviewed by the Material Review Board (MRB). MRB review guidelines are defined in the company procedures
- 5.3.2 MRB review is established to provide a means for evaluating discrepant material and initiating corrective action. The board consists of Quality Assurance, Production, and Engineering. The MRB decision authority performed on final manufactured product rests solely with the Quality Assurance Manager or designated representative within the Quality department. Only the President or Chairman can override this decision.
- 5.3.3 MRB reviews are conducted to determine the status of non-conforming material which may include:
  - 5.3.3.1 Rework
  - 5.3.3.2 Acceptable
  - 5.3.3.3 Regraded
  - 5.3.3.4 Scrapped
- 5.3.4 A description of non-conforming product or lots and its condition shall be recorded on the traveler in accordance with written procedures.
- 5.3.5 The decision of the MRB shall be entered on the lot traveler and the material processed accordingly.
- 5.3.6 Established procedures shall take into account process nonconformity that may result in product nonconformity.
- 5.3.7 Parties requiring notification of nonconforming product may include:
  - 5.3.7.1 Subcontractors
  - 5.3.7.2 Internal organizations
  - 5.3.7.3 Customers
  - 5.3.7.4 Distributors and regulatory authorities
- 5.3.8 The company's documented procedures shall define the process for approving personnel making material review decisions.

- 5.3.9 The company shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if (1) the product is produced to customer design, or (2) the nonconformity results in a departure from the contract requirements. Unless otherwise restricted in the contract, company-designed product which is controlled via a customer specification may be dispositioned by the company as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirement.
- 5.3.10 Product dispositioned for regrade requires a change in product identification to preclude the product's original use. Adequate test reports and certifications shall reflect the regrading.
- 5.3.11 Product that has been reworked shall be subject to re-verification to demonstrate conformity to requirements.
- 5.3.12 When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects or potential effects of the nonconformity.

## **5.4 Analysis of Data**

For the purpose of continuous improvement, XYZ shall determine, collect and analyze appropriate data to demonstrate the quality system suitability and effectiveness. The data provides information for:

- 5.4.1 Customer satisfaction
- 5.4.2 Conformity of product requirements
- 5.4.3 Process and Product Characteristics
- 5.4.4 Suppliers

## **5.5 Improvement**

### **5.5.1 Continual Improvement**

Rather than waiting for problems to reveal opportunities for improvement, XYZ management shall continually seek to improve the effectiveness and efficiency of the processes of the organization. The organization has a process in place to identify and manage improvement activities. This process is partially based on results from the following:

- 5.5.1.1 Quality Policy
- 5.5.1.2 Quality Objectives
- 5.5.1.3 Audit Results
- 5.5.1.4 Analysis of Data
- 5.5.1.5 Corrective Action
- 5.5.1.6 Preventive Action
- 5.5.1.7 Management Review

### **5.5.2 Corrective Action**

The XYZ corrective action system, (), is used to eliminate the cause of internal or external nonconformities in order to prevent reoccurrence. Corrective Action shall be appropriate to the level of the nonconformity. The corrective action procedure describes:

- 5.5.2.1 The responsibility, authorities and situations warranting corrective action.
- 5.5.2.2 The identification of corrective action and responsibilities on internal reports or non-conformances or other tracking systems
- 5.5.2.3 The recording of non-conformances and review of such to determine the causes of non-conformance.
- 5.5.2.4 The review of non-conformances which shall include a review of the following as appropriate to determine the necessary corrective action:

- 5.5.2.4.1 processes
- 5.5.2.4.2 reject reports
- 5.5.2.4.3 inspection and/or test reports
- 5.5.2.4.4 customer complaints

5.5.2.5 When corrective action results in changes to existing procedures, such changes shall be approved, recorded and communicated to the appropriate personnel using the company engineering change notice system (ECN).

5.5.2.6 Product recall and authorization by the company president or chairman.

5.5.2.7 The review of Corrective actions to ensure that they have been correctly implemented and are effective.

5.5.2.8 That corrective action will be flowed down to a subcontractor, when it is determined that the subcontractor is responsible for the root cause.

**5.5.3 Preventive Action**

XYZ preventive action system, (), is used to eliminate or prevent the occurrence of potential non-conformities. Preventive action is essential to supporting the company's philosophy of continuous improvement.

5.5.3.1 Management uses appropriate sources of information from business and manufacturing processes, quality audits, quality records and test data, employee suggestions, benchmarking, and others to reduce variation and eliminate potential causes of nonconformities.

5.5.3.2 Preventive action initiation, methods, actions and reviews are documented in accordance with written procedures.

5.5.3.3 Preventive action procedures include the determination of steps needed to deal with any problems requiring preventive action, the application of controls to ensure that actions are effective, and reviewed by management.

## 6.0 SUMMARY OF QA MANUAL CHANGE

[illegible]