

Precision
Sheet
Metal
Fabrication



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Quality Management System Manual

Approvals

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Revision History		System Manual		
REV	PAGE	DESCRIPTION	DATE	REVISED BY
		New Issue	5/24/07	
A	Pg. 4 Pg. 35	Added goals to objectives Removed Market share and Repeat customers from customer satisfaction	12/11/07	
B		Added New ISO standard Q9001-2008	1/15/10	Phil Cardwell
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Business Management System (Reference to Procedures)

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02 Introduction

JIT developed and implemented a quality management system in order to document the company's best business practices, better satisfy, the requirements and expectations of its customers and improve the overall management of the company.
The quality system complies with the International Standards ISO 9001: 2015.

The manual is divided into sections that correlate to the ISO 9001: 2015 standard. Each section begins with a policy statement expressing JIT Manufacturing Inc.'s obligation to implement the basic requirements of the referenced quality management system section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the quality management system, delineates authorities, interrelationships responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the quality management system to ensure compliance to the necessary requirements of the standard. This manual is used internally to guide the company's employees through the various requirements of the JIT standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our quality management system to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the quality management system is maintained and focused on customer satisfaction and continuous improvement.

03 Company Overview:

Founded in 1986, JIT Manufacturing, Inc.'s commitment is to produce precision, high tolerance sheet metal and machined parts for a variety of industries. Located just northeast of Seattle on the I-405 corridor in Woodinville, WA, in the Park 144 Industrial Complex, JIT Manufacturing, Inc. occupies an 28,528 sq. ft. facility dedicated to the manufacture of precision sheet metal and machined parts. Our quality control procedures are designed to meet the demanding requirements of our customers. We use only precision measuring equipment that is calibrated yearly to referenced and traceable National Standards. We guarantee our quality, whether your parts are simple panels or complex assemblies. Through the years we have developed an excellent working relationship with the region's best specialty finishing houses to provide you with the finishes your products require. Our partners can do it all, whether that need is painting, powder coating, plating, silk-screening or anodizing. We are very proud of our superior quality, quick turn around, on-time delivery and of our total commitment to excellence.

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Mission Statement

JIT Manufacturing, Inc.'s mission is to be an outstanding precision sheet metal and machining manufacturer for the Aerospace, Medical and Electronics industries. Everything we do is based upon providing reliability, and service to our customers. We continually strive to improve, and to meet or exceed our commitments for the highest quality products and on-time delivery. Our growth depends on it.

Quality Policy

Management's commitment to continually improve, and policy for quality are reflected in the company's mission statement and in the following quality objectives:

Objectives:

- Consistently meeting or exceeding our customer's expectations.
- Quality will not take second place to quantity.
- Timely delivery of products, to meet our customer's requirements.
- Continuous Improvement of our processes, and our systems thru semi-annual management review.
- Ensuring our personnel are properly trained so they are better able to serve our customers.

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SECTION 4 Context of the organization

4.1 Understanding the organization and its context

JIT'S strategic direction is to grow slowly, organically, based upon providing reliability and service to our customers.

External issues:

- 1) The difficulty in finding qualified, skilled people to join our team.
- 2) Unpredictable price fluctuation in key products and services we use regularly such as, Sheet metal, hardware, and shipping services.
- 3) The limited supply of finishing suppliers (plating, painting, etc.) which makes it difficult to enforce Requirements and commitments.
- 4) Price competition from competitors, which hampers the ability to provide a quality product and Service.

Internal Issues:

- 1) Capacity. We are limited by the space we occupy, the equipment we have, and the people we Have. These limitations hamper our growth.
- 2) Lead-times. Our customers would prefer shorter lead times.
- 3) Training. The need for training is continual and ongoing.

We review the status of our strategic direction, the effect of the external and internal Issues, and consider any changes that occur during the management meetings.

4.2 Needs and expectations of interested parties

Interested Parties:

Owner – The owner is active in the business, so she is aware of what is transpiring. Her needs get an open And full hearing.

Customers – JIT has built the business on customer service. In comparing themselves to their competitors, they feel That they provide the best service in the area.

Employees – The employees want a safe and comfortable place to work, fair compensation and open channels of Communication.

Suppliers – The suppliers want clear, well-described instructions to accompany the work they are given. They Want open channels of communication and mutual respect.

We review the status of our interested parties and their needs and expectations during management review meetings.

4.3 The scope of the quality management system

Located in Woodinville, WA, northeast of Seattle on the I-405 corridor JIT Manufacturing, Inc.'s commitment is to produce, high tolerance precision sheet metal parts for a variety of industries.

Exclusions

Policy

The quality management system shall be relevant to the nature of our organization and products, and to customer and regulatory requirements. For this reason, those requirements of ISO 9001(2015) that do not apply are excluded from the scope of our quality system.

Procedural Policies

The following rules and criteria are used for excluding irrelevant requirements:

1. An ISO 9001:2015 requirement may be excluded only when both of the following conditions are met:
 - The requirement must be within ISO 9001 Clause 8.3, Design and development of products and services.
 - The exclusion may not affect our ability, nor absolve us from the responsibility, to provide product that meet customer and applicable regulatory requirements.
2. The Management team is responsible for identifying those requirements of ISO 9001:2015 that do not apply to our organization or products, and to propose exclusions of such requirements from the scope of the quality system.
3. Any exclusion taken is documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and /or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

Exclusions

1. **Exclusion:** ISO 9001:2015, Section 8.3 Design and/or development, including all subsection.

Justification: JIT Manufacturing does not design or develop products. All principle product characteristics are specified by the customer or their consultants. Our engineering activities are limited to developing methods and means of production, fabrication, or assembly.

4.4 Quality management system and its processes

- 4.4.1 Processes needed for the quality management system are identified in this quality manual and in associated operating procedures, work instructions, and/or training guides. The documentation defines these quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.
- 4.4.2 Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This usually includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.
- 4.4.3 Resources and information
 - 4.4.3.1 The Quality Assurance Manager is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to the senior management. The President is responsible for ensuring the availability of necessary resources and information. Section 7.1 of this quality manual, Resources, explains in more detail how resource requirements are identified and satisfied.
 - 4.4.3.2 The performance of quality system processes is systematically monitored and/or measured. This is to ensure their effectiveness and identify opportunities for improvement.
 - 4.4.3.3 The performance of product realization processes is usually monitored by measuring process parameters and/or product characteristics resulting from the process; and through the program of inspections and tests applied to the product. The performance of processes required for quality management is usually monitored through internal quality audits. Measuring customer satisfaction monitors the overall performance of the quality system.
 - 4.4.3.4 Monitoring and measuring activities are defined in Sections 7.1.5 and 7.1.5.2 of this quality manual and in the corresponding operating procedures.
 - 4.4.3.6 Conformance and continual improvement
 - 4.4.3.7 Quality management system processes are regularly reviewed by Senior management to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and management improvement projects. Section 10.2 and 10.3 of this quality manual and the corresponding operating procedures define how management reviews and corrective/preventive actions are used to ensure conformance and improvement.

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4.4.5.3 Subcontracted processes

4.4.5.4 When processes that affect product conformity are subcontracted, controls are implemented to ensure that processes meet specified requirements. Such controls may include, as appropriate: evaluation and pre-qualification of suppliers; assessment of supplier realization processes and quality system; monitoring of supplier quality performance; requirements for inspection, testing or other records demonstrating product conformity; or containment and verification of the supplied product. Section 8.4 of this quality manual and the corresponding operating procedures define the purchasing control system.

Associated Documents

- Quality Manual: All Sections

5 Leadership

5.1 Leadership and Commitment

Policy

Senior management is ultimately responsible for establishing, implementing, maintaining, and improving the quality system. Management commitment is demonstrated by communicating to the organization the importance of meeting requirements, establishing the quality policy and quality objectives, conducting management reviews of the quality system, and ensuring the availability of necessary resources. Procedural Policies

5.1.1 General

The principal objective of the quality management system is to focus our organization on customer satisfaction. The key to achieving high customer satisfaction is a good understanding of customer requirements and a capability to consistently fulfill these requirements.

5.1.1.2 Determining customer requirements

5.1.1.3 Customer requirements are understood broadly to include all aspects of product offering and associated services, that are relevant to customer satisfaction.

5.1.1.4 Customer requirements are determined and verified through the process of order review. This process is defined in this manual in Section 8.2, Sec. 8.2.2, Determining the requirements for products and services, and in Operating Procedure OP-02-01: Contract review.

Associated Documents

- Operating Procedure OP-01-01, Management Review
- Operating Procedure OP-02-01, Cont.

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5.1.2 Customer Focus

Policy

The principal objective of the quality management system is to focus our organization on the customer in particular, on customer satisfaction. The key to achieving high customer satisfaction is a good understanding of customer requirements and a capability to consistently fulfill these requirements.

5.1.2.1 Determining customer requirements

5.1.2.2 Customer requirements are understood broadly to include all aspects of product offering and associated services, that are relevant to customer satisfaction.

5.1.2.3 Customer requirements are determined and verified through the process of order review. This process is defined in this manual in Section 8, 8.2.2, Determining the requirements for products and services, and 8.2.3 review of the requirements for products and services, and in Operating Procedure OP-02-01: Contract Review

5.1.2.4 Meeting customer requirements

5.1.2.5 Processes and elements of the quality system are designed and implemented specifically to ensure that customer requirements are met. This starts with provision of required training, and adequate infrastructure and suitable work environment (Section 7, Support). Followed by planning and implementation of reliable and effective product realization processes (Section 8, Operation). And finally, activities related to product and process monitoring and verification (Section 7, 7.1.5 Monitoring and measurement resources).

5.1.2.6 Meeting of customer requirements is monitored and/or verified by a variety of methods defined in Section 7, 7.1.5, Monitoring and Measuring resources, and in associated operating procedures. Results of these verification activities are recorded to provide evidence of product conformity, as defined in Section 7.5, Documented Information.

5.1.2.7 Customer satisfaction

Focusing on customer requirements and on meeting those requirements will result in enhancing customer satisfaction. Specific methods for determining customer satisfaction is defined in quality manual Section 9.1.2, *Customer satisfaction* This information is reported and used as described in Section 9.3, Management Review.

Associated Documents

- Operating Procedure OP-01-01, Management Review
- Operating Procedure OP-02-01, Contract Review

5.2 Policy Policy

The JIT Manufacturing, Inc. quality policy, mission, and objectives are reflected in Section 04 on page 4. Top management ensures that the quality policy aligns the organizational goals with a focus on the customers' needs and expectations.

Procedural Policies

5.2.1 Establishing the quality policy

The quality policy, mission and supporting objectives are established by top management and documented in the Quality Management System Manual. JIT Manufacturing, Inc.'s commitment to quality is demonstrated through its extensive training program focused on assisting all employees with understanding their roles and responsibilities in the fulfillment of the JIT Manufacturing's Quality Policy. Management is responsible for insuring that employees are properly supervised and the supervisor or trainer to which they are assigned assumes that responsibility for quality of the product. The main role of the quality policy is to communicate the company's commitment to quality, and to define principle objectives for the quality management system.

The quality policy provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort. The use of the quality policy in setting quality objectives is addressed in this manual in Section 5.2, Policy and 5.2.1 Establishing the Quality Policy.

5.2.2 Communicating the quality policy

5.2.2.1 The quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all employees.

5.2.2.2 Review

5.2.2.3 The quality policy is periodically reviewed within the framework of management reviews of the quality system. This is to ensure its continual relevance and suitability. The process for reviewing the quality policy is defined in Operating Procedure OP-01-01, Management Review.

Associated Documents

- Operating Procedure OP-01-01, Management Review

5.3 Organizational roles, responsibilities and authorities

Policy

Function and their interrelation within the company are defined and communicated. Top management appoints a management team responsible for establishment and maintenance of the quality system, and for reporting to the top management on the performance of the system. Issues regarding the quality system are communicated internally through distribution of pertinent documents, meetings, training, and awareness programs, and management reviews.

Procedural Policies

5.3.1 Responsibility and authority

Departments, groups, and functions within the company, and their interrelations, are defined in the organizational chart and Authority matrix enclosed at the end of this section.

- 5.3.1.1 All departments and functions in the company are responsible for implementing, maintaining, and improving the quality system.

The following specific responsibilities and authorities are assigned:

Top Management:

- Formulates the quality policy
- Provides resources necessary to maintain and improve the quality system
- Conducts management reviews of the quality system

Note: Throughout this manual, the term Top Management refers to a management team including the President, VP, QA, and Managers responsible for operations.

Marketing and Sales:

- Conducts market research to anticipate customer expectations
- Determines customer satisfaction
- Advertises and promotes company's processes and capabilities
- Monitors the performance of competitors
- Provides customer liaison and service
- Handles customer feedback and complaints
- Carries out contract and order reviews
- Provides or obtains training for its personnel
- Contact Customer: Changes in top management, New machines, Catastrophic event, or shop moves etc.

Production Planning

- Schedules production
- Issues production work orders

Production

- Plans production facilities, equipment, and processes
- Develops production processes
- Develops process operator and setup instructions
- Controls and monitors processes
- Conducts in-process inspections
- Applies and maintains in-process product identification
- Maintains production equipment
- Provides or obtains training for its personnel

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Purchasing

- Selects qualified suppliers, subcontractors and conducts quality surveys and audits.
- Prepares and approves purchasing documents
- Monitors and evaluates supplier performance
- Provides or obtains training for its personnel

Receiving/ Shipping

- Receives purchased products
- Applies or verifies product identification for purchased products
- Operates the material storage areas
- Package products
- Ships product to customers
- Provides or obtains training for its personnel
- Operates the finished product storage

Human Resources

- Documents personnel qualification requirements.
- Implements measures to motivate personnel.
- Establishes needs for training programs
- Conducts various company-wide training programs including quality systems
- Maintains a system for collection of training records.
- Provides or obtains training for its personnel

Quality Assurance and Quality Control

- Establishes and maintains the quality management system
- Audits implementation and effectiveness of the quality system
- Identifies opportunities for improvement of the quality system
- Develops quality plans
- Initiates corrective and preventive actions
- Maintains and calibrates measuring and test equipment
- Conducts subcontractor quality surveys and audits
- Performs inspections and testing
- Identifies the need for the use of statistical techniques
- Handles non-conforming products
- Coordinates document control activities
- Maintains or coordinates the maintenance of quality records
- Coordinates collection of quality performance data
- Provides required training for its personnel

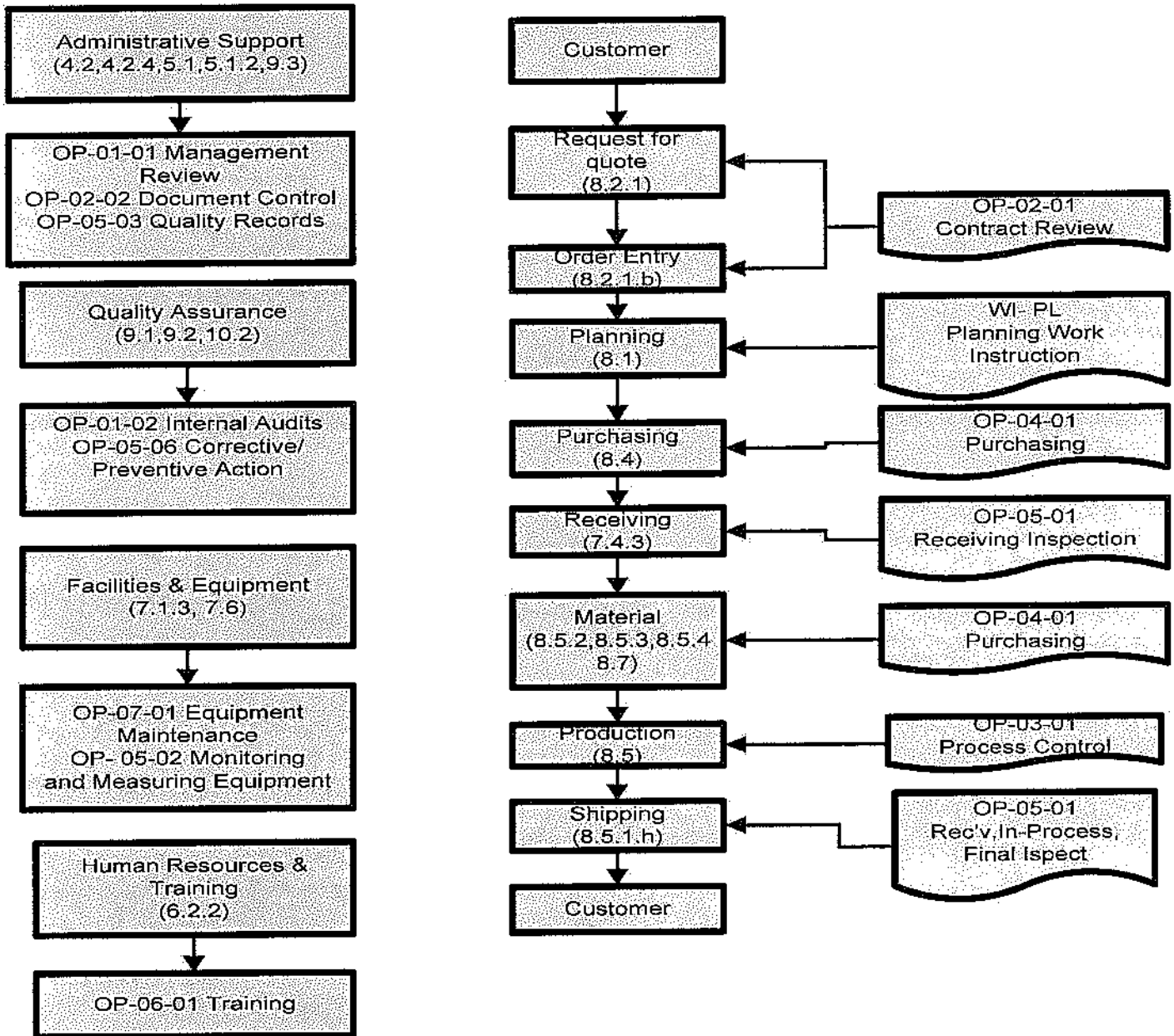
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Business Management System Process Model (ISO 9001-2015,4.1a,4.1b,4.2.2c)

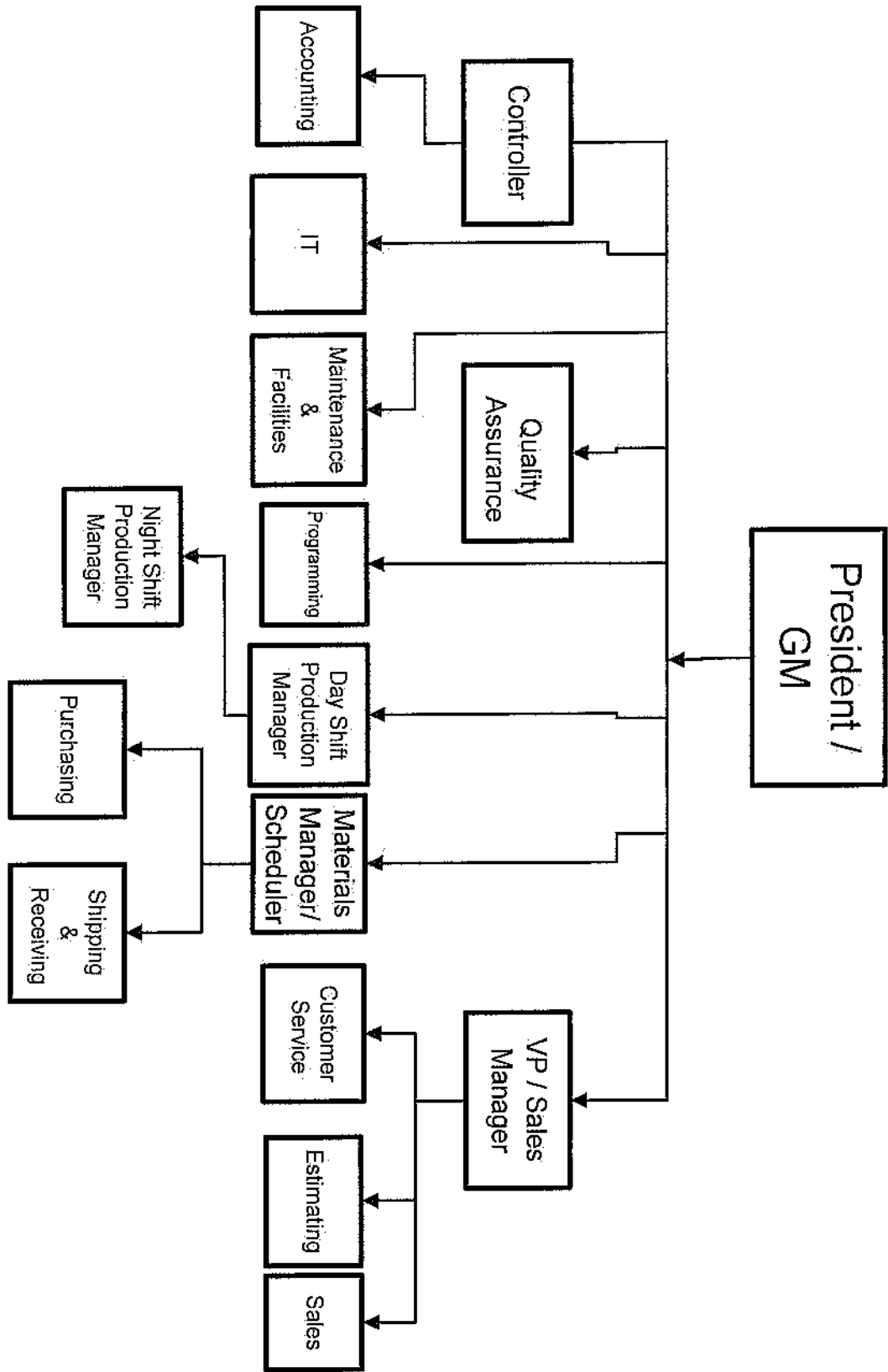
Business Functions
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JIT Organizational Chart



6 Planning

Policy

Quality objectives are established to support and implement the quality policy and continual improvement. Quality planning includes identification and determination of quality system processes; priorities for continual improvement; and resources needed to achieve quality objectives and to maintain the integrity of the quality system during organizational and other changes.

Procedural Policies

6.1 Actions to address risks and opportunities

6.1.1

Each management meeting the external and internal issues will be discussed to evaluate the risks and opportunities as outlined in section 4.1. Each interested party from section 4.2 will have a representative to discuss their needs and expectations.

6.1.2

During each management meeting actions from the discussions on the external issues, internal issues and the needs and expectations of the interested parties may come up. At the following management meeting those actions will be discussed to understand their effectiveness.

6.2 Quality objectives and planning to achieve them

6.2.1

Quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products and processes, and to improve the quality system and quality performance.

Quality objectives define the direction and priorities for continual improvement. Quality objectives are classified into the following three categories:

- **Policy objectives:** These are principal, strategic objectives that apply to the whole organization. They are included in the quality policy, and in addition may be communicated in memoranda from top management. The President authorizes policy objectives.
- **Quality performance objectives:** These objectives set specific, measurable targets for improving operational performance to ensure product conformity and customer satisfaction. They apply to departments and functions having direct responsibility for activities that require improvement. Performance objectives are established, documented, and monitored within the framework of management reviews of the quality system, in accordance with Operating Procedure OP-01-01, Management Review.

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- **Quality system objectives:** These objectives pertain to improvement of quality system processes and performance. Quality system objectives are established, documented, and monitored within the framework of management reviews of the quality system, in accordance with Operating Procedure OP-01-01, Management Review.

6.2.2 Quality system planning

Quality system elements and processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is:

- To achieve the quality policy;
- To ensure and demonstrate our ability to consistently provide product that meets customer and regulatory requirements;
- To ensure high levels of customer satisfaction;
- To facilitate continual improvement; and
- To comply with requirements of ISO 9001:2015 standards.

The output of quality system planning is documented in this quality manual, in associated operating procedures, and in other referenced documents.

6.2.3 Product realization and verification planning

Planning of product realization, verification, and validation processes is addressed in Section 8.1 of this manual. Documents identify and define all elements and processes of the quality system.

6.3 Planning of changes

Changes to the quality system are planned within the framework of management reviews. These changes may be in response to changing circumstances, such as product, process, capacity, or other operational or organizational change; or to improve the effectiveness and efficiency of the quality system.

6.3.1 Continual improvement planning

6.3.2 Improvements of the quality system are planned within the framework of management reviews

The output of this planning is expressed in the form of quality system objectives, as defined above in Clause of this section, and in Operating Procedure OP-01-01, Management Review.

Associated Documents

- Operating Procedure OP-01-01, Management Review

SECTION 7 Support

7.1 Provision of Resources

Policy

Top management is committed to provide adequate resources for the implementation and improvement of the quality system, and for addressing customer satisfaction.

Procedural Policies

7.1.1 General

7.1.1.2 Resources required for implementation and improvement of the quality system, and for addressing customer satisfaction, may include people, suppliers, information, infrastructure, work environment, and financial resources.

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7.1.1.3 Determination of resource requirements

7.1.1.4 Quality Assurance Manager and other management personnel involved in the quality system are responsible for determining resource requirements for implementation and improvement of the system.

7.1.1.5 The Sales Manager is responsible for determining resource requirements for addressing customer satisfaction. This is based on input from other management personnel responsible for activities relevant to particular aspects of customer satisfaction.

7.1.1.6 The principal forum for determining and communicating resource requirements are management reviews of the quality system. Operating Procedure OP-01-01, Management Review, explains this process.

7.1.2. People

7.1.2.1 Top management has the responsibility and authority for provision of resources.

7.1.2.2 Allocation of resources for particular activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space, or equipment, training, procurement decisions, budgets, etc.

7.1.2.3 Allocation of resources may be documented in the quality manual, operational procedures, minutes of meetings, memoranda, or any other form. Approvals of resource allocations may also be communicated verbally.

7.1.2.4 Management review of the quality system is the principal forum for allocation of resources for the operation and improvement of the system. All actions initiated by the review are supported by allocation of specific resources necessary for implementation. Operation Procedure OP-01-01 Management Review, defines this process.

Associated Documents

- Operating Procedure OP-01-01 Management Review

7.1.3 Infrastructure

Policy

Suitable facilities, process equipment, supporting services, and other necessary infrastructure are determined, provided, and maintained, as required to achieve conformity to product requirements.

Procedural Policies

7.1.3.1 Infrastructure and Facilities

7.1.3.2 Planning of new, and/or modification of existing infrastructure and facilities is usually conducted in conjunction with product or process changes; capacity and/or work force expansions; and other such events. Facilities may also be expanded or modified to improve productivity and/or quality, or to improve the work environment.

7.1.3.3 Department Managers are responsible for identifying the need and requirements for new, and/or modification of existing infrastructure and facilities in their departments. Requests for significant changes and/or expansions of facilities are submitted to the top management for review and approval.

7.1.3.4 When relevant, Quality Assurance reviews the proposed facilities or changes to ensure that they enhance the achievement of product conformity and quality.

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7.1.3.5 Supporting services and maintenance of facilities

7.1.3.6 Supporting services required by JIT Manufacturing, Inc. include transportation, communication, and information technology services:

- Transportation services for local delivery are provided by JIT Manufacturing, Inc.. Transportation services for deliveries made outside the local area are purchased from parcel delivery, courier services, or from trucking or other transportation companies or consolidators. Purchasing of these services is managed by the shipping department.
- Communication and facility services are provided by various telephone, wireless, Internet, and intranet services. Information technology (IT) and Maintenance are responsible for administrating and coordinating these services. IT systems are designed and implemented by information technology service personnel, and operated internally.

7.1.3.7 Maintenance of buildings and facilities is performed by the maintenance and facilities department. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, landscaping, and cleaning. Repairs of buildings and other such facilities are contracted as needed. JIT Manufacturing, Inc. maintenance and facilities departments are responsible for coordinating and supervising outside contractors.

7.1.3.8 Process equipment maintenance

7.1.3.9 Key process equipment, machines, hardware, and software are regularly maintained in accordance with maintenance plans specified by equipment manufacturers or JIT Manufacturing, Inc.'s maintenance department. Requirements for the maintenance of production equipment are specified in Operating Procedure OP-07-01, Equipment Maintenance.

Associated Documents

- Operating Procedure OP-07-01 Equipment Maintenance

7.1.3.9.1 Effectiveness of training

7.1.3.9.2 Effectiveness of training is evaluated using the following approaches:

- Follow-up performance evaluation of trained employees;
 - Review of the overall performance in areas relevant to particular training programs;
 - Consideration of competency and training when investigating causes of quality system failures and product or process nonconformities;
 - A global review of all training and awareness programs, conducted within the framework of management reviews of the quality system.
- Operating Procedure OP-06-01, Training and Awareness, and OP-01-01, Management Review, describe more specific methods for evaluating particular categories of training and awareness programs.

7.1.3.9.3 Training records

7.1.3.9.4 Training records are established for all types of training. Records are normally established and maintained by Human Resource department or its designee. Human Resources maintain as-hired qualification records.

Associated Documents

- Operating Procedure OP-01-01, Management Review
- Operating Procedure OP-06-01, Training and Awareness

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7.1.4 Environment for the operation of processes

Policy

JIT Manufacturing, Inc. provides its employees a suitable work environment needed to achieve conformity to product requirements.

Procedural Policies

7.1.4.1 Human factors

7.1.4.2 Human Resources and departmental managers are responsible for ensuring suitable social and psychological conditions in the workplace. This is to include such aspects as interaction and communication between employees, employee harassment, conflict resolution, and so forth. Relevant workplace policies are implemented mainly through training and awareness programs and, where necessary, disciplinary actions.

7.1.4.3 Physical factors

7.1.4.4 Production and Quality Assurance are responsible for identifying those operations where extreme environmental conditions could impact quality performance of personnel and result in product nonconformities. Where appropriate, limits of exposure and/or mitigating measures shall be defined and implemented for these operations.

7.1.4.5 Health and safety

7.1.4.6 Health and safety is independent from the quality management system. It is administrated by Human Resources and Safety Administration, and is documented procedure.

Associated Documents

None

7.1.5 Monitoring, Measuring, resources

Policy

Appropriate measuring and monitoring equipment is maintained and selected to ensure that measurement capability is consistent with the measurement requirements. Equipment used for assuring product conformity is calibrated using calibration standards traceable to the national standard. Calibration status of measuring equipment is identified with calibration labels. Measuring equipment is properly maintained and its placement and use are controlled.

Procedural Policies

7.1.5.1 General

7.1.5.1.1 The scope of the calibration control system extends to the inspection, measuring and test equipment used to demonstrate the conformance of product to specified requirements.

7.1.5.1.2 Identification of measurements to be made and the tolerance of the measured characteristics are documented in product drawings and specifications.

7.1.5.1.3 Gauges, instruments, and other measuring and test equipment are selected on the basis of their capability to provide the necessary accuracy of the measurement. Quality Assurance is responsible for selecting appropriate measuring equipment.

7.1.5.1.4 Where test software or comparative references are used as forms of inspection, they are checked to ensure capability of verifying product acceptability, prior to release for use, and are periodically rechecked at prescribed intervals.

7.1.5.1.2 Calibrations, inspections, measurements, and tests are being carried out in environmental conditions suitable to the product being produced.

7.1.5.1.3 Equipment used for other purposes may be exempted from calibration. Such equipment is labeled with stickers ("Reference Only").

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- 7.1.5.2 Measurement Traceability
- 7.1.5.3 Quality Assurance is responsible for calibration and maintenance of inspection, measuring, and test equipment. A master list of all calibrated measuring equipment is maintained (Form# OP-05-02-2) Type, identification, location, frequency of checks, and calibration recall date.
- 7.1.5.4 Inspection, measuring and testing equipment is identified, calibrated and adjusted at prescribed intervals, or prior to use, against certified equipment traceable to nationally recognized standards. When no standard exist, the basis for calibration is documented.
- 7.1.5.5 The equipment calibration process ensures that environmental conditions are suitable for the tests being performed and that the equipment is properly handled and stored to preserve the accuracy of the calibration and the fitness for use is maintained.
- 7.1.5.6 Records for each calibrated device are maintained describing the results of the verification of that device. When requested by the customer, these records and other technical data on the device are made available for their review.
- 7.1.5.7 Methods are used to safeguard inspection, measuring, and test equipment from adjustments that could invalidate the calibration setting.
- 7.1.5.8 When a device is found to be out of calibration, appropriate action is taken and documented (#05-02-1) to determine the consequence of the potentially invalid measurements.
Product is recalled for re-inspection
- 7.1.5.9 Operating Procedure OP-05-02, Monitoring and Measuring Equipment describes calibration and recall methods.

Associated Documents

Operating Procedure OP-05-02, Monitoring and Measuring Equipment

7.1.6 Organizational Knowledge

Policy

JIT Manufacturing, Inc. has established and maintains documented procedures to identify training needs and provide for training of all personnel performing activities affecting quality. It is the responsibility of each manager to establish the method, parameter, or function and criteria for employee training in concert with the Human Resource Manager or approved designee. The method of training may be formal, informal, or On-the-Job Training (OJT). All formal training programs must be approved by the Human Resource Manager, or approved designee, before implementation.

Procedural Policies

- 7.1.6.1 Human Resources is responsible for fulfilling training needs and awareness programs for company-wide participation, such as: general orientation, company policies and procedures, supervisory skills, and other company-wide systems and issues.
- 7.1.6.2 The Human Resource department or its designee provides classroom instruction that includes but not limited to:
- Basic training programs
 - Quality systems
 - On-the-job training to improve skills

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7.2 COMPETENCE

Departmental managers are responsible for identifying competency requirements and training needs in their departments, and for establishing departmental training programs. Departmental training is primarily focused on increasing the level of skills in operating equipment and processes, conducting inspections and testing, using analytical and statistical techniques, etc.

7.2.1 In addition, training needs are often identified in response to corrective or preventive action requests (forms), as nonconformities may be caused by inadequate training.

7.3 Awareness and training programs

7.3.1 JIT Manufacturing, Inc. provides, or supports, the following categories of company-wide and departmental training and awareness programs:

- **General orientation and quality system awareness training**—Explains how the product is used and how the quality system works to ensure product quality. Provided to all employees.
- **Safety training**—Instructs in safe working practices, use of personal protective equipment, first aid, etc. Provided to all employees during orientation.
- **External training**—External seminars, conferences, and courses. Provided to individual employees on as-needed basis.
- **Skills training in production, and quality control**—departmental training in specific skills. Often provided as on-the-job training.

7.3.2 Operating Procedure OP-06-01, Training and Awareness describes the training and awareness programs provided by JIT Manufacturing, Inc.,

7.4 communication

7.4.1 Internal communication regarding the quality system flows two ways:

The management communicates to the organization 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.

The organization communicates to the management information and data regarding customer needs and expectations, customer satisfaction, quality performance, the effectiveness of the quality system, and opportunities for improvement.

7.4.1.2 The information is communicated through manuals, procedures, instructions, drawings, specifications, quality records, reports, training, on the job instruction, and meetings. Procedures OP-02-02, Document Control; and OP-06-01, Training and Awareness, refer to these activities.

7.4.1.3 Management review meetings have a special role in ensuring proper communication between the top management and the organization. The meeting provides 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. This process is defined in OP-01-01, Management Review.

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7.4.1.4 The Quality Assurance Manager has the overall responsibility for ensuring that all pertinent documents, reports and records are distributed to appropriate departments and functions, and that information and data about quality performance and the effectiveness of the quality system are reported to the top management.

Associated Documents

- Operating Procedure OP-01-01, Management Review
- Operating Procedure OP-02-02, Document Control
- Operating Procedure OP-06-01, Training and A

7.5 Documented Information

Policy

Scope of the quality system documentation is defined. Establishment and revision of documents, and their distribution, are controlled. New documents and revisions are reviewed and approved prior to issue; and are identified with respect to their revision level. Appropriate documents are available at locations where they are used. Obsolete documents are removed from points of use. Documents of external origin are identified, and their distribution is controlled.

Quality records are identified and indexed to facilitate their retrieval, and are stored in a suitable environment to minimize deterioration. Quality records are retained for 10 years or as required by customer or regulatory agency.

7.5.1 General

7.5.1.1 JIT Manufacturing, Inc.'s quality system documentation comprises the following types of documents:

- Quality Systems Manual
- Operating Procedures
- Purchasing Procedures
- Workmanship Standards
- Forms
- Safety Procedures
- Standard Work Instructions
- External Standards and other technical reference material
- Product drawings and specifications
- Production and quality plans

7.5.1.2 The range and detail of documentation is based on the complexity of the work to be done and the skills and training of those personnel assigned to the task.

7.5.1.3 Management ensures the effective implementation of the quality system and its documented procedures, through appropriate training and the establishment of specific controls to monitor and report the results of the system.

7.5.1.4 Purpose, scope, and responsibility for controlling various types of documents are defined in Operating Procedure OP-02-02, Document Control.

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7.5.2 Creating and updating

- 7.5.2.1 New documents and document changes may be initiated by anyone in the organization, but May only be issued by an authorized function: Authorization, control, and issue of documents are defined in procedure OP-02-02, Document Control. All documents are reviewed and approved prior to issue.
- 7.5.2.2 A paper document is officially issued for use when it is approved by authorized function. An electronic document is issued by being placed in a public directory accessible from the network.
- 7.5.2.3 Current issues of documents are distributed to personnel and locations where they are used (electronic) via relevant terminals and computers. Operating Procedure OP-02-02 defines Document Placement.
- 7.5.2.4 Master copies are maintained and available to identify the current revision status and approval.
- 7.5.2.5 Obsolete documents are removed from points of use. Retained masters or copies of obsolete documents are properly marked and are kept separate from active documents. Obsolete electronic documents are removed from the network and, if retained, are stored in directories that are only accessible to authorized personnel.
- 7.5.2.3 Document changes are reviewed and authorized by the same function that issued the original document. Revised documents are distributed with a revision history briefly summarizing the changes. The latest issue and revision of electronic documents are available on the network.
- 7.5.2.4 A process is established to ensure the timely review, distribution and maintenance of all authorized and released engineering drawings, standards, specifications, and changes.

7.5.3 Control of documented information

- 7.5.3.1 Quality records are established and maintained to provide evidence that:
- Materials, components, and production processes meet specified requirements;
 - Records of subcontractor performance,
 - Finished products conform to specifications and,
 - The quality system is operated in accordance with documented procedures and that it is effective.
- 7.5.3.2 Records are established by personnel performing the task, operation, or activity the results of which need to be recorded. Records are dated, and identify the product, person, or event to which they pertain.
- 7.5.3.3 Records are indexed and grouped to facilitate their retrieval and distribution. Cabinets, binders, computer disks, and other storage media containing records are clearly labeled with identification of their content.
- 7.5.3.4 Records are normally stored by the same department that initially established them. Records are stored in clean, dry areas, and electronic records are regularly backed up. Quality records and documents may not be stored in private desk drawers, unauthorized computer drives, or other obscure locations that are not generally known.
- 7.5.3.5 Quality records retention is determined on the basis of the event to which the record pertains, or in accordance with contractual or regulatory requirements.
- 7.5.3.6 Maintenance, storage

Section 8 Support

8.1 Operational planning and Control

Policy

Planning of product realization processes includes determination of requirements and quality objectives for products; development of required processes and process documentation; and establishment of product verification and validation programs. The plan also defines requirements for records necessary to demonstrate process and product conformity.

8.1.1 Product requirements and quality objective

8.1.1.1 Product requirements and quality objectives for product are defined and communicated in contract documents, drawings, and specifications, internal and external standards, product samples, workmanship standards, and applicable legal and regulatory requirements. Sales and Estimating review these specifications before acceptance of the contract and Quality Assurance conducts a review prior to commencement of production, as instructed in Operating Procedure OP-02-01, Contract Review.

8.1.1.2 Section 8.2 of this manual explains in more detail how customer and product requirements are determined and reviewed.

8.1.1.3 Product realization planning

8.1.1.4 Product realization planning includes, as applicable:

- Definition and evaluation of manufacturing operations and processes,
- Development of adequate processes,
- Identification of special processes and consideration of associated risks and consequences,
- Establishment and implementation of appropriate process control measures,
- Development of instructions and training for process operators,
- Requirements for records necessary to demonstrate process conformity, and
- Product realization plans are established in collaboration between Planning and Quality Assurance. The plans are defined in various types of production documents, such as production work orders, operator instructions, and process specifications.

8.1.1.5 Operational procedures related to Section 8 Operations, explain how outputs of product realization planning are used.

8.1.1.6 Product verification and validation planning

8.1.1.7 Product verification and validation plans determine the inspection and testing program for a product, and for materials and components in corporate into the product. This includes:

- Identification of inspection and testing points,
- Inspection and testing scope, frequency, and method,
- Acceptance criteria, and
- Requirements for records necessary to demonstrate product conformity.

8.1.1.8 Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection explain how outputs of product verification and validation planning are used.

Associated Documents

- Operating Procedure OP-03-01, Process Control
- Operating Procedure OP-02-01, Contract Review

Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection

8.2 Requirements for products and services

Policy

Product requirements are determined, including customer requirements and legal, regulatory, and other necessary requirements that may not be specified by customers. Orders are reviewed to ensure that product and order requirements are defined and can be met, and to resolve any incomplete or conflicting requirements. Verbal orders are confirmed before acceptance. Order amendments and changes are likewise reviewed and are communicated to all relevant functions. Order reviews are recorded.

Arrangements for communication with customers relating to product information, order handling, and customer feedback and complaints are defined and implemented. Where appropriate, operating procedures and instructions for these activities are established and implemented

8.2.1 Customer Communication

8.2.1.1 Sales department is responsible for developing the content and format for company's brochures, Internet site, and other forms of promotional and process information.

8.2.1.2 Designated personnel from Sales, Engineering, and Materials are authorized to communicate with customers regarding product information. The appropriate managers are responsible for designating these personnel, and for supporting them with training.

8.2.2 Determining the requirements for products and services.

Product requirements are determined and reviewed with regard to requirements specified by the customer. This review may include input from Sales, production, engineering, and/or quality assurance and includes other relevant product requirements not specified by the customer.

8.2.3 Review of requirements for products and services

The company's capacity and capability to meet all applicable requirements Operating Procedure OP-02-01, Contract Review provides instructions on how to carry out this review.

8.2.3.1 The Sales department is responsible for receiving customer inquires and requests for quotes. Materials, Planning, and Quality Assurance review purchase orders for customer products.

8.2.3.2 handling of order amendments is controlled to the same extent as the handling of initial orders. Amendments are reviewed to verify that the new or modified requirements can be met, and a conformation of acceptance is sent back to the customer.

8.2.3.4 Operating Procedure OP-02-01, Contract Review provides instructions for how to handle inquiries, orders, and amendments for products.

8.2.1.7 Customer feedback and complaints

8.2.1.8 Sales is responsible for receiving and processing customer feedback and complaints.

Feedback and complaints are communicated to the relevant functions within and outside the organization. Materials, Sales, or Quality Assurance decide how to respond to the customer and, when appropriate, what corrective or preventive actions should be implemented.

Procedural Policies

8.2.4 Change to requirements for products for products and services.

- 8.2.4.1 Any incomplete or conflicting requirements are resolved with the customer before acceptance of the order if possible.
- 8.2.4.2 Verbal orders
- 8.2.4.3 Verbal orders are confirmed before acceptance. This may be by repeating the order requirements back to the customer, or by sending a confirming fax or e-mail.
- 8.2.4.4 Amendments
- 8.2.4.5 Change orders are received and reviewed by the same functions that are responsible for the review of the initial orders. Change orders are communicated to all functions within the organization that may be affected by the change of customer requirements. Operating Procedure OP-02-01, Contract Review provides instructions on how to process change orders.

8.4 Control of externally provided processes, products and services

8.4.1 General

JIT Manufacturing, Inc. evaluates its suppliers and purchases only from those that can satisfy quality requirements except where a supplier is specified by the customer. Quality performance of suppliers is monitored and evaluated. Purchasing documents clearly and completely describe ordered products, including quality requirements. Purchasing documents are reviewed and approved prior to release. Purchased products are verified before they are used or shipped.

Procedural Policies

8.4.2 Type and extent of control

- 8.4.2.1 Materials and components purchased for use in the final product are verified to ensure conformance to specifications. Verifications include product identity, visual inspection, physical measurements, and where applicable, verification that all requested documentation is included.
- 8.4.2.2 Verification of purchased product may also include:
 - Obtaining objective evidence from the suppliers (i.e., certificate of conformity, test/inspection reports, statistical and/or process records),
 - Inspection/audit at supplier's premises,
 - Review of required documentation,
 - Delegation of verification to the supplier (requirements for delegation are defined and a list of delegation is maintained).

8.4.3 Information for external providers

- *The title or other identification of applicable issues of specifications, drawings, process requirements, and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment, and personnel;*
- *Requirements for test, examination, inspection and related instructions for acceptance,*
- *Requirements for test specimens (production method, number, storage conditions, etc.) for inspection, investigation or auditing;*
- *Requirement regarding notification to JIT Manufacturing, Inc. of nonconforming product and arrangements for JIT Manufacturing, Inc. approval of such nonconforming material,*
- *Right of access by the purchaser, their customer and regulatory authorities to all facilities involved in the order and all applicable records;*
- *A flow-down of all applicable purchasing requirements to sub-tier suppliers including key characteristic;*

8.5 Production and Service provision

Policy

Product and process information and appropriate work instructions are established and are communicated to relevant personnel. Operations and production processes are monitored and controlled, and are validated where appropriate. Machines and equipment used in production and for monitoring and measurement activities are maintained. Methods for product release and delivery are defined.

Materials, components, subassemblies, and finished products are identified. When required, traceability of materials and processes are recorded and maintained. Inspection and test status of product is identified to ensure that only product that has passed the required inspections is used, installed, or dispatched.

Customer supplied products are normally controlled in the same manner as are purchased products.

Customer owned tools, equipment, software, or other property are marked to indicate ownership. Loss, damage, or unsuitability of a customer's product is recorded and reported to the customer.

Appropriate handling, storage, and preservation methods are implemented to prevent product damage or deterioration. Receipt and dispatch to and from storage areas are controlled. The condition of products in stock is regularly assessed. Product packaging materials and methods are specified and controlled.

Procedural Policies

8.5.1 Control of production and service provision

The scope of this policy includes the planning, analyzing, and processing of all production processes.

Product quality is assured through the planning and implementation of processes designed to be carried out under controlled conditions. The following items may be considered in planning and implementing all processes as required by customer contract:

- Availability of information that describes the characteristics of the product;
- Preparation, maintenance and monitoring of manufacturing plans that contain clear, concise and complete instructions for work affecting product quality;
- Identification of in-process verification points when adequate verification cannot be performed at a later stage of realization;
- Special processes;
- Equipment and tool requirements to ensure quality and repeatability;
- Equipment maintenance and repairs for ensuring on-going process capability;
- Any applicable safety, environmental, and regulatory requirements;
- Availability, use, and implementation of monitoring and measuring equipment;
- Monitoring and control of process parameters and product characteristics, and recording of key characteristics when required by purchase order/contract;
- Accountability for all product during manufacture (e.g., parts quantities, split orders, nonconformities), and evidence that all manufacturing and inspection operations have been completed in sequence, as planned, or as otherwise documented and authorized;
- Utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality;
- Criteria for workmanship is clearly stated (e.g., written standards, representative samples, or illustrations).

8.5.1.2 Validation

8.5.1.3 Special processes are validated and controlled by applicable methods, such as destructive or non-destructive testing of product samples, equipment, and/or personnel qualification, and work instructions or process specifications.

8.5.1.4 Manufacturing and Quality Assurance are responsible for selecting and implementing appropriate process validation and control measures for each special process. At a minimum, all special processes are documented in process specifications.

8.5.2 Identification and Traceability

8.5.2.1 When required by contracts, laws and regulations, or voluntary standards traceability is implemented to the extent specified. Traceability may also be implemented for internal reasons, to facilitate corrective action.

8.5.2.2 As required, traceability may apply to materials, components parts, production processes, environmental conditions, inspection and testing, and personnel responsible for processing and verification of products. The scope of traceability is documented in the customer purchase order, product specifications or the production work order. When the level of traceability is specified by customer contract, regulatory, or other established requirements, quality system procedures are initiated as required to ensure:

- Identification maintained throughout the product life;
- Products manufactured from the same batch of raw material or from the same production batch is traced, including the destination (delivery, scrap) of all products of the same batch;
- The identification of assembly components and those of the next higher assembly are traced;
- Access and retrieval of sequential production record for a given product (manufacture, assembly, inspection).

8.5.2.3 Activities related to establishment and maintenance of traceability are described in Operating Procedure OP-03-02, Product Identification and Traceability.

8.5.2.4 Product Identification

8.5.2.5 Purchased products may be identified with either unique numbers, codes, or names. The identification is the same as, or is cross-referenced with, the designations used in drawings, specifications, bill of materials, parts lists, purchase orders, etc. Purchased products are identified by marking, labeling, or tagging the products or their packaging, or by identification of the area where the products are held.

8.5.2.6 During all stages of production, products are identified by work orders, or other documents that accompany them through the production cycle. Labels or tags, or the containers in which they are held may also identify parts and components.

- 8.5.2.7 Final products are identified by their part number, which is labeled or marked on the products and/or is printed on the primary product packaging as required by customer.
- 8.5.2.8 Operating Procedure OP-03-02, Product Identification and Traceability defines activities related to identification of products. Additional relevant procedures are; OP-05-01, Receiving, In-Process, and Final Inspection and OP-02-03, Control of Non-conforming Product

- 8.5.2.9 Special process records are established and maintained as appropriate. Depending on the control measures implemented, these records may include process qualification and validation reports, equipment qualification and maintenance records, first article inspections and tests, operator qualification and training records, etc

8.5.3 Property belonging to customers or external providers

8.5.3.1 Receiving

8.5.3.2 Customer supplied products are received and inspected following the same procedures that applies to purchased products, i.e., Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection. In the event the supplied products fail inspection, or are not suitable for any other reason, the customer is notified.

8.5.3.3 Marking, storage, and handling

8.5.3.4 Marking, storage, handling, and preservation of customer supplied product follows the same procedures that apply to purchased products. Operating Procedure OP-03-02, Product Identification and Traceability.

8.5.3.5 Customer owned tooling and returnable packaging are permanently marked so that ownership of each item is visually apparent.

8.5.3.6 Special requirements

8.5.3.7 When specified in a contract, special handling instructions from customers will take precedence over the company's standard procedures.

8.5.3.8 Loss or damage

8.5.3.9 Customers are contacted in the event of loss, damage, deterioration, or unsuitability of their products.

8.5.4 Preservation

8.5.4.1 Product handling and preservation

8.5.4.2 Production is responsible for product handling and preservation; and in particular for ensuring that containers holding products and constituent parts are suitable, and are in good condition, that equipment used for internal transportation of products is well maintained and is properly operated, and that products are adequately protected during production and storage.

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8.5.4.3 Storage

8.5.4.4 Storage, staging, and holding areas are controlled by the department that brings in new stock or uses the area. Only products that are properly identified and that have passed required inspections are authorized to enter and leave the storage areas. Stockrooms are periodically inspected to assess the condition of stock.

8.5.4.5 When special storage conditions are specified (for example, temperature or humidity), products are stored in special rooms, boxes, or containers where specified conditions can be continuously maintained. These special conditions are monitored to ensure that they are maintained without interruption and that the product is not compromised.

8.5.4.6 Products with limited shelf life are identified with expiration dates. These perishable products are also rotated in the stockroom to ensure that product is not compromised

8.5.5 Post-delivery activities

8.5.1.1 Validation of Processes

8.5.1.2 Servicing provided by JIT Manufacturing, Inc. is limited to product rework or repair under the direction of the customer. Rework or Repair is generally accomplished at JIT Manufacturing, Inc.'s facility but may be performed at the customer's facility under their direction.

8.5.6 Control of changes

8.5.6.1 Control of production process changes

- Personnel approving changes to production processes are identified and authorized.
- Changes requiring customer approval are identified in accordance with contractual requirements prior to making the change.
- Changes affecting processes, production equipment, tools and programs are documented and assessed to ensure that the desired affect has been achieved without affecting product quality.

8.5.6.2 Control of production Equipment, tools, and Numerical Control (NC) Machine Programs:

- Production equipment, tools, and programs are validated prior to use, maintained and inspected periodically for preservation and condition. Validation prior to production use includes verification of the first article produced to the design or specification.
- Production equipment and tooling is checked periodically for condition during storage.

8.5.6.3 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities:

- Work may be transferred to an outside facility on a temporary basis due to work overload, special processes or if equipment or processes are temporarily inoperable due to circumstances beyond our control.
- The Quality Assurance Manager and General Manager, prior to work being performed, must approve such outside facilities.
- Outside facilities may be required to submit such documentation as Certificates of Conformance, First Article, and/or Inspection Reports, and will be subject to receiving Inspection to validate work performed.

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8.6 Release of products and services

8.6.1 Monitoring and Measurement of Product

8.6.1.2 Product verification

- 8.6.1.3 Product verification is defined in various types of documents, such as customer purchase orders, product drawings, specifications, production work orders, purchasing documents and inspection and testing procedures.
- 8.6.1.4 When identified by contract or product drawing, key characteristics are monitored and controlled.
- 8.6.1.5 The use of sampling inspection is described in Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection, and when required is approved by the customer.
- 8.6.1.6 All material or product is held until it has been verified to requirements specified in the purchase order, plans, or procedures. Incoming product is not released or processed until it has been inspected and verified as conforming to specified requirements.

8.7 Control of nonconforming outputs

8.7.1 Product verification

- 8.7.1.1 Product verification is defined in various types of documents, such as customer purchase orders, product drawings, specifications, production work orders, purchasing documents and inspection and testing procedures.
- 8.7.1.2 When identified by contract or product drawing, key characteristics are monitored and controlled.
- 8.7.1.3 The use of sampling inspection is described in Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection, and when required is approved by the customer.
- 8.7.1.4 All material or product is held until it has been verified to requirements specified in the purchase order, plans, or procedures. Incoming product is not released or processed until it has been inspected and verified as conforming to specified requirements.
- 8.7.1.5 Verification of purchased product: All purchased products are subjected to QA inspection and verification. Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection, defines incoming inspections.
- 8.7.1.6 In-process inspections: In-process inspections may be in the form of first article inspections, operator or QA inspections. The focus is on defect prevention rather than detection. In process inspection activities are described in Operating Procedure OP-05-01, Receiving, In-Process and Final Inspection.
- 8.7.1.7 Final inspection: Finished products are subjected to the final QA inspection. Final inspection includes verification that all specified receiving and in-process inspections have been carried out satisfactorily. The remaining inspections and tests are performed as necessary to complete the evidence of product conformity. Only products that pass the final inspection can be shipped. Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection
- 8.7.1.8 Inspection, test and monitoring records
- 8.7.1.9 Results of inspections and tests are recorded. Instructions for establishing records for specific types of inspections are defined in Operating Procedures OP-05-01, Receiving, In-Process, and Final Inspection and OP-05-03, Quality Records.

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8.7.2.1 Product release

8.7.2.2 Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Only personnel performing final product inspections and tests have the authority to release products. The identity of the person authorizing product release is recorded. Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection describes methods for product release.

8.7.2.3 Inspection documentation

8.7.2.4 Inspection and testing processes are documented for each specific activity throughout manufacturing. This includes incoming, in-process, and final inspection and describes as applicable:

- The criteria for acceptance and rejection;
- Inspection and testing operations;
- Documents recording inspection results;
- Identification of production inspection instruments.

8.7.2.5 When required by customer contract, test records are to be maintained showing actual test data in accordance with specification or acceptance test plan requirements.

8.7.2.6 When product qualification is specified as a contract requirement, quality records contain data as evidence that the product meets the defined requirements.

8.7.2.7 First Article Inspection

8.7.2.8 When it is a specified requirement, first article inspections are performed for first production units. Detailed data showing complete results of first article inspections is recorded and maintained. Operating Procedure OP-05-04, First Article Inspection further describes methods for First Article Inspection.

8.7.9.9 First article inspection is updated to include production process changes or changes in configuration.

Associated Documents

- Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection
- Operating Procedure OP-01-02, Internal Quality Audits
- Operating Procedure OP-05-04, First Article Inspection
- Operating Procedure OP-05-03, Quality Records

8.7.2 When a process or product nonconformity is discovered that may affect product already delivered, customers are notified and instructed what to do with the product. In situations where the nonconformity may affect reliability or safety, customer are notified immediately of the nonconformity and disposition instructions.

A Return of Material Authorization (RMA) number must be issued for discrepant products returned to JIT Manufacturing, Inc. before receipt.

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Associated Documents

- Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection
- Operating Procedure OP-02-03, Control of Nonconforming Product

SECTION 9

9 Performance Evaluation

9.1 Monitoring, Measuring, analysis and evaluation

Policy

Customer satisfaction is the principal objective of the quality system, and the level of customer satisfaction is most important measure of the effectiveness of the system. Customer satisfaction is measured by collecting and analyzing direct customer feedback, and by measuring secondary indicators of customer satisfaction. Customer satisfaction data is used by management to identify opportunities and priorities for improvement. All activities and areas relevant to the quality system are audited at least once a year. Audits are scheduled on the basis of the status and importance of the activity. Internal auditors are independent of those having direct responsibility for the audited activity. Identified nonconforming conditions are brought to the attention of the responsible managers and corrective actions are implemented in response to audit findings.

Quality system processes are monitored to ensure that they achieve planned results. Relevant product characteristics are measured through inspections, tests, and other product verification activities, as specified in control plans. Evidence of product conformity is recorded. Products are released for delivery only after all specified activities have been satisfactorily completed and verified

Measurement and monitoring activities required to assure product conformity, and to achieve improvement, are planned and defined. When applicable, statistical techniques are used for analyzing measurement data.

Procedural Policies

9.1.1 General

9.1.1.1 To assure and verify product conformity, measurement, and monitoring activities are defined in engineering specifications and drawings, production work orders, inspection and test procedures, and operating procedures. These activities are further defined in this manual in Section 7.1.5, Monitoring and measuring of resources, and in several operating procedures referenced at the end of this section.

9.1.1.2 The effectiveness of the quality system is monitored by internal audits and by measuring quality performance and customer satisfaction. Results of these activities are reported to the top management and are used to identify opportunities for improvement. Activities related to internal audits and to measuring customer satisfaction and quality performance are further defined in this manual in Section 9.2.

9.1.1.3 Statistical techniques

9.1.1.4 According to the nature of the product and depending on the criticality and the specified requirements, statistical techniques may be used to support:

- process control
 - selection and inspection of key characteristics;
 - process capability measurements;
- inspection-matching sampling rate to the criticality of the product and to the process capability;

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Associated Documents

- Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection
- Operating Procedure OP-01-02, Internal Audits

Procedural Policies

9.1.2 Customer Satisfaction

Sales is responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analyzing the pertinent information. Information and data pertaining to customer satisfaction are collected from several sources specifically, these are:

- Customer feedback,
- Awards and recognitions,
- Product returns

9.1.2.1 Customer feedback and surveys

9.1.2.2 Customer complaints, expressions of satisfaction, and other unsolicited customer feedback are collected and processed by the Sales department. The resulting data is periodically analyzed by the President, and is presented and discussed at the management review meetings.

9.1.2.3 Awards and Recognitions

9.1.2.4 JIT Manufacturing, Inc. encourages customer to rate its performance, and seeks to participate in customer's award and recognition programs. These recognitions and ratings are considered as an important input into determining customer satisfaction.

9.1.2.5 Product return

9.1.2.6 Information about the rate of product returns is extracted from production control, and quality nonconformance records. Results and trends are reported and analyzed at management review meetings

9.1.3 Analysis and evaluation

Policy

JIT Manufacturing, Inc. collects, compiles, and analyzes information and data required for evaluating the suitability and effectiveness of the management system and for identifying opportunities for improvement.

Procedural Policies

9.1.3.1 General

9.1.3.2 Data and information recorded in quality records are compiled and analyzed periodically to determine trends in the performance and effectiveness of the management system and to identify opportunities for improvement.

9.1.3.3 Quality Assurance is responsible for coordinating these activities, and for reporting conclusions and trends to top management. Summaries of these activities are done within the framework of management reviews of the quality system, in accordance with Operating Procedure OP-01-01, Management Review.

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9.1.3.4 The following categories of information and data are recorded, compiled and analyzed:

Characteristics of processes and products:

- Process failures- causes of production/process non-conformances are coded and recorded in quality problem reports and analyzed for trends.
- Conformity to product and customer requirements:
- Product failures- reject and scrap is recorded in quality reports and analyzed for trends.
- On-time delivery performance-recorded in delivery performance reports and evaluated for trends by Materials.

9.1.3.5 Suppliers:

- Supplier performance, quality, on time delivery, customer service, and pricing is recorded in subcontractor quality performance records and evaluated for trends by purchasing and quality assurance.

9.1.3.6 Customer satisfaction and dissatisfaction:

- Customer satisfaction levels- recorded and evaluated for trends by top management.
- Customer complaints-recorded and evaluated for trends by Sales and Materials.

9.1.3.7 Quality Management System:

- Effectiveness of quality management system-recorded in internal audit reports (OP-01-02) and evaluated for trends by top management.

Associated Documents

- Operating Procedure OP-01-01, Management Review
- Operating Procedure OP-04-02, Supplier and Subcontractor Assessment
- Operating Procedure OP-01-02, Internal Quality Audits

9.2 Internal Audit

9.2.1 Planning and scheduling

9.2.2 The Quality Assurance Manager (or a designee) establishes an internal audit plan and schedule in accordance with Operating Procedure OP-01-02, Internal Quality Audits. Internal quality audits are carried out at least once a year to verify and assess the effectiveness of the management system, and to determine whether the operation of the management system conforms to the management system requirements. Selected activities may be audited more frequently, depending on their importance and quality performance history.

9.2.2. Audit team and preparation for audit

9.2.2.4 Only personnel independent of the audited activities are assigned to conduct internal audits. Auditors prepare by reviewing applicable standards and procedures, analyzing quality records, and establishing questionnaires, checklists, or process flowcharts. Selection of auditors and preparation for the audit is described in Operating Procedure OP-01-02, Internal Quality Audits

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9.2.5 Conducting the audit

9.2.6 Conducting the audit, auditors seek objective evidence indicating whether the audited activities comply with the requirements of the documented management system, ISO 9001:2015, and whether the management system is effective. The evidence is collected by observing activities, interviewing personnel, and examining records

9.2.7 Nonconforming conditions are recorded on the Internal Discrepancy form (E-2) defined by Operating Procedure OP-02-03, Control of Nonconforming Product. Audits are conducted in a way that minimizes disruption of the audited activities.

9.2.8 Corrective action and follow up

9.2.9 When nonconforming conditions are identified, the manager responsible for the affected area or activity is requested to propose and implement a corrective action. Implementation and effectiveness of the action are verified by a follow-up audit. The corrective/preventive action request form is used for monitoring and recording the implementation of the corrective actions. When the auditing cycle is completed, all nonconformity reports established during the cycle are compiled and analyzed, and are presented at the management meeting.

9.3 Management Review

Policy

Top management conducts periodic reviews of the quality system. The review evaluates the suitability and effectiveness of the system, identifies opportunities for improvement, and considers the need for changes to the quality policy and quality objectives. Results of the review are documented.

Procedural Policies

9.3.1 General

9.3.1.1 The purpose of management reviews is to:

- Ensure the suitability, adequacy and effectiveness of the quality system;
- Consider changes to the quality management system and to the quality policy and quality objectives;
- Identify opportunities for improvement of the quality system, processes and product

9.3.1.2 Management reviews are chaired by the President and are attended by VP's, manager's (or their designee) representing Quality Assurance, Sales, Production, Purchasing, and Human Resources.

9.3.1.3 Management reviews are conducted at least once a year. More frequent reviews are scheduled in periods when organizational or product changes, or other circumstances require increased attention and input from top management.

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9.3.2 Management Review input

9.3.2.1 Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

- Results of audits;
- Customer feedback and complaints;
- Process performance and product conformance data;
- Status of preventive and corrective actions;
- Changes that could effect the quality management system;
- Follow-up actions from earlier management reviews; and
- Recommendations for improvement.

9.3.2.2 Section 9.1.3 of this manual, Analysis and evaluation, and Operating Procedure OP-01-01, Management Review, define the scope, and method of presentation, of the input information and data.

9.3.3 Management Review output

9.3.3.1 Management reviews are concluded with actions related to improvement of the quality management system, and improvement of processes and products to better meet customer requirements. The review also identifies resource needs to implement these actions.

9.3.3.2 Results of management reviews are documented in minutes of the review meeting. The minutes include improvement actions, and assign responsibilities and allocate resources for implementation of these actions.

Associated Documents

Operating Procedure OP-01-01, Management

10 Improvement

10.1 General

10.1.1 JIT Manufacturing, Inc. employs a continual improvement philosophy throughout the entire organization. The improvement effort is driven by goals defined in the quality policy and quality objectives. Improvement opportunities are identified by analyzing quality performance data and information.

10.1.2 Improvement projects are defined and implemented through the system of corrective and preventive actions and management review actions.

10.1.3 Causes of identified nonconformities are investigated and, where appropriate, corrective actions are implemented to ensure that nonconformities do not recur. Preventive actions are implemented to eliminate the causes of potential nonconformities. Corrective and preventive actions taken are recorded and are followed up to ensure that they have been properly implemented and that they are effective.

10.2 Nonconforming and corrective action Policy

Non-conforming product is identified, documented, evaluated, and prevented from being used or shipped. Repaired or reworked products are re-inspected. Appropriate actions are taken when product nonconformity is identified after delivery. When appropriate, corrective and preventive actions are implemented to prevent reoccurrence of identified nonconformities.

Procedural Policies

10.2.1 Identification and documentation

JIT Manufacturing, Inc. identifies, documents, and controls all product nonconformities (including those returned from the customer). Product nonconformity records are invaluable for tracking performance and trends, and for identifying areas where corrective or preventive actions should be implemented.

10.2.2 Nonconforming products are documented using a Discrepancy Report. The form describes the nonconformity, documents the disposition decision, and records cause of the nonconformity. Their use and processing are described in Operating Procedure OP-02-03, Control of Nonconforming Product.

10.2.3 To prevent nonconforming products from being used or shipped, the products are tagged with a discrepancy report and are segregated.

10.2.4 Nonconformity review and disposition

10.2.5 Nonconforming product or material is subject to evaluation and disposition prior to any further use or processing. Documented procedures define the responsibility for review and disposition. Dispositions may include:

- Rework to meet specified requirements;
- Accept-as-is with concessions;
- Re-graded for alternate applications;
- Rejected or scrapped.

10.2.6 Dispositions for repair, accept-as-is, or re-grade require customer authorization.

10.2.7 The evaluation and disposition of nonconforming material is conducted by authorized personnel to determine the potential for rework or repair of the item.

10.2.8 QA inspectors, and production supervisors may make the disposition decision for nonconforming product when it is obvious that the product must be scrapped or when it can be reworked by a simple process without affecting its quality or appearance. In all other cases, Quality Assurance together with Production, and when required, a customer representative are responsible for making disposition decisions.

10.2.9 Material shipped under a customer-authorized concession is properly identified and recorded per customer requirements.

10.2.9.1 Products dispositioned to scrap are conspicuously and permanently marked until physically rendered useless for the original production purpose.

10.2.9.2 Procedures for nonconformity review, making the disposition decision, and for recording these activities are provided in Operating Procedure OP-02-03, Control of Nonconforming Product.

10.2.9.3 Re-verification of repaired or reworked product

10.2.9.4 Repaired or reworked products are re-inspected in accordance with applicable procedures and instructions. Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection.

10.2.9.5 Product returns and recalls

10.2.9.6 When product nonconformity is detected by the customer after delivery or use, the customer is instructed to return the product to JIT.

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- 10.2.9.7 When a process or product nonconformity is discovered that may affect product already delivered, customers are notified and instructed what to do with the product. In situations where the nonconformity may affect reliability or safety, customer are notified immediately of the nonconformity and disposition instructions.
- 10.2.9.8 A Return of Material Authorization (RMA) number must be issued for discrepant products returned to JIT Manufacturing, Inc. before receipt.

Associated Documents

- Operating Procedure OP-05-01, Receiving, In-Process, and Final Inspection
- Operating Procedure OP-02-03, Control of Nonconforming Product

10.3 Continual Improvement

10.3.1 Opportunities for Improvement

10.3.2 Opportunities and priorities for improvement are identified by comparing present quality performance to objectives defined in the quality policy and quality objectives.

10.3.3 Quality performance is determined by analyzing information about customer satisfaction, records of product and process nonconformity, results of internal audits, and other data and information relevant to quality performance. Section 8.4, Analysis of Data, defines the scope and system for collecting and analyzing such information.

10.3.4 Quality performance is evaluated by management reviews of the quality system. Where quality performance falls short of a defined objective, the management review identifies specific improvement actions to reach the objective. When a quality objective is reached, the management review may set a new, higher objective in this area and specify new improvement actions for reaching it.

10.3.5 In addition to management reviews, managers and area supervisors are encouraged to identify improvement opportunities, based on daily feedback from operations and other activities. Employees are also encouraged to come forward with ideas for improving products, processes, systems, productivity, and working environment. These improvement opportunities are evaluated and prioritized by Quality Assurance and, where appropriate, are implemented through the system of corrective and preventive actions.

10.3.6 Implementation of improvement projects

10.3.7 Improvement projects are usually implemented through management review actions and through corrective and preventive actions. Where appropriate, improvement projects may be also initiated by management directives, such as policy statements, announcements, memoranda, etc..

10.3.8 Preventive versus corrective action

10.3.9 Preventive actions are requested and implemented when there are trends in decreasing quality performance and/or effectiveness of the quality system that create a risk for a potential non-conformity. Corrective actions are used when an actual nonconformity is identified.

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