ED FAGAN INC.
QUALITY SYSTEM MANUAL

APPROVED BY:
Ed Fagan
President
ED FAGAN INC.
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Quality System Manual

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Quality System Manual

1. PURPOSE AND SCOPE

1.1 Purpose

This Quality System Manual is issued to assure that Ed Fagan, Inc. (EFI) has a uniform standard for the implementation of our quality management system that meets the requirements of our customers, of ISO 9001-2008, and of applicable laws and regulatory requirements.

The Manual establishes the need to consistently provide product that meets customer requirements, and, through the effective application of the quality management system, to implement processes for continual improvement.

1.2 Scope

This Quality System Manual, and the quality management system described herein apply to Ed Fagan, Inc., with facilities located in Franklin Lakes, NJ and Los Alamitos, CA engaged in the distribution of specialty metal alloys.

All persons employed by Ed Fagan, Inc. who manage, perform, and/or verify work affecting the quality of products provided by Ed Fagan, Inc. to our customers are expected to understand and comply with all applicable portions of the Quality System Manual and the quality management system. The quality management system has not been designed to control administrative and support functions (e.g., Management Information Systems, Finance, Accounting, etc.) except in so far as activities of those functions may affect the quality of work performed and products provided.

Customer-specific and part-specific requirements are incorporated into the EFI quality management system, and flowed down to working-level procedures and/or work instructions.

1.3 Exclusions

The quality management system and the Quality System Manual address all of the requirements of ISO 9001-2008 with the exception of Design and Service. These activities are not conducted by Ed Fagan, Inc.

1.4 Confidentiality Statement:

This Quality System Manual is intended for the exclusive use of EFI employees and customers. It is made available with the express understanding that it will not be copied or passed to a third party without the permission of Ed Fagan, Inc.. All information contained in this document is confidential and proprietary to Ed Fagan, Inc.. No license expressed or implied under any patent, copyright or trade secret right is granted or implied by the conveyance of this document. No part of this document may be reproduced, transmitted, transcribed, stored in a retrieval system, translated into any other language or computer language, in any form or by any means electronic, mechanical, magnetic, optical, chemical, manual or otherwise without the prior written permission of Ed Fagan, Inc.. This document is not intended as a warranty, either express or implied, nor is it intended to constitute a term or condition of any business transaction with EFI.

2.0 PRODUCTS, SERVICES AND CAPABILITIES

2.1 General:

Ed Fagan, Inc. has been in business as a distributor of specialty metal alloys for over 30 years serving, among others, the electronic, aerospace, refractory, and telecommunication industries. Operations are conducted in two (2) modern service center locations: a 28,000 square feet facility in Franklin Lakes, NJ with approximately 13 employees, and a 10,000 square feet facility in Los Alamitos, CA with approximately 6 employees. Custom fabrication services provided to customers include shearing, cutting, slitting, and centerless grinding.

3.0 REVISION HISTORY

3.1 Original

3.2 Revised: 12/01/03, 05/16/05, 5/25/06, 7/20/09, 01/13/10

3.3 Latest Revision Details:

3.3.1 Revised reference in Section 4.0 to Quality System Interactions in Sections 9.0 and 10.0 and added Section 11.0 flow chart

4.0 QUALITY MANAGEMENT SYSTEM

The quality management system is the collective, organized network of procedures, activities, resources, and events that are planned and conducted for the effective operation of Ed Fagan, Inc.'s processes to ensure that products and services satisfy customer needs and expectations. The quality management system and the processes contained within are defined to enable processes, activities and requirements to be clearly understood, managed and improved.

The Ed Fagan, Inc. Quality System can be visualized as two major interacting processes, each involving interacting sub-processes. The *Product Realization Process* is designed to produce and deliver product that meets requirements (see section 9.0 – Product Realization Process). The *Quality Management System Process* is intended to continually improve customer satisfaction and organizational effectiveness (see section 10.0 – Quality Management System Process). Each of these major processes follows a repeating cycle of planning, implementation, monitoring, and improvement.

Reference:
Quality System Manual Sections 9.0 and 10.0 and 11.0

4.1 General Requirements

The Quality management System is established, documented, implemented, maintained and continually improved in accordance with the needs and objectives of EFI and to meet the requirements with ANSI/ISO/ASQ Q9001 - 2000.

The quality management system:

a) Identifies the processes needed for the quality management system and their application throughout the organization;
b) Determines the sequence and interaction of these processes;
c) Determines criteria and methods required to ensure the effective operation and control of these processes;
d) Ensures the availability of information necessary to support the operation and monitoring of these processes;
e) Measures, monitors and analyses these processes;
f) Implements actions necessary to achieve planned results and continual improvement;
g) Ensures that any outsourced processes that affect product or service conformity with requirements are controlled.

Reference:
QSP 202.1 Quality System

4.2 Documentation Requirements

4.2.1 General

The quality management system is documented at six levels:

Level 0.1	Quality Policy
Level 0.2	Quality Objectives
Level 1	Quality System Manual (this document)
Level 2	Quality System Procedures (QSPs), including those required by ANSI/ISO/ASQ 9001-2000 as well as those required for the effective planning, operation and control of EFI's processes and activities
Level 3	Work Instructions
Level 4	Forms
Level 5	Records required by ISO 9001-2008 and/or for effective operation and control

The extent of the quality management system documentation is dependent on:

a) The type of activity;
b) The complexity and interaction of processes;
c) The competence of personnel performing the activities.

Reference:
QSP 202.1 Quality System

4.2.2 Quality System Manual

This Quality System Manual includes:

a) The scope of the quality management system, including details of, and justification for any exclusions to the elements of ISO 9001-2008;
b) References to documented procedures established for the quality management system;
c) A description of the interaction of the processes of the quality management system.

Reference:
QSP 202.1 Quality System; Quality System Manual Sections 9.0, 10.0 and 11.0

4.2.3 Control of documents

Documents required for the quality management system are controlled. Documented procedures are established to:

a) Approve documents for adequacy prior to issue;
b) Review, update as necessary and re-approve documents;
c) Identify the current revision status of documents;
d) Ensure that relevant versions of applicable documents are available at points of use;
e) Ensure that documents remain legible, readily identifiable and retrievable;
f) Ensure that documents of external origin are identified and their distribution controlled;
g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Reference:
QSP 205.1 Control of Quality System Manual, Procedures, Instructions and Forms
QSP 205.2 Control of External Quality System Documents

4.2.4 Control of quality records

Records are established and maintained to provide evidence of conformance to requirements and of effective operation of the quality management system.

Records are legible, identifiable and retrievable.

Documented procedures are established for the control of records, including identification, storage, protection, retrieval, retention time and disposition.

Reference:
QSP 216.1 Quality Records

5.0 MANAGEMENT RESPONSIBILITIES

Management realizes that leadership, commitment and involvement at all levels are essential for developing and maintaining an effective and efficient quality management system that achieves benefits for the company as well as for its customers, employees, and business partners.

Top management establishes policies and strategic objectives consistent with the purposes of the organization and supports all efforts needed to comply with the quality management system, to implement the Quality Policy, and to achieve Quality Objectives.

5.1 Management Commitment

Top management is committed to the development and improvement of the quality management system. This commitment is evidenced by:

a) Communicating the importance of meeting customer as well as regulatory and legal requirements;
b) Establishing the quality policy and quality objectives;
c) Conducting management reviews;
d) Ensuring the availability of necessary resources.

Reference:
QSP 201.1 Management Responsibility

5.2 Customer Focus

Top management ensures that customer needs and expectations are determined, converted into requirements and fulfilled with the aim of achieving and enhancing customer satisfaction.

Reference:
QSP 201.1 Management Responsibility
QSP 202.1 Quality System
QSP 203.1 Customer-Related Processes

5.3 Quality Policy

Top Management approves and issues the Quality Policy, ensuring that it:

a) Is appropriate to the organization's purpose;
b) Includes a commitment to meeting requirements and to continually improving effectiveness;
c) Provides a framework for establishing and reviewing quality objectives;
d) Is communicated and understood within the organization;
e) Is reviewed for continuing suitability, and updated if appropriate.

ED FAGAN INC.

Quality Policy

We will continually train our employees to the industry's dynamic service and product quality required so as to meet customer expectations and specifications.

Real time adjustment and continual improvement requires:

- continual updating and understanding of supplier capabilities and compliance history;
- timely upgrading of our in-house processing capability to match changing product demand levels and parameters;
- and to base these changes on customers' immediate needs and projected requirements, as well as statutory and regulatory requirements.

Ed Fagan, President

Reference:
QSP 201.1 Management Responsibility

5.4 Planning

5.4.1 Quality objectives

Top management ensures that quality objectives, including any needed to meet product and service requirements, are established at relevant functions and levels of the organization. Quality objectives are measurable and consistent with the quality policy.

Reference:
QSP 201.1 Management Responsibility

5.4.2 Quality planning

Top management ensures that all resources needed to achieve quality objectives are identified and planned. Quality planning includes:

a) The processes of the quality management system;
b) The resources needed;
c) Continual improvement of the quality management system.

The planning process ensures that change is conducted in a controlled manner and that the integrity of the quality management system is maintained during this change.

The output of planning activities is documented.

Reference:
QSP 201.1 Management Responsibility
QSP 202.1 Quality System

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and authority

Top management ensures that responsibilities and authorities are defined and communicated within the organization.

In general, all managers and supervisors share the responsibility for establishing and/or attaining relevant quality levels and objectives. All employees are responsible for performing assigned job functions or task assignments in accordance with established procedures and guidelines such that defined standards of quality are achieved.

Reference:
QSP 201.1 Management Responsibility
QSP 202.1 Quality System

5.5.2 Management Representative

Top management formally designates a Quality Management Representative for the quality management system. The Quality Management Representative has the authority and responsibility to:

a) Ensure the processes of the quality management system are established, implemented and maintained;
b) Report to top management on the performance of the quality management system, including needs for improvement;
c) Ensure the promotion of awareness of customer requirements throughout the organization.

Reference:
QSP 201.1 Management Responsibility

5.5.3 Internal communication

Top management ensures communication between various levels and functions regarding the processes of the quality management system and their effectiveness.

Reference:
QSP 201.1 Management Responsibility

5.6 Management Review

5.6.1 General

Top management reviews the quality management system quarterly to:

a) Evaluate the need for any changes to the quality management system, Quality Policy and/or Quality Objectives in order to ensure continuing suitability, adequacy and effectiveness;
b) Assess opportunities for improvement.

Records for management review are maintained.

Reference:
QSP 201.1 Management Responsibility

5.6.2 Management review input

Inputs to management review include:
a) Results of audits;
b) Customer feedback;
c) Process performance and product conformance;
d) Status of preventive and corrective actions;
e) Follow-up actions from earlier management review;
f) Changes that could affect the quality management system;
g) Opportunities for improvement.

Reference:
QSP 201.1 Management Responsibility

5.6.3 Management review output

Outputs from the management review include decisions and actions related to:

a) Improvement of the quality management system and its processes;
b) Improvement of product related to customer requirements;
c) Resource needs.

Reference:
QSP 201.1 Management Responsibility

6.0 RESOURCE MANAGEMENT

Management ensures that resources essential to the implementation and achievement of the organization's strategies and objectives, as well as those needed to meet the requirements of the quality management system, are identified and made available. These may include people, suppliers, information, infrastructure, work environment and financial resources.

6.1 Provisions of Resources

Management determines and provides in a timely manner the resources needed to:

a) Implement, maintain and improve the processes of the quality management system, and continually improve its effectiveness;
b) Enhance customer satisfaction.

Reference:
QSP 201.1 Management Responsibility

6.2 Human Resources

6.2.1. General

Managers and supervisors are responsible for ensuring that all personnel assigned to work affecting quality are competent on the basis of applicable education, training, skill and experience.

Reference:
QSP 218.1 Training

6.2.2. Competence, awareness and training

Documented procedures are established and maintained for:

a) Identifying competency requirements for personnel performing activities affecting quality;
b) Taking appropriate actions to satisfy these requirements (such as providing or obtaining training, education, certification, etc.);
c) Evaluating the effectiveness of the training or other actions taken;
d) Ensuring that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality criteria and objectives;
e) Maintaining appropriate records of education, training, skills, experience and qualifications.

Reference:
QSP 218.1 Training

6.3 Infrastructure

The infrastructure needed to achieve conformity of product is identified, provided and maintained, including, as applicable:

a) Workspace and associated facilities and utilities;
b) Process equipment, hardware and software;
c) Supporting services, including transport and communication.

Reference:
QSP 201.1 Management Responsibility
QSP 209.1 Control of Warehouse Operations

6.4 Work Environment

The work environment needed to achieve conformity of product is identified and managed.

Reference:
QSP 209.1 Control of Warehouse Operations

7.0 PRODUCT REALIZATION

The quality management system is utilized to analyze customer requirements, define the processes that contribute to the achievement of product that is acceptable to the customer, and to keep these processes under control.

7.1 Planning of Product Realization

Planning of the realization processes is consistent with other requirements of the quality management system, and is documented in a manner appropriate for the specific product, processes, and/or customer requirements.

In planning the processes for realization of product, the following are determined, as appropriate:

a) Quality objectives and requirements for the product, project or contract;
b) Processes, documentation and resources specific to the product;
c) Verification, validation, monitoring, inspection and test activities, and criteria for acceptability;
d) Records necessary to provide confidence of conformity of the processes and resulting product.

Reference:
QSP 202.1 Quality System
QSP 209.1 Control of Warehouse Operations
QSP 216 .1Quality Records

7.2 Customer - Related Processes

7.2.1 Determination of requirements related to the product

To ensure complete understanding of product requirements, the following are determined:

a) Product requirements specified by the customer, including the requirements for delivery and post-delivery activities, if any;
b) Product requirements not specified by the customer but necessary for intended or specified use, where known;
c) Statutory and regulatory requirements related to the product;
d) Any additional requirements determined to be applicable.

Reference:
QSP 203.1 Customer-Related Processes

7.2.2 Review of product requirements

Requirements are reviewed prior to the commitment to supply a product to the customer (e.g. submission of a tender, acceptance of a contract or order) to ensure that:

a) Product requirements are defined;
b) Contract or order requirements differing from those previously expressed (e.g. in a tender, quotation or previous order) are resolved;
c) The organization has the ability to meet defined requirements.

The results of the review and any subsequent follow-up are recorded.

If the customer provides no documented statement of requirement, the customer requirements are confirmed before acceptance;

If product requirements are changed, relevant documentation is amended and relevant personnel are made aware of the changed requirements.

Reference:
QSP 203.1 Customer-Related Processes

7.2.3 Customer communication

Arrangements for communication with customers are identified and implemented for matters relating to:

a) Product information;
b) Enquiries, contracts or order handling, including amendments;
c) Customer feedback, including customer complaints.

Reference:
QSP 203.1 Customer-Related Processes
QSP 209.1 Control of Warehouse Operations
QSP 214.1 Corrective and Preventive Action

7.3 Design and Development

Ed Fagan, Inc. produces products in accordance with customer-specified requirements. EFI does not provide design and development services and design and development are excluded from the Quality System.

7.4 Purchasing

7.4.1 Purchasing process

Purchasing processes are controlled to ensure purchased product conforms to requirements. The type and extent of control is dependent upon the effect on subsequent realization processes and their output.

Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements. Criteria for selection and periodic evaluation are defined.

The results of evaluations and any follow-up actions are recorded.

Reference:
QSP 206.1 Purchasing

7.4.2 Purchasing information

Purchasing documents contain information describing the product to be purchased, including where appropriate:

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

The adequacy of specified purchase requirements are ensured prior to their communication to the supplier.

Reference:
QSP 206.1 Purchasing

7.4.3 Verification of purchased product

Activities necessary for verification of purchased product are established and implemented.

If EFI or its customer proposes to perform verification activities at the supplier's premises, the intended arrangements and method of product release are stated in the purchasing information.

Reference:
QSP 206.1 Purchasing
QSP 209.1 Control of Warehouse Operations

7.5 Production and Service Provision

7.5.1 Control of production and provision of services

Production and provision of services are planned and carried out under controlled conditions, including, as applicable:

a) The availability of information that specifies the characteristics of the product or service;
b) Where necessary, the availability of work instructions;
c) The use of suitable equipment;
d) The availability and use of measuring and monitoring devices;
e) The implementation of measuring and monitoring activities;
f) The implementation of defined processes for release, delivery and post-delivery activities, if any.

Reference:
QSP 202.1 Quality System
QSP 203.1 Customer-Related Processes
QSP 209.1 Control of Warehouse Operations
QSP 211.1 Inspection, Measuring and Test Equipment

7.5.2 Validation of processes for production and provision of services

Any processes where the resulting output cannot be verified by subsequent monitoring or measurement, including those processes where deficiencies become apparent only after the product or service is delivered or in use, are validated to demonstrate the ability to achieve planned results.

Validation arrangements include, as applicable:
a) Defined criteria for review and approval of the processes;
b) Approval of equipment;
c) Qualification of personnel;
d) Use of specific methods and procedures;
e) Requirements for records;
f) Revalidation.

Reference:
There are currently no processes at EFI where the resulting output cannot be verified by subsequent monitoring or measurement. If any such processes are implemented, management will ensure that procedures are developed and implemented in accordance with the above requirements.

7.5.3 Identification and traceability

Product is identified by suitable means throughout product realization, and status of product is identified with respect to measurement and monitoring requirements.

Where traceability is a requirement, the unique identification of product is controlled and recorded.

Reference:

QSP 209.1 Control of Warehouse Operations

7.5.4 Customer property

Care is exercised with customer property while it is EFI's control or being used by EFI. Customer property provided for use or incorporation into the product is identified, verified, protected and maintained. Should any customer property become lost, damaged or otherwise unsuitable for use, it is recorded and reported to the customer.

Reference:
QSP 209.1 Control of Warehouse Operations

7.5.5 Preservation of product

Identification, handling, packaging, storage, and protection processes preserve the conformity of product and constituent parts of product during internal processing and delivery to the intended destination.

Reference:
QSP 209.1 Control of Warehouse Operations

7.6 Control of Measuring and Monitoring Devices

The measurements to be made and the measuring and monitoring devices required to assure the conformity of product to specified requirements are determined. Processes are established to ensure that monitoring and measurement are carried out in a manner that is consistent with the monitoring and measuring requirements.

Where applicable, measuring and monitoring devices are:

a) Calibrated or verified at specified intervals against standards traceable to international or national standards; where no such standard exist, the basis used for calibration or verification is recorded;
b) Adjusted or readjusted as necessary;
c) Identified so as to allow determination of the calibration status;
d) Safeguarded from adjustments that would invalidate the measurements taken;
e) Protected from damage and deterioration during handling, maintenance and storage.

Records of calibration and verification are maintained.

If equipment is found not to conform to requirements, the validity of previous measuring results are assessed and recorded, and appropriate action is taken on the equipment and on any affected product.

If used in the monitoring and/or measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed prior to initial use and reconfirmed as necessary.

Reference:
QSP 211.1 Inspection, Measuring and Test Equipment

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

The quality management system provides for the measurement and evaluation of products, services, processes, customer satisfaction, and other activities and results related to monitoring and improving organizational performance. Relevant data is, collected, analyzed, summarized and communicated in order to initiate corrective and preventive action as necessary and as a basis for continual improvement.

8.1 General

Monitoring, measurement, analysis, and improvement processes and applicable methods, including statistical techniques, are planned and implemented to:

a) Demonstrate conformity of product;
b) Ensure conformity of the quality management system;
c) Continually improve the effectiveness of the quality management system.

Reference:
QSP 209.1 Control of Warehouse Operations
QSP 217.1 Internal Quality Audits
QSP 214.1 Corrective and Preventive Action

8.2 Measurement and Monitoring

8.2.1 Customer satisfaction

Methods are determined for obtaining and using information that monitors customer perception as to whether the organization has met customer requirements.

Reference:
QSP 201.1 Management Responsibility
QSP 214.1 Corrective and Preventive Action

8.2.2 Internal audit

Periodic internal audits are conducted to determine if the quality management system:

a) Conforms to the requirements of ISO 9001-2008 as well as to the requirements established by the organization;
b) Is effectively implemented and maintained.

The audit program is planned, taking into consideration the status and importance of the activities and areas to be audited as well as the results of previous audits. Audit criteria, scope, frequency and methodologies are defined. Selection of auditors and conduct of audits ensure the objectivity and impartiality of the audit. Auditors do not audit their own work.

Documented procedures define the responsibilities and requirements for:

a) Selection of auditors;
b) Conducting audits;
c) Reporting audit results to management;
d) Maintaining audit records.

Management responsible for the area being audited ensures that timely corrective actions are taken to eliminate nonconformities found during the audit and their causes. Follow-up actions include the verification of the implementation of corrective action, and the reporting of verification results.

Reference:
QSP 217.1 Internal Quality Audits
QSP 214.1 Corrective and Preventive Action

8.2.3 Monitoring and measurement of processes

Suitable methods are applied to monitor and/or measure processes in order to demonstrate their ability to achieve planned results.

When planned results are not achieved, correction and corrective action are taken to assure conformity of product.

Reference:
QSP 209.1 Control of Warehouse Operations

8.2.4 Measurement and Monitoring of Product

At appropriate stages of the product realization process, the characteristics of the product are monitored and measured to verify that requirements for the product have been met.

Records are maintained to demonstrate evidence of conformity. Records indicate the person(s)authorizing release of product.

Product release and/or service delivery does not proceed until all specified activities have been satisfactory completed, unless otherwise approved by relevant authority, and, if required, by the customer.

Reference:
QSP 209.1 Control of Warehouse Operations

8.3 Control of Nonconforming Product

Documented procedures define the controls and related responsibilities and authorities for dealing with nonconforming product.

Nonconforming product is identified and controlled to prevent unintended use or delivery.

Nonconforming product may be:

a) Reworked or otherwise corrected to eliminate the detected nonconformity;
b) Authorized for use, release, repair, or acceptance under concession by a relevant authority, including, if required, by the customer, end user, regulatory agency, or other body,
c) Precluded from its original intended use or application, and used in an application for which the relevant characteristics are conforming.

Product that is reworked, repaired, or otherwise corrected is re-verified to demonstrate conformity.

If nonconforming product is detected after delivery or use has started, appropriate actions are taken depending upon the effects or potential effects of the nonconformity.

Reference:
QSP 209.1 Control of Warehouse Operations

8.4 Analysis of Data

Appropriate data, generated as a result of monitoring and measurement as well as from other sources, is collected and analyzed to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made.

Analysis of data provides information pertaining to:

a) Customer satisfaction;
b) Conformity to product requirements;
c) Characteristics and trends of processes, products, and opportunities for preventive action;
d) Suppliers.

Reference:
QSP 201.1 Management Responsibility
QSP 214.1 Corrective and Preventive Action

8.5 Improvement

8.5.1 Continual improvement

The effectiveness of the quality management system is continually improved through the use of:

a) The Quality Policy;
b) Quality Objectives;
c) Audit results;
d) Analysis of data;
e) Corrective and preventive actions;
f) Management review.

Reference:
QSP 201.1 Management Responsibility
QSP 214.1 Corrective and Preventive Action
QSP 217.1 Internal Quality Audits

8.5.2 Corrective action

Actions are taken to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions taken are appropriate to the impact of the problems encountered.

Documented procedures define requirements for:

a) Reviewing non-conformities (including customer complaints);
b) Determining the causes of nonconformities;
c) Evaluating the need for actions to ensure that nonconformities do not recur;
d) Determining and implementing the actions needed;
e) Recording results of actions taken;
f) Reviewing corrective actions taken.

Reference:
QSP 214.1 Corrective and Preventive Action

8.5.3 Preventive action

Preventive actions are determined to eliminate the causes of potential nonconformities in order to prevent occurrence. Preventive actions taken are appropriate to the effects of the potential problems.

Documented procedures define requirements for:

a) Determining potential nonconformities and their causes;
b) Evaluating the need for actions to ensure that nonconformities do not occur;
c) Determining and implementing the actions needed;
d) Recording results of actions taken;
e) Reviewing preventive actions taken.

Reference:
QSP 214.1 Corrective and Preventive Action

9.0 PRODUCT REALIZATION PROCESS

9.1 PLANNING

(See Quality Management System Process below for description of how overall capabilities, responsibilities, processes, criteria and methods are planned, managed and controlled)
Customer requirements, statutory and regulatory requirements, and any additional requirements are determined and reviewed (see Quality System Procedure 203.1).
Records of the review of requirements and any resulting actions are maintained (QSP216.1).
The materials, sequence of operations, and specific criteria for each order are documented (QSP203.1).
Suppliers are evaluated and selected based on their ability to supply product and/or services in accordance with requirements (QSP206.1).
Records of supplier evaluation are maintained (QSP216.1).

9.2 IMPLEMENTATION

Work instructions, equipment, monitoring and measurement devices, and order-specific documentation are available at each step of production (QSP203.1, QSP205.1, QSP209.1).
Product is identified throughout the production process (QSP209.1).
Traceability records are maintained (QSP216.1).
Product status with respect to monitoring and measurement requirements is identified throughout the production process (QSP209.1).
Product is handled, protected, and/or preserved during processing, storage and delivery (QSP209.1).
Any customer property used or incorporated into product is identified, verified, and protected. Customer property that is lost, damaged or found to be unsuitable for use is reported to the customer (QSP209.1).
Records of customer property are maintained (QSP216.1).

9.3 MONITORING

Equipment is monitored to ensure the ability to continue to achieve planned results (QSP209.1).
Product is monitored and measured to verify that product requirements have been met, and that processes are achieving planned results (QSP209.1).
Records that processes and resulting product meet requirements are maintained (QSP216.1).
To ensure valid results, measuring equipment is calibrated or verified at specified intervals (QSP211.1).
Records of calibration are maintained (QSP216.1)

9.4 IMPROVEMEMENT

Processes which are not achieving planned results are adjusted or repaired as needed (QSP209.1).
Product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery (QSP209.1).
Records of nonconformities and any subsequent actions taken are maintained (QSP216.1).
If measuring equipment is out of compliance, the validity of previous measuring results is assessed, and appropriate action is taken on the equipment and any product affected (QSP211.1).
Records of assessment and actions on measuring equipment are maintained (QSP216.1).
Corrective actions are taken to eliminate the causes of nonconformities and prevent recurrence, and preventive actions are taken to eliminate the causes of potential nonconformities and prevent occurrence ***(See Quality Management System Process section 10 below).***

10. QUALITY MANAGEMENT SYSTEM PROCESS

10.1 PLANNING

Management periodically reviews the effectiveness of the quality management system, including customer satisfaction, results of internal audits, corrective actions, performance versus objectives, availability of necessary resources, and changes which may affect the organization, and initiates preventive action as needed to improve effectiveness (see Quality System Procedure 201.1).

Records of management reviews are maintained (QSP216.1)

10.2 IMPLEMENTATION

Top management establishes, and updates as necessary, the quality policy, and communicates it within the organization (QSP201.1).

Top management establishes quality objectives that support the quality policy, and communicates them within the organization (QSP201.1).

Top management appoints a member of management as management representative, with responsibility and authority to ensure that processes needed for the quality management system are established, implemented and maintained (QSP201.1).

Management ensures that appropriate documentation is developed, approved, implemented and maintained to define the processes, responsibilities, authorities, sequences, interactions, criteria, methods, resources and/or records required for continued effective operation and control (QSP202.1 and QSP205.1).

Personnel are assigned responsibilities and trained to effectively implement the processes. (QSP218.1).

Records of education, training, skills, and experience are maintained (QSP216.1).

10.3 MONITORING

Internal Audits are conducted to determine whether the quality management system is effectively documented, implemented and maintained (QSP217.1).

Records of Internal Audits are maintained (QSP216.1).

Processes are monitored to demonstrate their ability to achieve planned results ***(see Product Realization Process section 9 above).***

Product is monitored and measured to verify that product requirements are met ***(see Product Realization Process section 9 above).***

10.4 IMPROVEMENT

Corrective actions are taken to eliminate the causes of nonconformities and prevent recurrence, and preventive actions are taken to eliminate the causes of potential nonconformities and prevent occurrence (QSP214.1).

Records of the results of corrective and preventive actions taken are maintained (QSP216.1).

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11.0 QUALITY SYSTEM PROCESS FLOW CHART