1.0 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, ISO 9001:2015 and ***AS 9100 (Rev D), as well as applicable statutory and regulatory quality management system requirements.***

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

1.2 Scope

Ed Fagan Inc. is certified to:

The Distribution of Specialty Metals and Alloys

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.

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 and ***AS9100D*** 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 Normative References

2.1 ISO 9001-2005, “Quality Management Systems – Fundamentals and Vocabulary

2.2 ISO 9001:2015, “Quality Management Systems – Requirements”

2.3 AS 9100 (Rev D), “Quality Management Systems – Requirements for Aviation, Space, and Defense Distributors”

3.0 Terms and Definitions

3.1 Ed Fagan Inc. has adopted the terms and definitions contained in ISO 9001:2015 as applicable for i6s certified ISO 9001:2015 and AS 9100 (Rev D) complaint Quality Management System

3.2 Within this standard, the term manufacture is intentionally used to clearly delineate the relationship between the product creator and the organization. The terms “external provider” and “original manufacturer” can be synonymous.

3.3 Within this quality system, the terms ”Production and Service Provision” refers to all aspects of product realization. When referring to action the terms “production”, “warehouse” and “warehousing” may be used in the titles and bodies of documents, procedures, forms, work Instructions, and memos and they refer to the activity of producing product and rendering service.

3.4 Within this quality system the term “Sales”, “quoting”, “order taking”, and “invoicing” are used. These terms refer to the processes of “Contract-Review” and “Customer-Related Process” and may be used interchangeably.

4.0 Context of the Organization (See Procedure P-400)

4.1 Understanding the organization and its context

As part of the Presidential Management Review (See Quality System Procedure QSP 930) of the Quality Management System (QMS), management determines external and internal issues that are relevant to EFI's purpose and strategic direction and that affect our ability to achieve intended results.

4.2 Understanding the needs and expectations of interested parties3.

Due to their effect or potential effect on the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, top management (QSP 930):

a) identifies interested parties that are relevant to the QMS, including: customers, employees, approved suppliers, community, financial institutions, ownership
b) determines the requirements of these interested parties that are relevant to the QMS.
    a. Customers (add bullets)
    b. Employees
        i. Be provided tools and training to perform all aspects of their jobs
        ii. Perform their job functions in a safe workplace and environment for the operation of processes
        iii. Operating in a work environment where their contributions are recognized with the opportunity for professional advancement
    c. Approved Suppliers
    d. Community
    e. Financial Institutions
    f. Ownership

Management monitors and reviews information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

Management determines the boundaries and applicability of the QMS to establish its scope, considering:

a) external and internal issues (QSP 930);

b) requirements of relevant interested parties (QSP 930);

c) the products and services offered by EFI and ***assignment of the responsibilities and authorities for these processes.***

All requirements of applicable quality management system standards are applied if they are relevant within the determined scope of the EFI QMS (See Section 1, 2, or 3).

d) Exclusions

The quality management system and the Quality System Manual address all of the requirements of ISO 9001:2015 ***and AS 9100 (Rev D)*** with the exception of:

8.3 Design and Development. These activities are not conducted by Ed Fagan Inc.

8.5.1 f – Validation

This does not affect EFI's ability or responsibility to ensure the conformity of products or services.

4.4 Quality management system and its processes (QSP 400)

4.4.1 In accordance with the requirements of applicable quality management system standards as defined in the scope of the QMS ***and to address customer and applicable statutory and regulatory quality management system requirements***, the QMS is established, documented, maintained and continually improved, including the processes needed, their interactions, and their application throughout the organization, including:

a) inputs required and outputs expected from processes

i. Sales - QSPs 820

ii. Purchasing – QSP 840

iii. Product Realization – QSP 850

b) sequence and interactions of processes; (See a. above)

c) criteria and methods (including monitoring, measurements, and related performance indicators) needed to ensure the effective operation and control of processes; (See a. above)

i. Sales - QSPs 820
   a. Results of annual customer survey. (P820 4.7)
   b. Tracking of sales generated non-conformities

ii. Purchasing – QSP 840

a. Vendor ontime performance
b. Vendor concessions on orders

iii. Product Realization – QSP 850

a. On time shipments (WI-850)
b. Tracking of warehouse generated non-conformities

d) the resources needed for processes and to ensure their availability; (QSP 930)

e) assignment of responsibilities and authorities for processes; (See a. above)

f) addressing risks and opportunities (QSP 930);

g) evaluation of processes and implementation of any changes needed to ensure that processes achieve intended results;(See a. above)

h) improvement of processes and the QMS (See QSP 1000)

4.4.2 To the extent necessary, EFI:

a) Creates and maintains documented information to support the operation of processes (QSP 752)

b) retains documented information to have confidence that the processes are being carried out as planned. (QSP 753)

Documented information that is established and maintained includes:

***a) a general description of relevant interested parties* (QSP 930);**

b) the scope of the quality management system, including boundaries and applicability (see Section 1, 2, or 3);

c) a description of the processes needed for the quality management system and their application throughout the organization; (This Quality System Manual)

d) the sequence and interaction of these processes; (all QSPs; particularly QSPs 820, 840, and 850)

e) assignment of the responsibilities and authorities for these processes. (See d. above)

5.0 Leadership (QSP 500)

5.1 Leadership and Commitment

5.1.1 General

The President demonstrates leadership, commitment and accountability with respect to the quality management system by (QSP 930):

a***) personally assuming the title and responsibilities of Management Representative;***

b) ensuring that the quality policy and quality objectives are established and are compatible with the context of and strategic direction of the organization;

c) integrating the QMS requirements into the organization's business processes;

d) promoting the use of the process approach and risk-based thinking**;**

e) ensuring that the resources needed for the QMS are available;

f) communicating the importance of effective quality management and of conforming to the QMS requirements;

g) ensuring that the QMS achieves its intended results;

h) engaging, directing and supporting persons to contribute to the effectiveness of the QMS;

i) promoting improvements;

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer focus

Management demonstrates leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met (QSP 820);

b) risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed (QSPs 820, 930);

c) the focus on enhancing customer satisfaction is maintained (QSP 930);

d) product and service conformity and on-time delivery performance are measured, and appropriate action is taken if planned results are not, or will not be, achieved (QSP 930)

5.2 Policy

5.2.1 Establishing the Quality Policy:

The Quality Policy was initially established by the ISO Steering Committee, chaired by the President and consisting of management representatives of all departments, and was approved by the President. The policy is reviewed at all Presidential Management Review (QSP930). Any future revisions to the policy will be established, implemented, maintained and approved by the President. The policy is established to:

a) be appropriate to the purpose and context of the organization and to support its strategic direction;

b) provide a framework for setting quality objectives;

c) include a commitment to satisfy applicable requirements;

d) include a commitment to continual improvement of the QMS.

5.2.2 Communicating the Quality Policy

The Quality Policy is:

a) available and maintained as documented information;

b) communicated, understood and applied within the organization;

c) available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities:

Through documented Quality System Procedures (QSPs), management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization including:

a) ensuring that the quality management system conforms to the requirements of the relevant quality system standards (QSP 920);

b) ensuring that processes are delivering their intended outputs (QSP 850);

c) reporting on the performance of the quality management system and on opportunities for improvement (QSP 930);

d) ensuring the promotion of customer focus throughout the organization QSP 930);

e) ensuring that the integrity of the QMS is maintained when changes are planned and implemented (QSPs 752, 930).

The president has appointed himself as the management representative, with the responsibility and authority for oversight of the above requirements.

6.0 Planning

6.1 Actions to address risks and opportunities (QSPs 500, 930)

6.1.1 Planning for the Quality Management System (QMS) starts with the Presidential management review (QSP 930), identifying internal and external issues that are relevant to EFI's purpose, strategic direction, and ability to achieve intended results including meeting the requirements of customers and other relevant interested parties in order to:

a) give assurance that the QMS can meet its intended results;

b) enhance desirable effects;

c) prevent or reduce undesired effects;

d) achieve improvement.

e) conducting annual SWOT analysis

6.1.2 Using the Corrective / Improvement Action system (QSP1000), the President assigns responsibilities for:

a) taking actions to address risks and opportunities;

b) integrating and implementing the actions taken into the QMS and its relevant processes and procedures; and evaluating the effectiveness of the actions taken.

6.2 Quality objectives and planning to achieve them (QSP 500, 930)

6.2.1 Quality objectives are established at relevant functions, levels and processes needed for the QMS. Quality objectives:

a) are consistent with the Quality Policy;

b) are measurable;

c) take into account applicable requirements;

d) are relevant to conformity of products and services and to enhancement of customer satisfaction;

e) are monitored;

f) are communicated;

g) are updated as appropriate.

Documented information on quality objectives is retained (QSP 753).

6.2.2 When planning to achieve quality objectives, the planner(s) determine (QSP 1000):

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

6.3 Planning of changes

Changes to the QMS are carried out in a planned manner, considering:

a) the purpose of the changes and their potential consequences;

b) the integrity of the QMS;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

7.0 Support

7.1 Resources

7.1.1 General

Top management determines and provides the resources needed to establish, implement, maintain, and continually improve the quality management system (QMS), considering (QSP 930):

a) the capabilities of, and constraints on, existing internal resources;

b) what needs to be obtained from external providers.

7.1.2 People

Top management determines and provides the persons necessary for the effective implementation of the QMS and for the operation and control of processes.

7.1.3 Infrastructure

For the operation of processes and to achieve conformity of products and services, top management determines, provides and maintains the necessary infrastructure, which can include:

a) buildings and associated utilities;

b) equipment, including hardware and software;

c) transportation resources;

d) information and communication technology.

7.1.4 Environment for the operation of processes (QSP 850)

In QMS procedures, top management assigns responsibilities for provision and maintenance of the environment necessary for the operation of processes and to achieve conformity of products and services.

Environmental factors to be considered may include heat, humidity, light airflow, hygiene, noise, safety or any factor which could have a detrimental effect on the quality of products or services provided to customers.

7.1.5 Monitoring and measuring resources (QSP 715)

7.1.5.1 General

In QMS procedures, top management assigns responsibility to appropriate persons to determine and recommend for purchase resources needed to ensure valid and reliable results when monitoring or measuring is use to verify the conformity of products and services to requirements.

The responsible persons ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;

b) are maintained to ensure their continuing fitness for their purpose;

Appropriate records (documented information) are retained as evidence of fitness for purpose of monitoring and measurement resources (QSP 753).

7.1.5.2 Measurement traceability

Measurement equipment is (QSP 715):

a) calibrated or verified, or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification is retained as document information;

b) identified in order to determine status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

A Quality System Procedure (QSP 715) is established, implemented, and maintained for the recall of monitoring and measuring equipment requiring calibration or verification.

A register of monitoring and measuring equipment is maintained, including equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

Calibration or verification of monitoring and measuring equipment is carried out under suitable environmental conditions.

When measurement equipment is found to be unfit for its intended purpose, it is determined if the validity of previous measurement results has been adversely affected and appropriate action is taken if necessary.

7.1.6 Organizational knowledge (QSP 720)

The knowledge necessary for the operation of processes and to achieve conformity of products and services is determined and documented on Qualification Cards/Training Records which are made available to the extent necessary. Cross training of individuals in various operations is encouraged by management and is a key component in fulfilling the organizational knowledge requirement.

When addressing changing needs and trends, management considers the current knowledge level and determines how to acquire or access any necessary additional knowledge and required updates (QSP 930).

7.2 Competence (QSP 720)

A QMS procedure (QSP 720)

a) defines the necessary competence of persons doing work that affects the performance and effectiveness of the QMS;

b) ensures that these persons are competent on the basis of appropriate education, training, and/or experience;

c) where applicable, requires taking actions to acquire the necessary competence, and evaluating the effectiveness of the actions taken;

d) specifies appropriate documented information as evidence of competence.

7.3 Awareness (QSP 500)

Persons doing work under EFI's control are made aware of:

a) the Quality Policy (see 5.2);

b) relevant quality objectives (see 6.2);

c) their contribution to the effectiveness of the QMS, including the benefits of improved performance (QSP 930);

d) the implications of not conforming with the QMS requirements (QSP 930).

e) relevant quality management system documented information and changes thereto (QSP 752);

f) their contributions to product or service conformity (QSP 930);

g) their contributions to product safety (QSP 930);

h) the importance of ethical behavior (QSP 930).

7.4 Communication (QSP 752)

Quality System Procedures (QSPs) define the internal and external communications relevant to the QSM, including:

a) what is communicated;

b) when it is communicated;

c) with whom it is communicated;

d) how it is communicated;

e) who communicates it.

7.5 Documented information

7.5.1 General

The QMS includes:

a) documented information required by any quality management standard included in the QMS scope;

b) other documented information that is necessary for the effectiveness of the QMS.

7.5.2 Creating and updating (QSP 752)

When documented information is created and updated, the QMS ensures appropriate:

a) identification and description (e.g. title, date, author, reference number, …)

b) format (e.g. language, applicable software version, graphics, …) and media (e.g. paper, electronic, …).

c) review and approval for suitability and adequacy.

7.5.3 Control of documented information (QSPs 752 and 753)

7.5.3.1 Documented information required by the QMS and/or by any quality management standard included in the QMS scope is controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected e.g. from loss of confidentiality, improper use, loss of integrity, …)

7.5.3.2 For the control of documented information, Quality System Procedure (QSP 753) addresses, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition;

e) prevention of unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

Documented information retained as evidence of conformity determined to be necessary for the planning and operation of the quality management system are identified as appropriate and are controlled.

Documented information retained as evidence of conformity is protected from unintended alterations.

When documented information is managed electronically, data protection processes are defined (e.g. protection from loss, unauthorized changes, unintended alteration, corruption, physical damage, …)

Documented information that provides evidence of product origin, conformity, and shipment are retained.

8.0 Operation

8.1 Operational planning and control

Processes are planned, implemented, and controlled, suitable for the operations, to meet product and service requirements, by:

a) determining the requirements for the products and services (QSP 820);

b) establishing criteria for the processes and for the acceptance of products and services (QSP 850);

c) determining the resources needed to achieve conformity to the product and service requirement (QSP 930);

d) implementing control of the processes in accordance with the criteria (QSP 850);

e) determining, maintaining and retaining documented information as needed to have confidence that the processes have been carried out as planned; and to demonstrate the conformity of products and services to their requirements (QSP 753);

f) engaging representatives of affected functions for operational planning and control (QSPs 820 and 850);

g) determining products and services to be obtained from external providers (QSP 840);

h) establishing the controls needed to prevent delivery of nonconforming products and services to the customer (QSP 850).

Product and service provision is planned and managed in a structured and controlled manner, as appropriate to customer requirements, products and services, and suitability for EFI's operations. Scheduled planning events are performed in a planned sequence to meet requirements at an acceptable risk, within resource and schedule constraints (QSP 820 and QSP 850).

Planned changes are controlled; the consequences of any unintended changes are reviewed; and action is taken to mitigate any adverse effects, as necessary (QSP 820).

Outsourced processes are controlled ***to ensure that work transfer impacts and risks are managed. A process is established, implemented and maintained to plan and control the temporary or permanent transfer or work, so as to ensure the continuing conformity of the work to requirements (QSP 850).***

8.1.1 The organization shall plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization and the products and services. Management:

a: is responsibilities for operational risk management;

b. establishing risk assessment criteria (e.g., likelihood, consequences, risk acceptance);

c. the identification, assessment, and communication of risks throughout operations;

d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

e. acceptance of risks remaining after implementation of mitigating actions.

8.1.2 Configuration management (QSP 850)

Processes that are appropriate to EFI's operations, products and services are planned, implemented, and controlled for configuration management, in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. These processes (QSP 850):

a) control product identity and traceability to requirements, including the implementation of identified changes;

b) ensure that documented information (e.g. requirements, verification, validation, and acceptance documentation is consistent with the actual attributes of the products and services.

8.1.3 (Not Used)

8.1.4 Prevention of Counterfeit Parts

Processes are planned, implemented and controlled, appropriate to product and to EFI's operations, for the prevention of counterfeit or suspected counterfeit part use and their inclusion in product(s) delivered to the customer. Counterfeit part prevention considers:

a) training of appropriate persons in the awareness and prevention of counterfeit parts (QSP 720);

b) application of a parts obsolescence monitoring program;

c) controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources (QSP 840);

d) requirements for assuring traceability of parts and components to their original or authorized manufacturers (QSP 850);

e) verification and test methodologies to detect counterfeit parts (QSP 850);

f) monitoring of counterfeit parts reporting from external sources;

g) quarantine and reporting of suspected or detected counterfeit parts QSP 850).

8.1.5 Prevention of Suspected Unapproved Parts.

Processes that are appropriate to EFI's operations and products are planned, implemented and controlled in order to identify and prevent release of unapproved and suspected unapproved parts (QSP 850).

These processes consider:

a) training of appropriate persons in the awareness and identification of suspected unapproved parts (QSP 720);

b) requirements for assuring traceability of parts and components to an authorized source (QSP 850);

c) inspection processes to detect suspected unapproved parts (QSP 850);

d) monitoring of suspected unapproved parts reporting from external sources;

e) quarantine and reporting of suspected unapproved parts in accordance with applicable requirements from the competent authority or customers, as required (QSP 850).

8.2 Requirements for Products and Services

8.2.1 Customer communication

Communication with customers includes (QSP 820):

a) providing customers with information relating to products and services;

b) handling enquiries, contracts, or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property (QSP 850);

e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements for Products and Services

Processes for determining the requirements for the products and services to be offered to customers ensure that: (QSP 820)

a) the requirements for the products and services are defined, including any applicable statutory and regulatory requirements, and requirements considered necessary by EFI.

b) EFI can meet the claims for the products and services it offers.

8.2.3 Review of the Requirements for Products and Services (QSP 820)

8.2.3.1 Processes ensure that EFI has the ability to meet the requirements for products and services to be offered to customers. A review is conducted and coordinated with applicable functions before committing to supply products and services to the customer, including review of:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, if any;

b) requirements not stated by the customer, but necessary for the specified or intended use, when known;

c) requirements specified by EFI;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed.

This review is coordinated with applicable functions.

If upon review it is determined that some customer requirements cannot be met or can only partially be met a mutually acceptable requirement will be negotiated with the customer.

Contract or order requirements differing from those previously defined are resolved.

When the customer does not provide a documented statement of their requirements, the requirements are confirmed before acceptance.

8.2.3.2 Documented information is retained, as applicable (QSP 753):

a) information on the results of the review;

b) information on any new requirements for the products and services.

8.2.3.4 Changes to Requirements for Products and Services

Relevant documented information is amended, and relevant persons are made aware of the changed requirements, when the requirements for products and services are changed (QSPs 820, 850).

8.3 Design and development of products and services

Design and development ***are excluded*** from the scope of this quality management system. EFI does not design products and/or services. All design requirements are specified by the customer.

8.4 Control of externally provided processes, products, and services

8.4.1 General

Processes are defined and Quality System Procedures are documented to ensure that externally provided processes, products, and services conform to requirements (QSPs 820, 840, 850):

EFI is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer;

When required, customer-designated or approved external providers, including process sources (e.g., special processes), are used;

Risks associated with the external provision of processes, products and services, as well as with the selection and use of external providers are identified and managed.

External providers are required to apply appropriate controls to their external providers, to ensure that requirements are met.

Quality System Procedures stipulate the form of controls to be applied to externally provided processes, products, and services when:

a) products and services from external providers are intended for incorporation into EFI's own products and services (QSPs 820, 840, 850);

b) products and services are provided directly to the customer by an external provider on EFI's behalf (QSPs 820, 840, 850);

c) a process, or part of a process, is provided by an external provider as a result of a decision by EFI (QSP 820, 840, 850).

Criteria is applied for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements (QSP 840). Documented information of evaluation and any necessary actions arising from evaluation is retained (QSP 753).

NOTE: During external provider evaluation and selection, EFI may use quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, external provider approvals from government authorities or customers, etc.). Use of such data would be only one element of external provider control. EFI remains responsible for verifying that externally provided processes, products, and services meet specified requirements.

8.4.1.1 Quality System Procedure (QSP 840) specifies:

a) the processes, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;

b) maintenance of a register of external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family, authorized approval to distribute, …);

c) periodic review of external provider performance including process, product and service conformity, and on-time delivery performance;

d) the necessary actions to be taken when dealing with external providers that do not meet requirements;

e) the requirements for controlling documented information created by and/or retained by external providers (QSP 850).

8.4.2 Type and extent of control

To ensure that externally provided processes, products, and services do not adversely affect EFI's ability to consistently deliver conforming products and services to customers, Quality System Procedures:

a) stipulate that externally provided processes remain within the control of the QMS; (QSP 840)

b) define the controls to be applied to an external provider and those to be applied to the resulting output (QSP 840 and QSP 850);

c) take into consideration:

1) the potential impact of the externally provided processes, products, and services on EFI's ability to consistently meet customer and applicable statutory and regulatory requirements (QSP 820);

2) the effectiveness of the controls applied by the external provider (QSP 840);

3) the results of the periodic review of external provider performance (QSP 840).

d. defines the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements (QSP 850).

Verification activities of externally provided processes, products, and services are performed according to the risks identified, including inspection or periodic testing, as applicable, when there is high risk of nonconformities, including counterfeit parts (QSP 850) .

NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve EFI of the responsibility to provide acceptable processes, products, and services and to comply with all requirements.

NOTE 2: Verification activities can include (QSP 850):

a) review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);

b) inspection and audit at the external provider's premises;

c) review of the required documentation;

d) review of production part approval process data;

e) inspection of products or verification of services upon receipt.

When external provider test reports are utilized to verify externally provided products, a process is implemented to evaluate the data in the test reports to confirm that the product meets requirements (QSP 850S) . When a customer or organization has identified raw material as a significant risk, the organization shall implement a process to validate the accuracy of test reports.

8.4.3 Information for external providers (QSP 840)

Prior to communicating requirements to external supplier, the adequacy of the requirements is ensured.

Depending on the product or service, and appropriate to EFI's operations, requirements communicated to external supplier may include, as needed:

a) the processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);

b) the approval of:

1) products and services;

2) methods, processes, and equipment;

3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers' interactions with the organization;

e) control and monitoring of the external providers' performance to be applied by EFI;

f) verification or validation activities that EFI, or its customer, intends to perform at the external providers' premises;

g) test, inspection, and/or verification;

h) the use of statistical techniques for product acceptance and related instructions for acceptance by the organization.

i) the need to:

1) implement a quality management system;

2) use customer-designated or approved external providers, including process sources (e.g., special processes);

3) notify EFI of nonconforming processes, products, or services; and to obtain approval from EFI for their disposition;

4) prevent the use of suspected unapproved, unapproved, and counterfeit parts;

5) notify EFI of changes to processes, products, or services, including changes of any the external supplier's own external providers or locations of manufacture;

6) flow down to external providers applicable requirements including customer requirements;

7) provide a certificate of conformity, test reports, or authorized release certificate, as applicable;

8) retain documented information, including retention periods and disposition requirements;

j) the right of access by EFI, our customer, and/or regulatory authorities to the applicable areas of the supplier's facilities and to applicable documented information, at any level of the supply chain;

k) ensuring that persons are aware of:

1) their contribution to product or service conformity;

2) their contribution to product safety;

3) the importance of ethical behavior.

8.5 Production and Service Provision

8.5.1 Control of production and service provision

Production and service provision are implemented under controlled conditions including, as applicable:

a) the availability of documented information that defines (QSP 850):

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2) the results to be achieved;

NOTE 1: Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts lists, materials, and process specifications.

NOTE 2: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, documents (e.g., travelers, routers, work orders), and verification documents.

b) the availability and use of suitable monitoring and measuring resources; (QSPs 715, 850)

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met (QSP 850);

1) ensuring that documented information for monitoring and measurement activity for product acceptance includes:

- criteria for acceptance and rejection;

- where in the sequence verification operations are to be performed;

- measurement results to be retained (at a minimum an indication of acceptance or rejection);

- any specific monitoring and measurement equipment required and instructions associated with their use;

2) ensuring that if sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use.

d) the use of suitable infrastructure and environment for the operation of processes; (QSP 850, 930)

NOTE: Suitable infrastructure can include product specific tools (e.g., jigs, fixtures, molds) and software programs.

e) the appointment of competent persons, including any required qualification; (QSP 720)

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) actions implemented to prevent human error include training and qualification (QSP 720); procedures, instructions, forms, etc. placed on-line (QSP 752); and the built-in control afforded by the production and traceability verification system (QSP 850).

h) the implementation of release, delivery, and post-delivery activities (QSP 850);

i) the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations) (QSP 850 and related Work Instructions);

j) the accountability for all products (e.g., parts quantities, split orders, nonconforming product) (QSP 850);

k) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized (QSP 850, 860);

l) the provision for the prevention, detection, and removal of foreign objects (QSP 850);

m) the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements;

n) the consequences of obsolescence (e.g., materials, components, equipment, products).

8.5.1.1 Control of equipment, tools, and software programs

Equipment, tools, and software programs used to automate, control, monitor, or measure processes are validated and maintained. Storage requirements are defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

8.5.2 Identification and traceability

Suitable means are used to identify outputs when it is necessary to ensure the conformity of products and services.

EFI maintains the identification of the configuration of products and services in order to identify any differences between the actual configuration and the required configuration. (QSPs 820, 840, 850)

Throughout production and service provision, the status of outputs is identified with respect to monitoring and measurement requirements. (QSP 850)

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish controls for the media.

When traceability is a requirement, the unique identification of outputs is controlled, and the documented information necessary to enable traceability is retained (QSPs 820, 840, 850).

Unserviceable product is controlled and physically segregated from serviceable product. (QSP 850)

NOTE: Traceability requirements can include: (QSPs 820, 840, 850)

- the identification to be maintained throughout the product life;

- the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);

- the identification of the product's condition in inventory (e.g., new, overhauled, repaired, altered, rebuilt) (QSPs 850, 920).

Product identification and traceability is maintained by suitable means (e.g., labels, bar codes) from receipt; during splitting, storage, packaging, and preservation operations and until delivery. This includes handling or packing operations outsourced to external providers.(QSP 820, 840, 850)

When delivering split product, the following information is retained:

- amount delivered relative to amount received from external provider,

- purchase order number(s),

- customer's name(s).

8.5.3 Property belonging to customers or external providers (QSP 850)

Care is exercised with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

Customers' or external providers' property provided for use or incorporation into products and services it is identified, verified, protected, and safeguarded.

When the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, it is reported the customer or external provider and documented information is retained on what has occurred.

NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property, and personal data.

8.5.4 Preservation (QSP 850)

The outputs during production and service provision are preserved, to the extent necessary to ensure conformity to requirements.

NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation of outputs also includes, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:

a. cleaning;

b. prevention, detection, and removal of foreign objects;

c. special handling and storage for sensitive products;

d. marking and labeling, including safety warnings and cautions;

e. shelf life control and stock rotation;

8.5.5 Post-delivery activities

Requirements for post-delivery activities associated with the products and services are determined and met. (QSP 820)

In determining the extent of post-delivery activities that are required, consideration is given to:

a) statutory and regulatory requirements;

b) the potential undesired consequences associated with products and services;

c) the nature, use, and intended lifetime of its products and services;

d) customer requirements;

e) customer feedback;

f) product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

When problems are detected after delivery, appropriate actions are taken, including investigation and reporting.

NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes (QSP 820)

Changes for production or service provision are reviewed and controlled to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve production or service provision changes are identified.

NOTE: Production or service provision changes can include changes affecting processes, equipment, tools, or software programs.

Documented information is retained describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review (QSP 753).

8.6 Release of products and services (QSP 850)

Verification that product and service requirements have been met takes placed at planned stages appropriate to the product and processes involved.

Unless otherwise approved by a relevant authority and, as applicable, the customer, release of products and services to the customer does not proceed until all planned arrangements have been satisfactorily completed.

Documented information is retained on the release of products and services, including: (QSPs 850, 753)

a. evidence of conformity with the acceptance criteria;

b. traceability to the person(s) authorizing the release.

All documented information required to accompany the products and services is present at delivery.

NOTE: Where there is a formal agreement with the customer, EFI can create and deliver a certifying statement that references the original manufacturer's certificate of conformity and documented information that is retained and traceable by EFI. The certifying statement indicates that defined requirements have been met throughout our processes.

8.7 Control of Nonconforming Outputs (QSP 850)

8.7.1 Outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

NOTE: The term "nonconforming outputs" includes suspected unapproved, unapproved, counterfeit, and nonconforming product or service generated internally, received from an external provider, or identified by a customer.

Appropriate actions are taken based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services (QSP 820).

The nonconformity control process is maintained as documented information including the provisions for:

a) defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;

b) taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;

c) timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties (QSP 820);

d) defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (QSP 1000).

NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.

Nonconforming outputs are dealt with in one or more of the following ways:

a) correction;

b) segregation, containment, return, or suspension of provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession.

Dispositions of nonconforming product shall be limited to:

a) scrap;

b) rejection for return to the external provider;

c) rejection for revalidation by the manufacturer;

d) submittal to either the customer or design authority for use-as-is disposition, as applicable.

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspected counterfeit, parts shall be controlled to prevent reentry into the supply chain.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 Documented information is retained that: (QSP 850,753)

a) describes the nonconformity;

b) describes the actions taken;

c) describes any concessions obtained;

d) identifies the authority deciding the action in respect of the nonconformity.

9.0 Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

A Quality System Procedure (QSP 850) determines:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;

c) when the monitoring and measuring are performed;

d) when the results from monitoring and measurement are analyzed and evaluated.

The performance and effectiveness of the QMS are evaluated during Presidential Management Reviews (QSP 930).

Appropriate documented information is retained as evidence of the results (QSP 753).

9.1.2 Customer satisfaction

Customers' perceptions of the degree to which their needs and expectations have been fulfilled are monitored (QSPs 820, 930). Examples of monitoring customer perceptions may include customer surveys, customer feedback on delivered products and services, meetings with customers, compliments, …

Information to be monitored and used for the evaluation of customer satisfaction includes product and service conformity, on-time delivery performance, customer complaints, and customer corrective action requests. Plans for customer satisfaction improvement are developed and implemented at Management Reviews to address deficiencies identified by these evaluations, and to assess the effectiveness of the results (QSP 930).

9.1.3 Analysis and evaluation

Appropriate data and information arising from monitoring and measurement is analyzed and evaluated (QSP 930).

NOTE: Appropriate data can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisories).

The results of analysis are used to evaluate:

a) conformity of products and services.

b) the degree of customer satisfaction.

c) the performance and effectiveness of the quality management system.

d) if planning has been implemented effectively.

e) the effectiveness of actions taken to address risks and opportunities.

f) the performance of external providers.

g) the need for improvements to the quality management system.

NOTE: Methods to analyze data can include statistical techniques.

9.2 Internal audit

9.2.1 Internal audits (QSP 920) are conducted at planned intervals to provide information on whether the QMS:

a) conforms to:

1) EFI's own requirements for the QMS, including customer and applicable statutory and regulatory requirements.

2) the requirements of the International Standards included in the scope of the QMS.

b) is effectively implemented and maintained.

NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.

9.2.2 QSP 920 documents how EFI :

a) plans, establishes, implements, and maintains the internal audit program, including the frequency, methods, responsibilities, planning requirements, and reporting, which taking into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) defines the audit criteria and scope for each audit;

c) selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensures that the results of the audits are reported to relevant management;

e) takes appropriate correction and corrective actions without undue delay;

f) retains documented information as evidence of the implementation of the audit program and the audit results (QSP 753).

NOTE: See ISO 19011 for guidance.

9.3 Management review

9.3.1 General

Top management reviews the QMS at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization (QSP 930).

9.3.2 Management review inputs

The management review is planned and carried out taking into consideration:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the quality management system;

c) information on the performance and effectiveness of the quality management system, including trends in:

1) customer satisfaction and feedback from relevant interested parties;

2) the extent to which quality objectives have been met;

3) process performance and conformity of products and services;

4) nonconformities and corrective actions;

5) monitoring and measurement results;

6) audit results;

7) the performance of external providers;

8) on-time delivery performance;

d) the adequacy of resources;

e) the effectiveness of actions taken to address risks and opportunities;

f) opportunities for improvement.

9.3.3 Management review outputs

The outputs of the management review include decisions and actions related to:

a) opportunities for improvement;

b) any need for changes to the QMS;

c) resource needs;

d) risks identified.

Documented information is retained as evidence of the results of management reviews (QSP 753).

10.0 Improvement

10.1 General

Opportunities for improvement are determined, and any necessary actions to meet customer requirements and enhance customer satisfaction are implemented, including (see Quality System Procedures QSP 930, 1000):

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing, or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

NOTE: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation, and reorganization.

10.2 Nonconformity and Corrective Action (QSPs 930, 1000)

10.2.1 When a nonconformity occurs, including any arising from complaints, appropriate persons:

a) react to the nonconformity and, as applicable:

1) take action to control and correct it;

2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) reviewing and analyzing the nonconformity;

2) determining the causes of the nonconformity***, including those related to human factors, as applicable*;**

3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the quality management system, if necessary*;*

g) flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;

h) take specific actions when timely and effective corrective actions are not achieved.

Corrective actions taken are appropriate to the effects of the nonconformities encountered.

10.2.2 Documented information is retained (QSP 753) as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action.

10.3 Continual Improvement

To continually improve the suitability, adequacy, and effectiveness of the quality management system, the results of analysis and evaluation, and the outputs from management review (QSP 930) are considered, to determine if there are needs or opportunities that need to be addressed as part of continual improvement.

The implementation of improvement activities are monitored, the effectiveness of the results are evaluated.

NOTE: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.

REVISION HISTORY

3.1 Original

3.2 Revised:

a. 9001-2008:12/01/03, 05/16/05, 5/25/06, 7/20/09, 01/13/10, 01/25/2010, 12/02/149001-2015: 6/27/18 (Original)

3.3 Latest Revision Details:

a. Throughout Manual: Corrected fonts and typeface to be consistent
b. In Section 7.51 – Removed (See Section ?)
c. In Section 8.1 – Removed word “with” at the end of the last sentence.

3.4 Historic revisions

a. Original 6/27/18

1. Throughout Manual: Replaced references to “ISO 9001-2000” to “ISO 9001-2015 and AS9120

2. Throughout Manual: Reworded and/or or added sections to comply with AS9120A

3. Throughout Manual: Re-numbered Quality System Procedures to new numbering system that is aligned with current ISO 9001-2015 and AS9120A structure

b .Revision 5/11/21

1. Corrected type of AS 0199 (Rev B) to (Rev D)

c. Revision 3/18/2022:

1. In section 1.x – Scope added language to clarify our goal to comply with statutory and legal requirements

2.In 8.4.2.e – Removed P852 & P860 reference. This was an inaccurate reference. Elements were covered in QSP 850.