



### RFI CORPORATION

# AS9100 Quality Management System Manual

100 Pine Aire Drive Bay Shore, New York 11706

(Not valid unless stamped "Controlled Copy" in red.)

Revision H Page 1 of 37

#### TABLE OF CONTENTS

Introduction	3
Section 1. Scope	7
1_1 General	7
1.2 Application	7
Section 2: Normative Reference	8
2.0 Quality Management System References	8
3.0 Quality Management System Definitions	9
4.1 General Requirements	10
4.2 Documentation Requirements	11
5.1 Management commitment	15
5.2 Customer focus	16
5.3 Quality policy	16
5.4 Planning	16
5.5 Responsibility, authority and communication	17
5.6 Management review	17
6.1 Provision of resources	19
6.1 Provision of resources	20
6.2 Human resources	20
6.3 Infrastructure	20
6.4 Work Environment	20
7.1 Planning of product realization	
7.1 Planning of product realization	23
7.2 Customer-related processes	23
7.3 Design and Development	24
7.4 Purchasing	26
7.5 Production Provision	27
7.6 Control of monitoring and measuring devices	30
8.1 General	32
8.2 Monitoring and Measurement	33
8.3 Control of Nonconforming Product	35
8.4 Analysis of Data	35
8.5 Improvement	36

#### Introduction

RFI Corporation, a wholly owned subsidiary of DEL Global Technologies Corp., has developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of RFI Corporation meets the requirements of the international standard SAE AS9100. This system addresses the design, development, and production of the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of the ISO 9001:2000 format and AS9100. Each section begins with a policy statement expressing RFI Corporation's obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references, as applicable, for activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the AS9100 standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

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

Vice President/General Manager:

**Rov Torzullo** 

Mr Tru

#### **QUALITY POLICY**

RFI Corporation's Quality Policy is to provide products that consistently meet or exceed our customers' requirements and expectations, are delivered on-time, and at the greatest value.

RFI Corporation is committed to continuously striving to improve our products, processes, and the overall effectiveness of our Quality Management System, through compliance with ISO 9001:2000 and the AS9100 Aerospace requirements.

This policy is communicated throughout our company and to our customers.

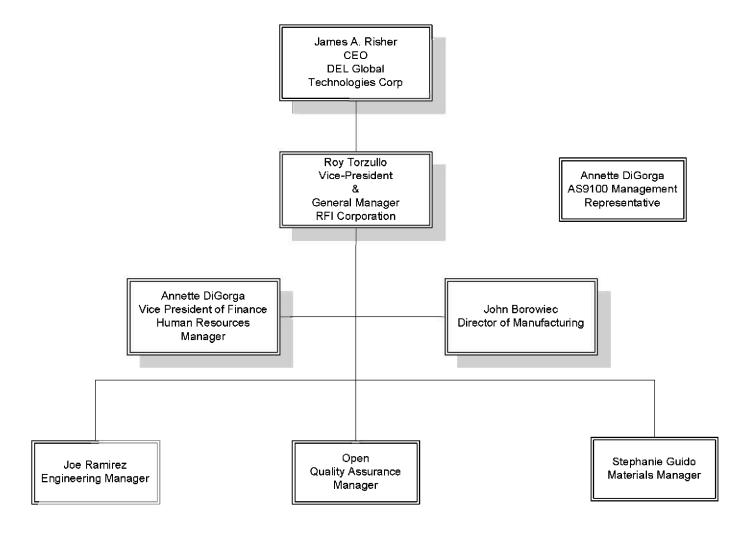
Revision H Page 4 of 37

#### **QUALITY SYSTEM MANUAL REVISIONS**

REV.	SECTION	SUB-SEC.	PARA.	CHANGE REQUEST#	DATE	AUTHORIZED BY
Α	Init	ial Release	)		2/7/08	F. Wolff
В	1	1.2	1.2	Y08-0126	2/18/08	F.Wolff
	Org Chart				2/18/08	F. Wolff
С		1.2	1.2		3/14/08	F.Wolff
D	Org Chart				34/2/08	F Wolff
E	7.0	7.2	7.2.3			
F	Org Chart				4/30/08	R. Torzullo
G	Quality Policy statement				5/9/08	R. Torzullo
Н	Product Realization	7.3	7.3.4		6/10/08	R. Torzullo

Revision H Page 5 of 37

### RFI CORPORATION ORGANIZATION CHART



#### Section 1: Scope

#### 1.1 General

The quality manual outlines the policies, procedures and requirements of RFI Corporation's Quality Management System. The system is structured to comply with the conditions set forth in the International Standard SAE AS9100.

#### 1.2 Application

RFI Corporation designs, develops, manufactures and upgrades noise suppression filters, magnetics & capacitors for the Aerospace, Military, Medical and Commercial industries.

Revision H Page 7 of 37

#### Section 2: Normative Reference

#### 2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- American National Standard ANSI/AS9100/ASQ Q9000-2005, Quality Management Systems - Vocabulary.
- American National Standard ANSI/AS9100/ASQ Q9001-2000, Quality Management Systems – Requirements
- Boeing D6-82479 Appendix B
- American National Standard ANSI AWS D17.1:2001, Specification for Fusion Welding for Aerospace Applications
- MIL-PRF-15733 Filters and capacitors, radio frequency interference, general specifications for
- MIL-STD-202 Test method standard electronic and electrical component parts
- IPC J-STD-001 Requirements for soldered electrical and electronic assemblies
- MIL-STD-2073-1 Standard practice for military packaging
- MIL-STD-129 Military marking for shipment and storage
- MIL-STD-130 Identification marking for U.S. military property

#### **Section 3: Definitions**

#### 3.0 Quality Management System Definitions

This section is for definitions unique to RFI Corporation.

- Top Management –Vice President/General Manager, Vice President Finance and Human Resources, and Director of Manufacturing.
- Customer owned property
  - a. Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
  - Customer purchased product returned for evaluation, repair, or modification.
- Customer furnished material Any type of material supplied to be utilized in the manufacture, modification or repair of customer-owned property.
- Product The end item result of meeting all contract terms and conditions. (eg: manufactured goods, merchandise, services etc.)
- Quality Records Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable
- Key Characteristics- The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.
- Nonconforming Product product that does not fulfill a requirement. This
  includes product returned from customers.
- QPL Quality Product Listing
- Deviation A specific written authorization, granted prior to the manufacture of an item, to depart from a particular requirement(s).
- Waiver A written authorization to accept an item, which during manufacture, or after having been submitted for Government inspection or acceptance, is found to depart from specified requirements, but nevertheless is considered suitable for use "as is" or after repair by an approved method.

## Section 4

## Quality Management System

#### 4.1 General Requirements

RFI Corporation has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of AS 9100. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS RFI Corporation has:

- Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end Section 4 of this Quality Manual
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective,
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- Established systems to monitor, measure and analyze these processes, and
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

#### 4.2 Documentation Requirements

#### 4.2.1 General

The QMS documentation includes:

- A documented Quality Policy
- This Quality Manual
- Documented Procedures
- Manufacturing Procedures (MP)
- Documents identified as needed for the effective planning, operation and control of our processes, and
- Records
- Forms and Tags, and
- Records required by contract and regulatory authorities.

RFI Corporation ensures that personnel have access to quality management system documentation and are aware of relevant procedures. We also provide customer or regulatory authorities access to quality management system documentation.

#### 4.2.2 Quality manual

This Quality Manual has been prepared to describe RFI Corporation's QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The Process Flow Diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system.

#### 4.2.3 Control of documents

All of the QMS documents are controlled according to the Control of Documents Procedure 423. This procedure defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring that documents of external origin are identified and their distribution controlled
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose and
- Obtaining customer / regulatory agency approvals when required by contract or regulatory requirements
- Coordinating document changes with customers or regulatory authorities in accordance with contract or regulatory requirements.

#### 4.2.4 Control of quality records

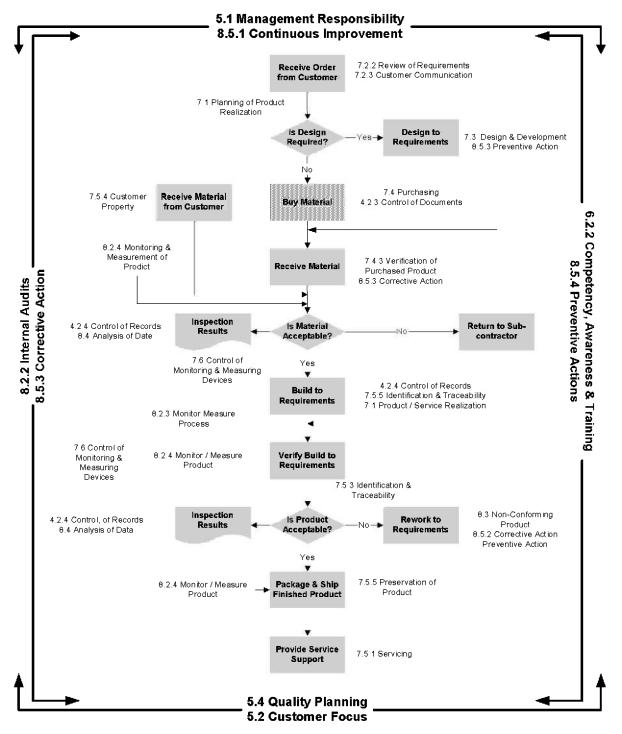
Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records, including those created by or maintained by suppliers, are maintained according to the Control of Records Procedure 424. This procedure requires that quality records remain legible, readily identifiable and retrievable. Records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records. Records are made available to customers / regulatory agencies when required by contract or regulatory requirements.

#### 4.3 Configuration Management:

The organization has established, documented and maintains a configuration management process that is appropriate to the product.

## **Related Procedures** Document Control 423 Control of Quality Record 424 Configuration Management 430

#### **QMS Process Flow Diagram**



## Section 5

## Management Responsibility

#### 5.1 Management commitment

Top management has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following.

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct quarterly management reviews.
- Ensure the availability of resources.

#### 5.2 Customer focus

RFI Corporation strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

Top management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization.

#### 5.3 Quality policy

Top management ensures that the quality policy is communicated to all employees. It is included in new employee training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

Management reviews the quality policy at each management review meeting to determine the policy's continuing suitability for our organization.

See page 3 of this document for RFI's Quality Policy.

#### 5.4 Planning

#### 5.4.1 Quality objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed quarterly for suitability. Objectives have been established for the company and, as applicable, individual departments. Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

#### 5.4.2 Quality management system planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the AS9100 standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

#### 5.5 Responsibility, authority and communication

#### 5.5.1 Responsibility and authority

An organizational chart has been established to show the interrelation of personnel in the organization. An Approved Signatory List defines the responsibilities and authorities of each of the positions on the organizational chart. The Approved Signatory List and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities. An organizational chart is located on page 5 of this manual.

#### 5.5.2 Management representative

Top management has appointed a management representative. See organization chart on page 5. As management representative, he/she has the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented and maintained
- Report to Top Management on the performance of the Quality Management System and any need for improvement
- Ensure the promotion of awareness of customer requirements throughout the organization, and
- Organizational freedom to resolve matters pertaining to the quality management system.

#### 5.5.3 Internal communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, circulation of minutes of management review meetings, Internal Audit Closing meetings, and other routine business communication.

#### 5.6 Management review

#### 5.6.1 General

Top management reviews the QMS quarterly at management review meetings scheduled in the months of January, April, August, and November each calendar year. This review assesses the continuing QMS suitability, adequacy and

Revision H

effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

#### 5.6.2 Review input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of audits, both internal and external
- Customer feedback
- Process performance and product conformity
- Company level quality data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for improvement

#### 5.6.3 Review output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

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

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

#### **Related Procedures:**

Management Review 560

## Section 6

## Resource Management

#### 6.1 Provision of resources

RFI Corporation has implemented a Quality Management System that complies with the AS9100 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides necessary resources.

#### 6.2 Human resources

#### 6.2.1 General

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

#### 6.2.2 Competence, awareness and training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human resources and department Managers maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

#### 6.3 Infrastructure

To meet quality objectives and product requirements RFI Corporation has determined the infrastructure needed. The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services. Existing infrastructure is maintained to ensure product conformity. Maintenance requirements are documented in:

- Preventive maintenance plans
- Building maintenance plans

#### 6.4 Work Environment

A work environment requirement suitable for achieving product conformance is maintained. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

Competence, Awarenes	ss and Training 622	

## Section 7

## **Product Realization**

#### 7.1 Planning of product realization

Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project. During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product,
- Processes, documentation and resources required
- Verification, monitoring, inspection and test requirements, and
- Criteria for product acceptance
- Resources necessary to support operation and maintenance of the product
- Resources to support operation and maintenance of the product.

The output of quality planning includes documented quality plans, processes, procedures and design outputs.

#### 7.2 Customer-related processes

#### 7.2.1 Determination of requirements related to the product

RFI Corporation determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities
- Not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- Additional requirements determined by RFI Corporation

#### 7.2.2 Review of requirements related to the product

RFI Corporation has a process in place for the review of requirements related to the product. The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- RFI Corporation has the ability to meet the defined requirements
- Records are maintained showing the results of the review and any actions arising from the review
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- When product requirements are changed, RFI Corporation communicates changes to relevant personnel and amends relevant documents
- Risks (e.g., new technology, short delivery time scale) have been evaluated

#### 7.2.3 Customer communication

RFI Corporation has implemented an effective process for communicating with customers in relation to:

- Product Information
- Enquiries, contracts and order handling, including amendments
- Customer Feedback, including customer complaints
- Customer to be notified of any changes that may affect quality prior to the effectivity of the change (e.g., changes in ownership, location, process or inspection techniques)

#### 7.3 Design and Development

#### 7.3.1 Design and development planning

The Engineering Department plans design and development and process for controlling the design. The design plan includes:

- Design and development stages including organization, task sequence, mandatory steps, significant stages and method of configuration control,
- Required design reviews, verification appropriate to each design stage
- Responsibilities and authorities for design and development.
- Where appropriate, due to complexity, the organization gives consideration to the following activities:
  - Structuring the design effort into significant elements;
  - For each element, analyzing the tasks and the necessary resources for its design and development. This analysis considers an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element is reviewed to ensure consistency with requirements.
- Verification methods appropriate to each design and development stage
- Responsibilities and authorities for design and development
- Identification of the technical interfaces required for the project
- Updating of the design plan as the project progresses
- The different design and development tasks to be carried out, defined according to specified safety or functional objectives of the product in accordance with customer or regulatory authority requirements.

#### 7.3.2 Design and development inputs

Inputs relating to product requirements are determined and documented. All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. Inputs include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements

- Where applicable, information derived from previous similar designs
- Other requirements essential for design and development

#### 7.3.3 Design and development outputs

Outputs of design and development are documented. They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

- Meet the input requirements
- Provide appropriate information for purchasing and production provision
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use.
- Identify key characteristics in accordance with design or contract requirements

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained is defined by the organization.

#### 7.3.4 Design and development review

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are signed off on the checklist plan, final design and overall schedule which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfill requirements
- Identify any problems and propose necessary actions
- Include representatives of functions concerned with the design and development stage being reviewed to authorize progression to the next stage.

#### 7.3.5 Design and development verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

#### 7.3.6 Design and development validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the design and development procedure.

#### 7.3.6.1 Documentation of Design and/or Development Verification and Validation

At the completion of design and/or development, the organization ensures that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

#### 7.3.6.2 Design and/or Development Verification and Validation Testing:

Where tests are necessary for verification and validation, these tests are planned, controlled, reviewed, and documented to ensure and prove the following:

- Test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria
- Test procedures describe the method of operation, the performance of the test, and the recording of the results
- The correct configuration standard of the product is submitted for the test
- The requirements of the test plan and the test procedures are observed
- The acceptance criteria are met

#### 7.3.7 Control of design and development changes

The design and development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review. This procedure provides for customer or regulatory authority approval of changes, when required by contract or regulatory requirement.

#### 7.4 Purchasing

#### 7.4.1 Purchasing process

A documented procedure 740 is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records.

RFI Corporation is responsible for the quality of all products purchased from suppliers, including customer-designated sources.

#### 7.4.2 Purchasing information

Purchasing information describes the product to be purchased, including where appropriate:

Revision H Page 26 of 37

- Requirements for approval of product, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements outlined in the Purchasing Procedure

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

#### 7.4.3 Verification of purchased product

The Purchasing procedure describes the process used to verify that purchased product meets specified purchase requirements. Purchased product is not used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure. If test reports are used to verify purchased product, the data must meet applicable specifications. Test reports for raw material are periodically validated.

When verification activities are delegated to the supplier the requirements are defined, and a register of delegations is maintained.

If RFI Corporation or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information. Where specified in the contract, the customer or the customer's representative is given the right to verify at the suppliers premises and organization's premises that product conforms to specified requirements

#### 7.5 Production Provision

#### 7.5.1 Control of production provision

RFI Corporation plans and carries out production provision under controlled conditions. Planning considers, as applicable:

- The establishment of process controls and development of control plans where key characteristics have been identified,
- The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization.
- The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and

Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product
- The availability of work instructions
- The use of suitable equipment
- The availability and use of monitoring and measuring devices
- The implementation of monitoring and measurement

Revision H

- The implementation of release, delivery and post-delivery activities
- accountability for all product during manufacture (e.g., parts, quantities, split orders, nonconforming product), part accountability to ensure bad parts have been permanently parted or destroyed
- evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized,
- provision for the prevention, detection, and removal of foreign objects (FOD).
- monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

#### 7.5.1.1 Production Documentation

Production operations are carried out in accordance with approved data. This data contains as necessary:

- Drawings, parts lists, process flow charts including inspection operations, production documents and inspection documents
- A list of specific or non-specific tools and numerical control (NC) machine programs required and specific instructions associated with their use.

#### 7.5.1.2 Control of Production Process Changes

Authorized people for approving changes to production processes are identified in the Approved Signatory List. RFI Corporation identifies and obtains acceptance of changes that require customer or regulatory authority approval in accordance with contract or regulatory requirements. Changes affecting processes, production equipment, tools and programs are documented and procedures are available to control the implementation of changes.

The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

#### 7.5.1.3 Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs

Production equipment, tools and programs are validated prior to use and maintained and inspected periodically. Validation prior to production use includes verification of the first article produced to the design data/specification. Storage requirements, including periodic preservation/condition checks, have been be established for production equipment or tooling in storage.

#### 7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities

When planning to temporarily transfer processes to a location outside the organization's facilities, the organization defines the process to control and validate the quality of the work.

#### 7.5.1.5 Control of Service Operations

Where servicing is a specified requirement, service operation processes provide for:

- A method of collecting and analyzing in-service data,
- Actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements,
- The control and updating of technical documentation,
- The approval, control, and use of repair schemes, and
- The controls required for off-site work

#### 7.5.2 Validation of processes for production and service provision

See exemption - Section 1.2 Application

#### 7.5.3 Identification and traceability

RFI Corporation identifies the product throughout product realization.

- RFI Corporation maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.
- Product is identified with respect to monitoring and measurement requirements.
- When acceptance authority media such as stamps, electronic signatures or passwords are used RFI Corporation establishes and documents controls for the media.
- According to the level of traceability required by contract, regulatory, or other established requirement, RFI Corporation system provides for:
  - Identification to be maintained throughout the product life;
  - All the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch:
  - For an assembly, the identity of its components and those of the next higher assembly to be traced;

Revision H

 For a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

RFI Corporation controls and records the unique identification of the product wherever traceability is a specified requirement.

#### 7.5.4 Customer property

RFI Corporation exercises care with customer property while it is under the organization's control or being used. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained. Customer property includes intellectual property, including customer furnished data used for design, production and/or inspection.

#### 7.5.4.1 Customer property identification

Customer property shall be clearly and permanently identified with customer name, part number, and revision level.

#### 7.5.5 Preservation of product

RFI Corporation preserves the conformity of product during internal processing and delivery to the intended destination per procedure. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Preservation of product also includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

- Cleaning;
- Prevention, detection and removal of foreign objects; (FOD)
- Special handling for sensitive products;
- Marking and labeling including safety warnings;
- Shelf life control and stock rotation;
- Special handling for hazardous materials.

The organization ensures that documents required by the contract or order to accompany the product are present at delivery and are protected against loss and deterioration.

#### 7.6 Control of monitoring and measuring devices

RFI Corporation has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. The process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.
- Adjusted or re-adjusted as necessary

Revision H

- Identified to enable the calibration status to be determined
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance and storage
- Be recalled according to a defined method when requiring calibration

In addition, Quality Assurance assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. RFI Corporation takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

RFI Corporation maintains a register of these monitoring and measuring devices. The process used for their calibration is defined in procedures, manufacturing procedures (MP) and equipment manuals and includes details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

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

RFI Corporation ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

#### **Related Documents**

Purchasing 740

## Section 8

## Measurement, Analysis and Improvement

#### 8.1 General

RFI Corporation plans and implements the monitoring, measurement, analysis and improvement processes as needed

- To demonstrate conformity of the product,
- To ensure conformity of the quality management system, and
- To continually improve the effectiveness of the quality management system.

These processes are identified in documented procedures and include determination of applicable methods, including statistical techniques, and the extent of their use.

#### 8.2 Monitoring and Measurement

#### 8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, RFI Corporation monitors information relating to customer perception as to whether the organization has fulfilled customer requirements.

#### 8.2.2 Internal Audit

RFI Corporation conducts internal audits at planned intervals to determine whether the quality management system

- Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization
- Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure 822.

The management responsible for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Detailed tools and techniques such as checksheets, process flowcharts, or any similar method to support audit of the quality management system requirements are developed, maintained and used according to the Internal Audit Procedure (OP#). The acceptability of the selected tools is measured against the effectiveness of the internal audit process and overall organization performance.

Internal audits meet contract and/or regulatory requirements.

#### 8.2.3 Monitoring and measurement of processes

RFI Corporation applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. In the event of process nonconformity, the organization:

- Takes appropriate action to correct the nonconforming process,
- Evaluates whether the process nonconformity has resulted in product nonconformity, and
- Identifies and controls the nonconforming product in accordance with clause 8.3.

#### 8.2.4 Monitoring and measurement of product

RFI Corporation monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

When key characteristics have been identified, they are monitored and controlled.

When the organization uses sampling inspection as a means of product acceptance, the plan is statistically valid and appropriate for use. The plan precludes the acceptance of lots whose samples have known nonconformities. When required, the plan is submitted for customer approval.

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

To ensure the highest reliability during test, all Measuring and Test Equipment shall have a minimum accuracy rating of 4:1 (product tolerance to test equipment tolerance).

#### 8.2.4.1 Inspection Documentation

Measurement requirements for product or service acceptance are documented. This documentation is part of the production documentation, and includes:

- Criteria for acceptance and/or rejection,
- Where in the sequence measurement and testing operations are performed,
- A record of the measurement results, and

- Type of measurement instruments required and any specific instructions associated with their use.
- Test records shall show actual test results data when required by specification or acceptance test plan.
- Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements.

#### 8.2.4.2 First Article Inspection

The organization's system shall provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result.

#### 8.3 Control of Nonconforming Product

RFI Corporation ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure 830.

The term "nonconforming product" includes nonconforming product returned from a customer.

Responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions is defined in the procedure.

#### 8.4 Analysis of Data

RFI Corporation determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for determining, collecting and analyzing this data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers

The organization does not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if:

The product is produced to customer design, or

Revision H

 The nonconformity results in a departure from the contract requirements.

Unless otherwise restricted in the contract, organization-designed product which is controlled via a customer specification may be dispositioned by RFI Corporation as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements.

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

In addition to any contract or regulatory authority reporting requirements, RFI Corporation system provides for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification includes a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.

#### 8.5 Improvement

#### 8.5.1 Continual improvement

RFI Corporation continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

#### 8.5.2 Corrective action

RFI Corporation takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure 852 defines requirements for

- Reviewing nonconformities (including customer complaints),
- Determining the causes of nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur.
- Determining and implementing action needed,
- Records of the results of action taken (see 4.2.4), and
- Reviewing corrective action taken.
- Flow down of the corrective action requirement to a supplier, when it
  is determined that the supplier is responsible for the root cause, and
  specific actions where timely and/or effective corrective actions are
  not achieved.

#### 8.5.3 Preventive action

RFI Corporation determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

Revision H

A documented procedure 853 defines requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken
- Reviewing preventive action taken

#### **Related Documents**

Internal Audits 822

Control of Nonconforming Product 830

Corrective Action 852

**Preventive Action 853**