AS 9100 Rev C Quality Systems Manual

AS-050C-QM

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Introduction

Innovative Control Systems 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 Innovative Control Systems meets the requirements of the international standard SAE AS 9100. 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 9001:2008 format and AS 9100C. Each section begins with a policy statement expressing *Innovative Control Systems'* 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.

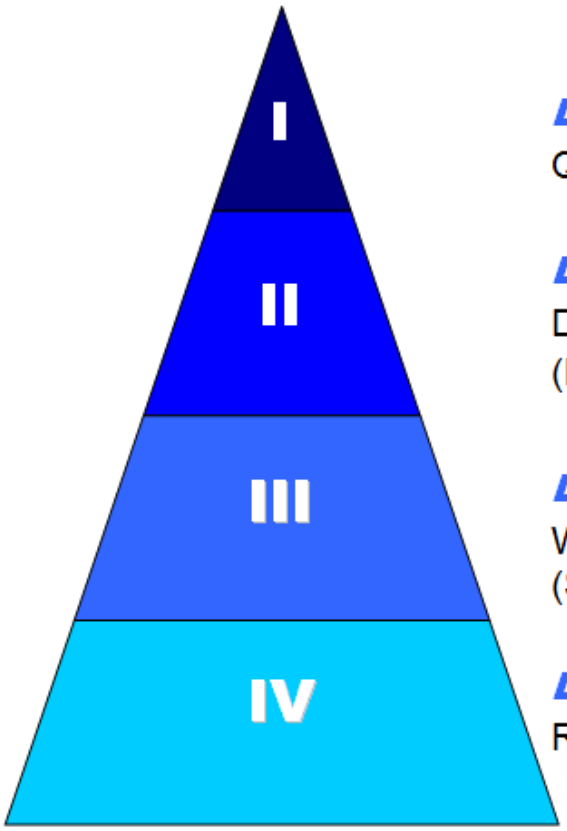
This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure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

This manual is used internally to guide the company's employees through the various requirements of the AS 9100 Rev C 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.

President: _____

Documentation Scheme



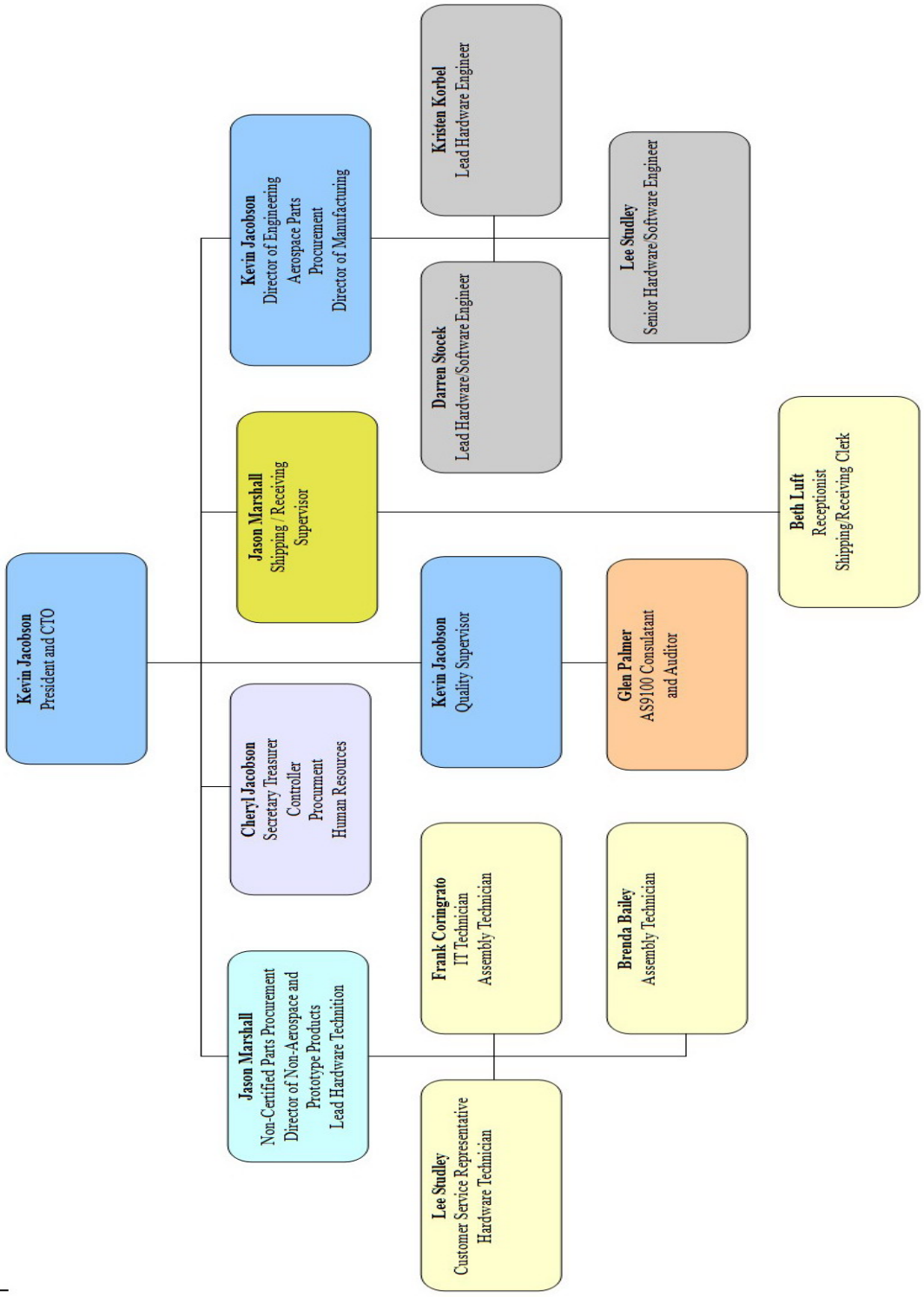
Level I
Quality Manual (QM)

Level II
Documented Procedures (xP-xxx)
(Referenced in the Quality Manual)

Level III
Work Instructions (WI-xxxx-001)
(Specific to your Organization)

Level IV
Records & Forms (F-xxx-001)

Organizational Flowchart



Quality Manual Distribution

The Quality Manual is distributed to the following:
President,
Engineering Manager,
Quality Manager,
Purchasing,
Shipping Department,
Receiving Department,

Section 1: Scope

1.1 General

The scope of the Quality Management System includes the design, manufacture and repair of avionics and avionics test instruments for the aerospace market.

The quality manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the International Standard ISO 9001:2008 and SAE AS 9100 Rev C.

NOTE:

- Should there be conflict between statutory & regulatory requirements and the requirements of AS9100C, the statutory and regulatory requirements take precedence.

1.2 Application

Innovative Control Systems has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

No Exclusions

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:

- ISO 9000:2005, Quality Management Systems - Vocabulary.
- ISO 9001:2008, Quality Management Systems – Requirements
- ISO 9004:2005, Quality Management Systems – Guidelines for performance Improvements
- SAE AS9100 Rev C (2009) - Quality Management Systems – Requirements for Aviation, Space and Defense Organizations

Section 3: Definitions

3.0 Quality Management System Definitions

This section is for definitions unique to *Innovative Control Systems*.

- Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
- Customer supplied product - Any type of service or 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.
- Risk - An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.
- Special requirements - Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved thus, requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity.
- Critical items - Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed.

Section 4

Quality Management System

4.1 General requirements

Innovative Control Systems has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of AS9100C. 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 Innovative Control Systems has:

- Determined the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the 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, *and documented them in quality plans, work instructions and the Measuring, Monitoring and Analysis Table*
- 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,
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes,
- Defined the controls for outsourced processes.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- A documented statements for the Quality Policy and Quality Objectives
- This Quality Manual
- Documented Procedures
- Documents identified as needed for the effective planning, operation and control of our processes, and
- Quality Records
- Records required by statutory and regulatory authorities.

Innovative Control Systems ensures that personnel have access to quality management system documentation and are aware of relevant procedures.

4.2.2 Quality manual

This Quality Manual has been prepared to describe Innovative Control Systems 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

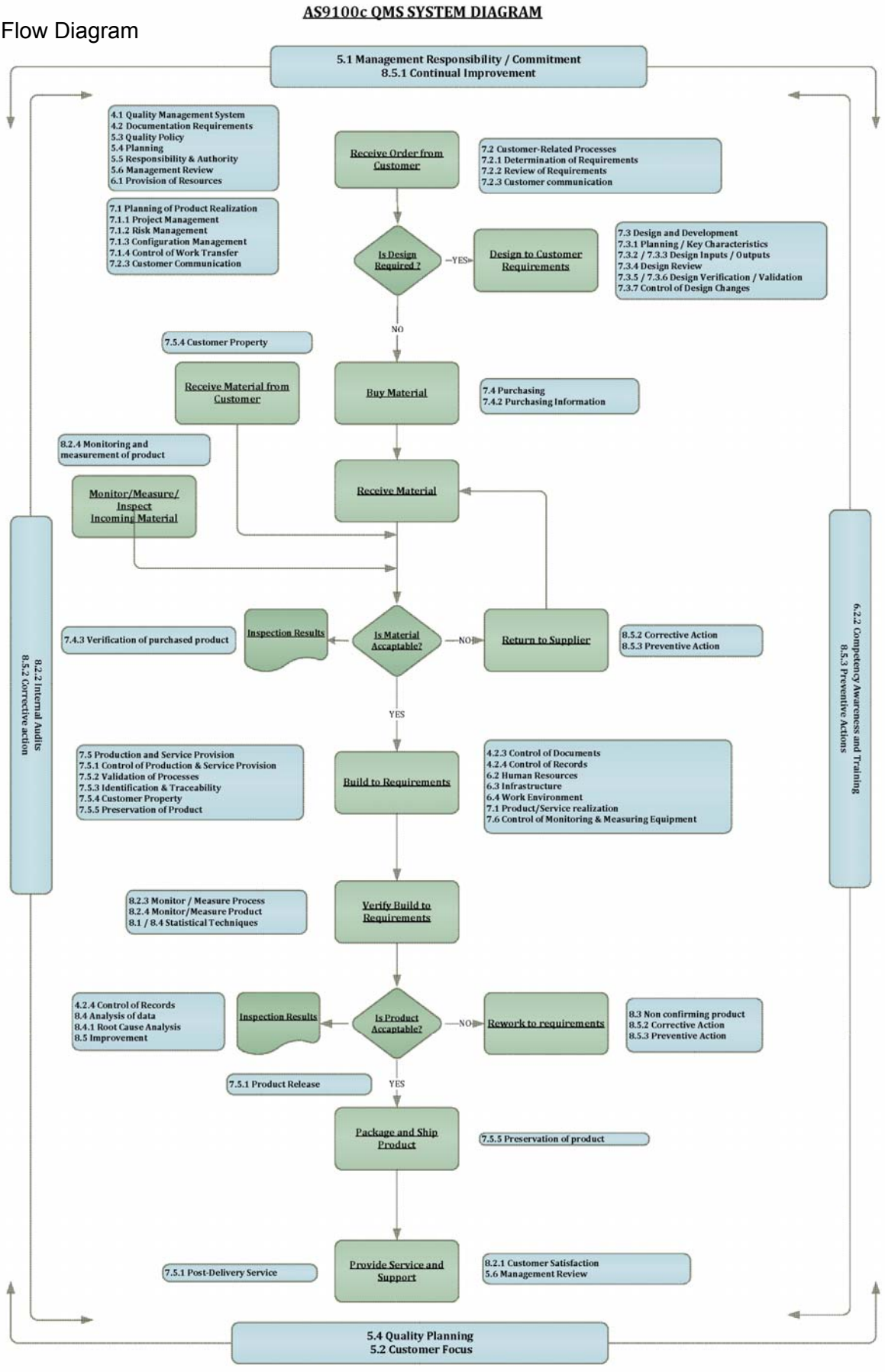
All of the QMS documents are controlled according to the Document Control Procedure (AP-423). This procedure defines the process for:

- 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 (statutory and regulatory) 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.
- Obtaining customer / statutory and regulatory agency approvals when required by contract or statutory and regulatory requirements
- Coordinating document changes with customers or statutory and regulatory authorities in accordance with contract or statutory and regulatory requirements.
- The requirement that external documents needed for the QMS are identified & distribution is controlled, stamps are used as a method of control.

4.2.4 Control of quality records

Quality records are controlled 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 Quality Records Procedure (AP-424). This procedure requires that quality records remain legible, readily identifiable and retrievable. Records are available for review by customers and statutory and regulatory authorities in accordance with contract or statutory and 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 / statutory and regulatory agencies when required by contract or statutory and regulatory requirements.

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 annual management reviews.
- Ensure the availability of resources.

5.2 Customer Focus

Innovative Control Systems strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

Top management ensures that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not achieved or will not be achieved.

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 (SP-720).

5.3 Quality Policy

Top management ensures that the quality policy is communicated to all employees. It is included in new employee training and 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. The Quality Policy is documented on A-500-001, 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 *annually* for suitability. Objectives have been established for *each department and team.* Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

Quality Objectives are documented in the Quality Policy document A-500-001.

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 AS 9100C 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. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions 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 (attachment A-550-001) is located on page 5 of this manual.*

5.5.2 Management representative

The Quality Manager has been appointed by top management as the management representative. As management representative, they have the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS and
- Resolve matters pertaining to quality issues
- Organizational freedom and unrestricted access to top management to resolve matters pertaining to quality.

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 annually at management review meetings. This review assesses the continuing QMS suitability, adequacy and 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
- 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:

Customer Related Processes	SP-720
Management Responsibility	AP-500

Section 6

Resource Management

6.1 Provision of Resources

Innovative Control has implemented a Quality Management System that complies with the AS9100C standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To enhance customer satisfaction and 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 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 ensure that the competence has been achieved. Training and evaluation are conducted according to the Training procedure. (AP-622)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 Innovative Control Systems has determined the infrastructure needed (EP-630). The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be documented in quality plans. Existing infrastructure is maintained to ensure product conformity. Maintenance requirements are documented in:

- Preventive maintenance plans
- Sanitation plans
- Building maintenance plans

6.4 Work Environment

A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the quality plan. 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.

Related Documents

Competence, Awareness and Training	AP-622
Infrastructure	EP-630

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, or according to the Planning of Product Realization procedure (P-710). During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product,
- Processes, documentation and resources required
- Verification, validation, monitoring, measuring, inspection and test requirements
- Configuration management.
- Criteria for product acceptance
- Resources necessary to support use 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.

7.1.1 Project Management

Management assigns responsibility for project management and ensuring that product realization is planned and managed in a controlled manner, meeting requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

Risks are managed according to the Risk Management procedure (MP-712). The process of risk management includes;

- Assigning responsibility for risk management
- Defining risk criteria
- Identification, assessment and communication of risks
- Identification, implementation and management of actions to mitigate risks
- Acceptance of risks remaining after implementation of mitigating actions

7.1.3 Configuration Management

The organization has established, documented and maintains a configuration management process that is appropriate to the product. Configuration management is defined in MP-713, Configuration Management. The procedure defines the process for:

- Configuration management planning
- Configuration identification
- Change control
- Configuration status accounting
- Configuration audit

7.1.4 Control of Work Transfers

Temporary or permanent transfer of work is planned to control and verify the conformity of the work to requirements. Planning of work transfers, for example, from one company facility to another, from the company to a supplier, from one supplier to another, takes place according to the Planning of Realization Processes procedure (MP-710) and coordination with the purchasing department with purchasing procedure (AP-740).

7.2 Customer-Related Processes

7.2.1 Determination of requirements related to the product

Innovative Control Systems 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 and special requirements related to the product
- Additional requirements determined by Innovative Control Systems.

Customer requirements are determined according to the Customer Related Processes Procedure. (SP-720)

7.2.2 Review of requirements related to the product

Innovative Control Systems has a process in place for the review of requirements related to the product (SP-720). 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
- Innovative Control Systems 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
- Contractual requirements are reviewed and special product requirements are determined
- When product requirements are changed, Innovative Control Systems communicates changes to relevant personnel and amends relevant documents
- Risks (e.g., new technology, short delivery time scale) have been evaluated (MP-712).

7.2.3 Customer communication

Innovative Control Systems has implemented an effective procedure (SP-720) for communicating with customers in relation to:

- Product Information
- Enquiries, contracts and order handling, including amendments
- Customer Feedback, including customer complaints

7.3 Design and Development

7.3.1 Design and development planning

The design and development procedure (EP-730) outlines the process for controlling the design and development process. The R&D Department plans design and development according to this procedure. The design plan includes:

- Design and development stages
- Required design reviews, verification and validation appropriate to each design stage
- Responsibilities and authorities for design and development.
- The division of the design effort into distinct activities where appropriate

- The tasks, resources, responsibilities, design content, input, output and planning constraints for each activity
- The ability to produce, inspect, test and maintain the product
- 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 statutory and regulatory authority requirements.

7.3.2 Design and development inputs

Inputs relating to product requirements are determined and documented according to the Design and Development procedure (EP-730). 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 according to the Design and Development Procedure (EP-730). 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, production and for service provision
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use.
- Identify critical items such as key characteristics in accordance with design or contract requirements (EP-731) and action to be taken for these items

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained is defined by the organization according to the Design and Development Procedure (EP-730)

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 recorded in minutes of the design review meetings 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 according to the Design and Development procedure (EP-730).

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 Design and 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

7.3.6.2 Documentation of Design and 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.

7.3.7 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. .Changes are controlled according to the Configuration Management Procedure. (EP-713)

7.4 Purchasing

7.4.1 Purchasing process

A documented procedure (AP-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.

Responsibilities and criteria for selection, evaluation and re-evaluation, status and status change and risk analysis are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records. The organization is responsible for the quality of all products purchased from suppliers, including customer-designated sources.

This is done following our documented Purchasing procedure and includes:

- Maintaining a register of suppliers
- Reviewing supplier performance
- Defining action to take when suppliers do not meet requirements
- Ensuring that our company and suppliers use customer-approved special process sources
- Defining responsibility, authority and the process for approval status decisions, changes of status, and conditions for controlled use of a supplier
- Determining and managing the risk when selecting and using suppliers

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7.4.2 Purchasing information

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

- Requirements for approval of product, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements outlined in the Purchasing Procedure (AP-740)
- Identification and revision status of documentation and relevant technical data

- Requirements for design, test, inspection, verification, use of statistical techniques for product acceptance and related instructions, critical items including key characteristics
- Requirements for test specimens, design approval, inspection/verification, investigation or auditing
- Requirements for the supplier to notify of nonconforming product, obtain approval for nonconforming product disposition, notify of changes in product or process, changes of suppliers, changes of manufacturing facility location, and flow down requirements to the supply chain
- Records retention
- Right of access to areas of the facilities and records

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 (AP-740) 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 Innovative Control Systems 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 and Service Provision

7.5.1 Control of production and service provision

Innovative Control Systems plans and carries out production and service provision under controlled conditions according to documented procedure (MP-750). 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 equipment
- The implementation of monitoring and measurement

- The implementation of release, delivery and post-delivery activities
- The accountability for all product during production (e.g., parts quantities, split orders, nonconforming product to account that scrap parts have been destroyed
- The evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,
- The provision for the prevention, detection, and removal of foreign objects,
- The 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).

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
- Special processes (see 7.5.2)..

7.5.1.1 Production Process Verification

Production processes are verified using a representative item form the first production run of a new part or assembly to verify that the process and tooling are capable of producing conforming parts. Verification is repeated when changes occur that could invalidate the original results.

7.5.1.2 Control of Production Process Changes:

Authorized people for approving changes to production processes are identified in the Procedure MP-750. Innovative Control Systems controls and documents changes affecting processes, production equipment, tools and software programs according to this procedure.

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 Software Programs

Production equipment, tools and programs are validated prior to use and maintained and inspected periodically according to documented procedures. 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.

7.5.1.5 Post-Delivery support

Where post-delivery support 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 statutory and 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

Innovative Control Systems validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these special processes to achieve planned results.

Innovative Control Systems has documented the process for validation including:

- Defined criteria for review and approval of the processes
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures,
- Requirements for records
- Revalidation

7.5.3 Identification and traceability

Innovative Control Systems identifies the product throughout product realization according to the Identification and Traceability procedure (MP-753).

- Innovative Control Systems maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.
- Product status is identified with respect to monitoring and measurement requirements.
- When acceptance authority media such as stamps, electronic signatures or passwords are used Innovative Control Systems establishes and documents controls for the media.
- According to the level of traceability required by contract, statutory and regulatory, or other established requirement, Innovative Control Systems 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;
- For a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

Innovative Control Systems controls and records the unique identification of the product where ever traceability is a specified requirement

7.5.4 Customer property

Innovative Control Systems exercises care with customer property while it is under the organization's control or being used. A procedure (MP-754) outlines the Identification, verification, protection and safeguarding of customer property provided for use.

If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained. NOTE: Customer property can include intellectual property and, personal data, including customer furnished data used for design, production and/or inspection.

7.5.5 Preservation of product

preserves the product during internal processing and delivery to the intended destination per procedure (MP-755). 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;
- Special handling for sensitive products;
- Marking and labeling including safety warnings;
- Shelf life control and stock rotation;
- Special handling for hazardous materials.

7.6 Control of Monitoring and Measuring Equipment

Innovative Control Systems has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

A register of monitoring and measuring equipment is maintained and the documented procedure (QP-760) outlines 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, verified or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.
- Adjusted or re-adjusted as necessary
- 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 Control assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Innovative Control Systems takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

Innovative Control Systems maintains a register of this monitoring and measuring equipment. The process used for their calibration is defined in procedures, work instructions 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.

Innovative Control Systems ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Related Documents

Planning of Product Realization Processes MP-710

Risk Management MP-712

Configuration Management MP-713

Customer Related Processes SP-720

Design and Development EP-730

Key Characteristics EP-731

Purchasing AP-740

Control of Production and Service Provision MP-750

Identification and Traceability MP-753

Customer Property MP-754

Preservation of Product MP-755

Control of Monitoring and Measuring Equipment QP-760

Section 8

Measurement, Analysis and Improvement

8.1 General

Innovative Control Systems 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. The processes for monitoring, measurement, analysis and improvement are planned and implemented to demonstrate conformity to product requirements.

NOTE

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

- Design verification (e.g., reliability, maintainability, safety);
- Process control:
- Selection and inspection of key characteristics;
- Process capability measurements;
- Statistical process control;
- Design of experiment;
- Inspection - matching sampling rate to the criticality of the product and to the process capability;
- Failure mode and effect analysis.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Innovative Control Systems monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The information monitored and used for the evaluation of customer satisfaction includes, and is not limited to product conformity, on-time delivery performance, customer complaints and corrective action requests. Improvements that address deficiencies are planned and implemented and the effectiveness of results assessed.

The method for obtaining and using this information is identified in the Customer Related Processes (SP-720), Monitoring, Measuring and Analysis of Customer Satisfaction (AP-821) and the Management Responsibility procedure (AP-500).

8.2.2 Internal Audit

Innovative Control Systems 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 (QP-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.

8.2.3 Monitoring and measurement of processes

Innovative Control Systems 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, to ensure conformity of the product. In the event of process nonconformity, the organization follows the Control of Nonconforming Product and Process procedure (QP-830) and:

- Takes appropriate action to correct the nonconforming process,
- Evaluates whether the process nonconformity has resulted in product nonconformity,
- Determines the scope of the process nonconformity,
- Determines if the process nonconformity is limited to a specific case or if it could have affected other processes or products, and
- Identifies and controls the nonconforming product in accordance with clause 8.3.

The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Monitoring, Measuring and Analysis of Product Realization Processes (MP-824) and Management Responsibility procedures (AP-500).

8.2.4 Monitoring and measurement of product

Innovative Control Systems 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 identified in Monitoring, Measuring and Analysis of Product Realization Processes (MP-824). Evidence of conformity with the acceptance criteria is maintained.

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.

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.

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released unless it is identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Records indicate the person authorizing release of product, and provide evidence that the product meets requirements.

When required to demonstrate product qualification, records provide the evidence that defined requirements are met.

Innovative Control Systems ensures that documents required by the contract or order to accompany the product are present at delivery and procedures implemented for the preparation and completion of Authority documentation.

8.3 Control of Nonconforming Product and Process

Innovative Control Systems 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 (QP-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.

This process includes:

- Appropriate action to eliminate the nonconformity
- Disposition of the nonconforming material
- Taking action to control the material, precluding its original use
- Taking appropriate action when nonconforming product is detected after delivery
- Taking actions to contain the effect on other processes or products.

Corrected nonconforming product is re-verified and product dispositioned for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

In addition to any contract or statutory and regulatory authority reporting requirements, Innovative Control Systems 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.

Use-as-is disposition is only used with authorization by a representative of the design. The organization also 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
- The nonconformity results in a departure from the contract requirements.

NOTE Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.

8.4 Analysis of Data

Innovative Control Systems 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 is defined in the Management Responsibility procedure (AP-500). Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources. Analysis is performed using Statistical Techniques (QP-840)

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

8.5 Improvement

8.5.1 Continual improvement

Innovative Control Systems 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. Management monitors the implementation of improvement activities and evaluates the effectiveness of results (AP-500).

8.5.2 Corrective action

Innovative Control Systems 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 (QP-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 the effectiveness of the 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,
- Specific actions where timely and/or effective corrective actions are not achieved,
- Identification of additional nonconforming product,
- Root cause is determined as needed (QP-841)

8.5.3 Preventive action

Innovative Control Systems 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.

A documented procedure (QP-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 the effectiveness of the preventive action taken

Related Documents

Management Responsibility AP-500

Customer Related Processes SP-720

Monitoring, Measuring and Analysis of Customer Satisfaction AP-821

Internal Audits QP-822

Monitoring and Measuring of Product and Realization Processes MP-824

Control of Nonconforming Product QP-830

Statistical Techniques QP-840

Root Cause Analysis QP-841

Corrective Action QP-852

Preventive Action QP-853

QUALITY SYSTEM MANUAL REVISIONS

REV.	SECTION	SUB-SEC.	PARA.	CHANGE REQUEST #	DATE	AUTHORIZED BY
A	ALL	ALL	ALL	Initial Creation	06-2009	K. W. Jacobson
B	1	1.2	2	1015091	10-16-09	K. W. Jacobson
B	5	5.2	ALL	1015091	10-16-09	K. W. Jacobson
C	1	1.1		Modification of Scope	03-24-10	K. W. Jacobson
C	1	1.2		Modification of Application to Exclusions	03-24-10	K. W. Jacobson
D	ORG CHART			201009031	09-03-10	K. W. Jacobson
E	1	1.2		Typo in Exclusions section Specified Exclusion was 7.1.15 and should have been 7.5.1.5	03-07-11	K. W. Jacobson
E	7	7.5.1.4	All	Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities needed additional definition	03-07-11	K. W. Jacobson
F	All	All	All	AS9100 Rev C modifications to QM.	03-07-12	K. W. Jacobson
G	4.2	4.2.4	Diagram	Updated QMS System Diagram	03-20-12	K. W. Jacobson