

Quality

Manual

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1 Introduction

1.1 Purpose of St. Vrain Manufacturing, Incorporated

St. Vrain Manufacturing, Incorporated, is a product and service providing organization. St. Vrain Manufacturing, Incorporated offers compressed delivery on manufacturing of high precision, machined parts, made from metals and other exotic materials.

1.2 Scope of this Document

This document establishes company policy, process requirements and operational procedures for the St. Vrain Manufacturing quality management system. This quality management system is prepared, implemented and maintained in accordance with the requirements of SAE AS9100, with the exclusion of the design element.

1.3 Quality Policy

The quality policy is reviewed during the Management Review meeting. The goal of the review is to ensure continued suitability of the St. Vrain Manufacturing quality management system to provide customer satisfaction by meeting and exceeding customer expectations. The quality policy is document number QM-001-2.

1.4 Quality Objectives

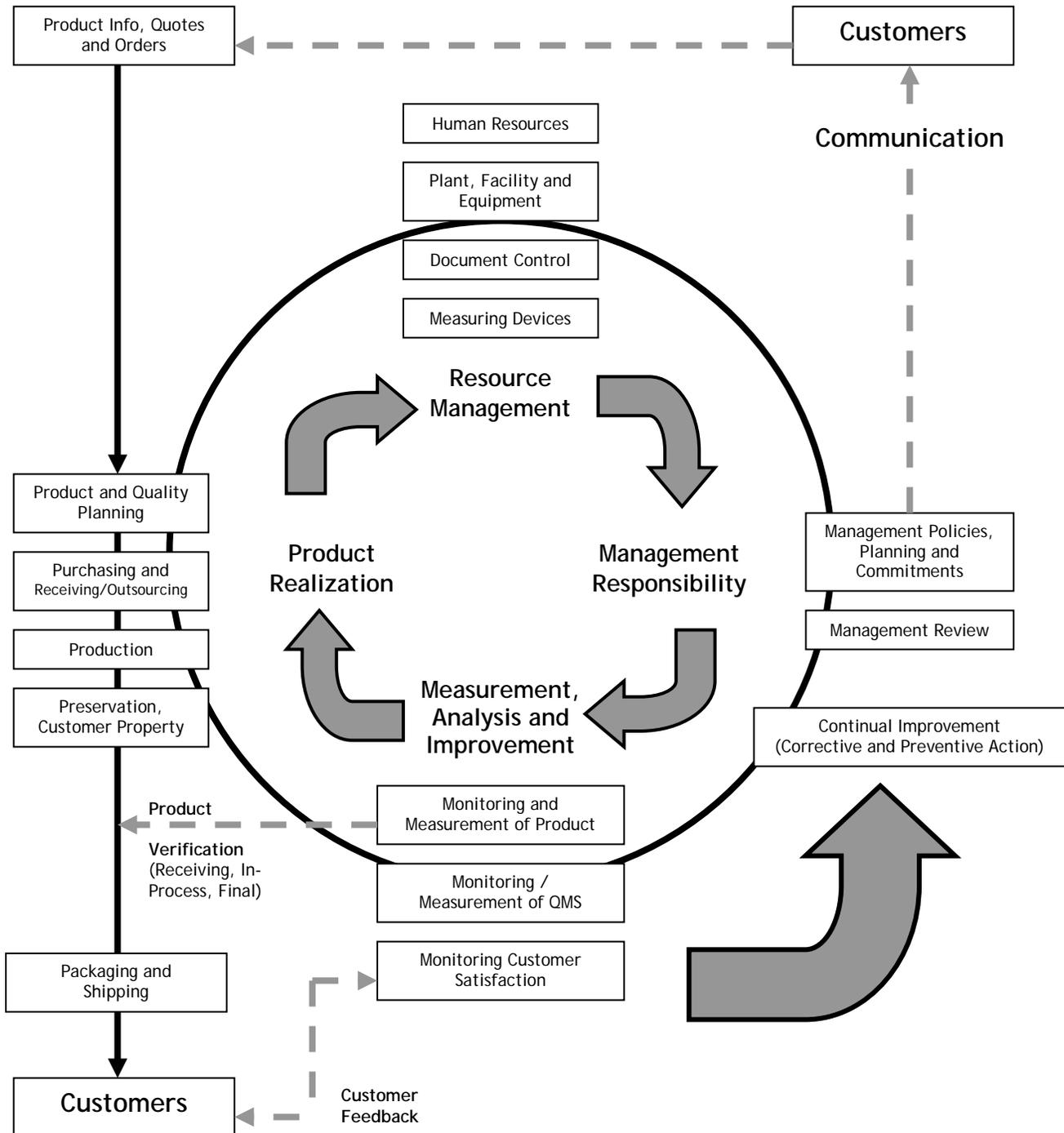
Objectives for the quality management system have been communicated through the president of St. Vrain Manufacturing. These measurable quality objectives include:

- product conformance at 98% or better
- on time delivery at 90%
- customer satisfaction at level 9 of 10 or better

1.5 Customer Focus

The St. Vrain Manufacturing vision is to be our customer's preferred "Supplier-of-Choice" by striving to be the best at what we do. St. Vrain Manufacturing will build and maintain a relationship with our suppliers and customers to ensure that quality is never compromised.

1.6 Product Realization Process
Quality Process Interface Map



2 Reference Documents

2.1 ISO Documents

- ISO 9001 : 2008 QMS - Requirements

2.2 St. Vrain Manufacturing - Primary Documents

* AS9100 Required

- AS-QMS-002 * Document Control
- AS-QMS-003 * Record Control
- AS-QMS-004 * Internal Audits
- AS-QMS-005 * Nonconforming Product
- AS-QMS-006 * Corrective Action
- AS-QMS-007 * Preventive Action

2.3 Other Documents

- ASME Y14.5 Dimensioning and Tolerancing
- Machinery's Handbook, Industrial Press Inc.

3.0 Deleted

4 Quality Management System

4.1 General Requirements

In accordance with the requirements of the SAE AS9100, St. Vrain Manufacturing has established, documented, implemented and maintains a quality management.

St. Vrain Manufacturing has:

- identified the processes needed for the quality management system and their application throughout the organization
- determined the sequence and interaction of the processes
- determined criteria and methods needed to ensure that both the operation and control of these processes are effective
- ensured the availability of resources and information necessary to support the operation and monitoring of these processes
- implemented systems to monitor, measure and analyze these processes
- implemented actions necessary to achieve planned results and continual improvement of these processes

When St. Vrain Manufacturing chooses to outsource any process that affects product conformity to requirements, St. Vrain Manufacturing has ensured control over such process. Type and extent of control to be applied to these outsourced processes have been identified within the quality management system.

4.2 Documented Requirements

4.2.1 General

St. Vrain Manufacturing's quality management system's documentation includes:

- documented statements of a quality policy and quality objectives
- a quality manual
- documented procedures required by the SAE AS9100
- documents needed by the organization to ensure the effective planning, operation and control of its processes
- quality records required by the SAE AS9100
- any additional quality system requirements imposed by the customer and/or applicable regulatory authorities as the need arises

St. Vrain Manufacturing ensures all company personnel have access to, and are aware of, relevant quality management system documentation and changes.

4.2.2 Quality Manual

St. Vrain Manufacturing has established and maintains a quality manual that includes:

- the scope of the quality management system, including details and justification for any exclusions (refer to Section 1.2 of SAE AS9100)
- the documented procedures established for the quality management system, or reference to them - when referencing the documented procedures, the relationship between the requirements of AS9100 and the documented procedures are clearly shown
- a description of the interaction between the processes of the quality management system

4.2.3 Control of Documents

St. Vrain Manufacturing's documents required by the quality management system are controlled. St. Vrain Manufacturing recognizes quality records as a special type of document and they are controlled according to requirements given in Section 4.2.4.

The documented procedure, AS-QMS-002 Document Control, defines controls needed:

- to approve documents for adequacy prior to issue
- to review and update as necessary and re-approve documents
- to ensure that changes and the current revision status of documents are identified
- to ensure that relevant versions of applicable documents are available at points of use
- to ensure that documents remain legible and readily identifiable
- to ensure that documents of external origin are identified and their distribution controlled
- to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose
- to coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements

4.2.4 Control of Quality Records

St. Vrain Manufacturing has established and controls quality records for the purpose of providing evidence of conformity to requirements and of the effective operation of the quality management system. The documented procedure, AS-QMS-003 Record Control, defines controls needed.

Quality records shall:

- remain legible
- be readily identifiable
- retrievable
- have needed controls for identification, storage, protection, retrieval, retention time and disposition of quality records

The documented procedure, AS-QMS-003 Record Control, defines the methods for controlling records that are created by and/or retained by suppliers.

All applicable records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

5 Management Responsibility

5.1 Management Commitment

St. Vrain Manufacturing's top management provides evidence of commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- communicating to the organization the importance of meeting customer, statutory and regulatory requirements
- establishing the quality policy
- ensuring that quality objectives are established
- conducting management reviews
- ensuring the availability of resources

5.2 Customer Focus

St. Vrain Manufacturing's top management ensures that customer needs and expectations are:

- determined
- converted into requirements
- fulfilled with the aim of achieving customer satisfaction

See Sections 7.2.1 and 8.2.1.

5.3 Quality Policy

St. Vrain Manufacturing's top management ensures that the quality policy:

- is appropriate to the purpose of the organization
- includes a commitment to comply with the requirements and continually improve the effectiveness of the quality management system
- provides a framework for establishing and reviewing quality objectives
- is communicated and understood within the organization
- is reviewed for continuing suitability

Refer to QM-001-2 for full text of St. Vrain Manufacturing's quality policy.

5.4 Planning

5.4.1 Quality Objectives

St. Vrain Manufacturing's top management ensures that quality objectives (see Section 1.4 and Section 7.1) are:

- established
- measurable
- consistent with the quality policy
- adequate for meeting all product requirements
- established at relevant functions/levels within the organization

5.4.2 Quality Management System Planning

St. Vrain Manufacturing's top management ensures that:

- the planning of the quality management system is carried out in order to meet the requirements given in Section 4.1, as well as the quality objectives in Section 1.4
- the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

St. Vrain Manufacturing's top management ensures that functions and interrelationships, including responsibilities and authorities are:

- defined
- communicated within the organization

This is accomplished through the use of:

- job descriptions
- organization charts
- performance appraisals

5.5.2 Management Representative, Quality Manager

St. Vrain Manufacturing's top management has appointed a member of management, with the title of Quality Manager, who, irrespective of other responsibilities, has responsibility and authority to:

- ensure that processes needed for the quality management system are established, documented, 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
- act as liaison with external parties on matters relating to the quality management system
- the organizational freedom and unrestricted access to top management to resolve quality management issues

5.5.3 Internal Communications

St. Vrain Manufacturing's top management ensures that appropriate communication processes are established between various levels and functions within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 General

St. Vrain Manufacturing's top management reviews the quality management system once a year to:

- ensure its continuing suitability
- adequacy
- effectiveness
- assess opportunities for improvement
- evaluate the need for changes to the quality management system, including the quality policy and quality objectives

5.6.2 Review Input

Management review input includes:

- results of internal and external audits
- customer feedback
- process performance and product conformity
- 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

Results from the Management Review Meeting are recorded on Form SVM-013

5.6.3 Review Output

Information output from management review to appropriate recipients includes any decisions and actions related to:

- improvement of the effectiveness of the quality management system and its processes
- improvement of product related to customer requirements
- resources needed

6 Resource Management

6.1 Provisions of Resources

St. Vrain Manufacturing studies processes, determines and provides the resources needed:

- to implement and maintain the quality management system
- to continually improve quality management system effectiveness
- to enhance customer satisfaction by meeting customer requirements

6.2 Human Resources

6.2.1 General

St. Vrain Manufacturing personnel performing work affecting conformity to product requirements are competent to process the work based on appropriate education, training, skills and experience.

6.2.2 Competence, Awareness and Training

St. Vrain Manufacturing:

- documents the necessary competence for personnel performing work affecting conformity to product requirements through job descriptions
- provides training and take other actions necessary to achieve the necessary competence through internal and external programs
- evaluates the effectiveness of actions taken through testing
- ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives
- maintains appropriate records of education, training, skills and experience (see Section 4.2.4) including skills matrices, certifications, tests, and travelers

6.3 Infrastructure

St. Vrain Manufacturing has determined, provides and maintains the infrastructure needed to achieve conformity to product requirements. Documentation is in the form of maintenance and calibration records. The infrastructure at St. Vrain Manufacturing includes:

- building, workspace and associated utilities
- process equipment including hardware and software
- supporting services including transportation, communication and information systems

6.4 Work Environment

St. Vrain Manufacturing has determined and manages the work environment necessary to achieve conformity to product requirements.

7 Product Realization

7.1 Planning of Product Realization

St. Vrain Manufacturing plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system (see Section 4.1).

In planning product realization, St. Vrain Manufacturing determines the following, as appropriate:

- quality objectives and requirements for the product, such as
 - product and personal safety
 - reliability, availability and maintainability
 - producibility and inspectability
 - suitability of parts and materials used in product
 - selection and development of embedded software
 - recycling or final disposal of the product at the end of its life
- the need to establish processes, documents and provide resources specific to the product
- required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance
- records needed to provide evidence that the realization processes and resulting product fulfill requirements (see Section 4.2.4)
- the identification of resources to support operation and maintenance of the product

The output of this planning is the E2 traveler containing routing suitable for the St. Vrain Manufacturing method of operation.

The traveler is based on the processes of the quality management system (including the product realization processes) and the resources applied to a specific product, project or contract. This document is also referred to as the quality plan.

7.1.1 Project Management

As appropriate to St. Vrain Manufacturing and the product, St. Vrain Manufacturing plans and manages product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

St. Vrain Manufacturing has established implemented and maintains a process for managing risk to the achievement of applicable requirements that include, as appropriate to the organization and the product:

- assignment of responsibility for risk management is given to personnel performing the quoting process on new and revised part numbers and product
- definition of risk criteria, including likelihood, consequences and risk acceptance
- identification, assessment and communication of risk throughout product realization
- identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria
- acceptance of risks remaining after implementation of mitigating actions

7.1.3 Configuration Management

St. Vrain Manufacturing has established implemented and maintains a configuration management process that includes, as appropriate to the product:

- configuration management planning
- configuration identification
- change control
- configuration status accounting
- configuration audit

7.1.4 Control of Work Transfers

St. Vrain Manufacturing has established, implemented and maintains a process to plan and control temporary or permanent transfer of work and to verify conformity of the work requirements.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

St. Vrain Manufacturing has determined:

- requirements specified by the customer, including the requirements for delivery and post-delivery activities
- requirements not stated by the customer but necessary for specified use or known and intended use
- statutory and regulatory requirements related to the product
- there may be additional requirements, yet to be identified, that St. Vrain Manufacturing will satisfy upon discovery, as related to the customer's product
- the customer is responsible for and must specify applicable ITAR and DFAR requirements

7.2.2 Review of Requirements Related to the Product

St. Vrain Manufacturing reviews the requirements related to the product. This review is conducted prior to St. Vrain Manufacturing's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that:

- product requirements are defined
- contract or order requirements differing from those previously expressed are resolved
- St. Vrain Manufacturing has the ability to meet the defined requirements
- Special requirements of the product are determined
- Risks (e.g., new technology, short delivery time scale) have been evaluated

Records of the results of the review and actions arising from the review are maintained in the E2 data base (see Section 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by St. Vrain Manufacturing before contract acceptance.

Where product requirements are changed, St. Vrain Manufacturing ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication

St. Vrain Manufacturing has determined and implemented effective arrangements for communicating with customers in relation to:

- product information
- enquiries, contracts or order handling, including amendments
- customer feedback, including customer complaints

7.3 Design and Development - Note the following exclusion

St. Vrain Manufacturing does not perform product design and claims exclusion from the requirements of Section 7.3, Design and Development.

7.4 Purchasing

7.4.1 Purchasing Process

St. Vrain Manufacturing ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

St. Vrain Manufacturing is responsible for the conformity of all products purchased from suppliers, including customer-designated sources

St. Vrain Manufacturing evaluates and selects suppliers based on their ability to supply product in accordance with St. Vrain Manufacturing requirements. Criteria for selection, evaluation and re-evaluation is established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained (see Section 4.2.4). Refer to AS-QMS-009, Purchasing Critical Materials.

St. Vrain Manufacturing:

- maintains a register of approved suppliers that includes the scope of approval
- periodically reviews supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented
- defines the necessary actions to take when dealing with suppliers that do not meet the requirements
- ensures where required that both St. Vrain Manufacturing and all suppliers use customer-approved special process sources
- ensures that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources
- determines and manages the risk when selecting and using suppliers

7.4.2 Purchasing Information

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

- requirements for approval of product, procedures, processes and equipment
- requirements for qualification of personnel
- quality management system requirements
- the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data
- requirements for design, test, examination, inspection and related instruction for acceptance by St. Vrain Manufacturing
- requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection investigation or auditing
- requirements relative to supplier notification to St. Vrain Manufacturing of nonconforming product
- requirements relative to arrangements for St. Vrain Manufacturing approval of supplier nonconforming material
- requirements for the supplier to notify St. Vrain Manufacturing of changes in product and/or process definition, changes of manufacturing facility location and, where required, obtain St. Vrain Manufacturing's approval
- flow down to the supply chain the applicable requirements including customer requirements
- record retention requirements
- right of access by St. Vrain Manufacturing, our customer, and regulatory authorities to all facilities involved in the order and to all applicable records
- requirements for the supplier to flow down to sub-tier suppliers the applicable requirements, including records retention requirements, in the purchasing documents, including key characteristics when required

St. Vrain Manufacturing ensures the adequacy of specified purchase requirements prior to communication with the supplier.

St. Vrain Manufacturing plans and carries out production and service provisions under controlled conditions. Controlled conditions shall include, as applicable:

- the availability of information that describes the characteristics of the product, including drawings, parts lists, materials and process specifications
- the availability of work instructions, production documents, travelers, work orders, and inspection documentation
- the use of suitable equipment
- the availability and use of monitoring and measuring devices
- the implementation of monitoring and measurement
- the implementation of product release, delivery and post-delivery activities
- accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product)
- evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized
- provisions for the prevention, detection, and removal of foreign objects
- monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality
- criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations)

Planning may also consider, as appropriate:

- establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified
- designing, manufacturing and using tooling to measure variable data
- identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization
- special processes

7.5.1.1 Production Process Verification - First Article Inspection

St. Vrain Manufacturing uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process is repeated when changes occur that invalidate the original results. These changes can include, but not be limited to:

- engineering changes
- manufacturing process changes
- tooling changes
- raw material changes
- special process changes

7.5.1.2 Control of Production Process Changes

Personnel authorized to approve changes to the production processes are identified.

St. Vrain Manufacturing identifies and obtains acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

Changes affecting processes, production equipment, tools and programs are documented. Procedures exist to control their implementation.

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

Personnel authorized to approve changes to production processes are identified.

St. Vrain Manufacturing controls and documents changes affecting:

- processes
- production equipment
- tools
- software programs

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

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and software programs used to automate control/monitor product realization processes are validated prior to release for production and are maintained for review and future recall.

Storage requirements, including periodic preservation/condition checks are defined for production equipment or tooling in storage.

7.5.1.4 Post-Delivery Support

Post-delivery support is provided as applicable for the

- collection and analysis of in-service data
- actions to be taken, including investigation and reporting, when problems are detected after delivery
- controlling and updating of technical documentation
- approval, control and use of repair schemes
- controls required for off-site work such as St. Vrain Manufacturing's work undertaken at the customer's facility

7.5.2 Validation of Processes for Production and Service Provision

St. Vrain Manufacturing validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any process where deficiencies become apparent only after the product is in use or the service has been delivered.

- these processes are often referred to as special processes

Validation demonstrates the ability of the process to achieve planned results.

St. Vrain Manufacturing established arrangements for these processes including, as applicable:

- defined criteria for review and approval of the process followed by qualification and approval of special processes prior to use
- approval of equipment and qualification of personnel
- use of specific methods and procedures in assuring control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto
- requirements for records (see Section 4.2.4)
- revalidation

Refer to AS-QMS-009, Purchasing Critical Materials.

7.5.3 Identification and Traceability

Where appropriate, St. Vrain Manufacturing identifies the product by suitable means throughout product realization. Refer to AS-QMS-009, Purchasing Critical Materials.

St. Vrain Manufacturing maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

St. Vrain Manufacturing identifies the product status with respect to monitoring and measurement requirements on the traveler.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), St. Vrain Manufacturing established and documented controls for the media.

Where traceability is a requirement, St. Vrain Manufacturing controls and records the unique identification of the product (see Section 4.2.4).

According to the level of traceability required by a contract, regulatory, or other established requirement, St. Vrain Manufacturing's 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
- an assembly, the identity of its components and those of the next higher assembly to be traced
- a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved

7.5.4 Customer Property

St. Vrain Manufacturing exercises care with customer property while it is under St. Vrain Manufacturing's control or being used by St. Vrain Manufacturing. St. Vrain Manufacturing identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this condition is reported to the customer and records maintained (see Section 4.2.4).

7.5.5 Preservation of Product

St. Vrain Manufacturing preserves the conformity of product during internal processing and delivery to the intended destination. 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. See FOD, AS-QMS-020
- special handling for sensitive products
- marking and labeling including safety warnings
- shelf life control and stock rotation
- special handling for hazardous materials

St. Vrain Manufacturing ensures that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

7.6 Control of Monitoring and Measuring Devices

St. Vrain Manufacturing determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence on conformity of product to determined requirements (see Section 7.2.1). See Calibration, AS-QMS-011.

St. Vrain Manufacturing maintains a register of these monitoring and measuring devices, and defines the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

St. Vrain Manufacturing establishes processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

St. Vrain Manufacturing ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Where necessary to ensure valid results, measuring equipment is:

- calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded
- 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 to a defined method when requiring calibration

St. Vrain Manufacturing established, implemented and maintains an automatic calibration recall system for the recall of monitoring and measuring equipment requiring calibration or verification.

In addition, St. Vrain Manufacturing assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. St. Vrain Manufacturing takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained (see Section 4.2.4).

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

8 Measurement, Analysis and Improvement

8.1 General

St. Vrain Manufacturing plans and implements the monitoring, measurement, analysis and improvement processes needed:

- to demonstrate conformity of the product to requirements
- to ensure conformity of the quality management system
- to continually improve the effectiveness of the quality management system

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

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, St. Vrain Manufacturing monitors information relating to customer perception as to whether St. Vrain Manufacturing has fulfilled customer requirements. Data is gathered via a yearly survey that is sent to all customers (Customer Survey Information, Form SVM-007)

Information to be monitored and used for evaluation of customer satisfaction includes, but is not limited to:

- product conformity
- on time delivery performance
- customer complaints
- corrective action requests

8.2.3 Monitoring and Measurement of Processes

St. Vrain Manufacturing 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 actions are taken, without undue delay, to ensure conformity of the product is achieved.

In the event of process nonconformity, St. Vrain Manufacturing:

- takes appropriate action to correct the nonconforming process
- evaluates whether the process nonconformity has resulted in product nonconformity
- determines if the process nonconformity is limited to a specific case or whether it could have affected other processes or products
- identifies and controls the nonconforming product in accordance with clause 8.3

8.2.4 Monitoring and Measurement of Product

St. Vrain Manufacturing 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 in accordance with the planned arrangements (see Section 7.1). Evidence of conformity with the acceptance criteria is maintained.

Measurement requirements for product acceptance are documented and include:

- criteria for acceptance and/or rejection
- where in the sequence measurements and testing operations are to be performed
- required records of the measurement results (at a minimum, indication of acceptance or rejection)
- any specific measurement instruments required and any specific instructions associated with their use

When key characteristics have been identified, they are monitored and controlled in accordance with established processes.

When St. Vrain Manufacturing uses sampling inspection as a means of product acceptance, the plan shall be based on customer requirements and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability). The plan precludes the acceptance of lots whose samples have nonconformities. When required, the plan is submitted for customer approval.

Product is not be 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.

Evidence of conformity with acceptance criteria is maintained on the traveler and inspection documents. Records indicate the person(s) authorizing release of product (see Section 4.2.4).

Where required to demonstrate product qualification, St. Vrain Manufacturing ensures that records provide evidence that the product meets the defined requirements.

Product release and service delivery do not proceed until all the planned arrangements (see Section 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

8.3 Control of Nonconforming Product

St. Vrain Manufacturing ensures that products, which do not conform to product requirements, are identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product have been defined in a documented procedure, AS-QMS-005 Nonconforming Product.

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

St. Vrain Manufacturing's documented procedure defines the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.

St. Vrain Manufacturing deals with nonconforming product by one or more of the following processes:

- by taking action to eliminate the detected nonconformity
- by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
- by taking action to preclude its original intended use or application
- by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started
- by taking actions necessary to contain the effect of the nonconformity on other processes or products

St. Vrain Manufacturing does not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if:

- the product is produced to customer design
- the nonconformity results in a departure from contract requirements

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

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained on the St. Vrain Manufacturing NCR report and customer documentation as appropriate (see Section 4.2.4).

When a nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, St. Vrain Manufacturing takes action appropriate to the effects, or potential effects, of the nonconformity.

In addition to any contract or regulatory authority reporting requirements, St. Vrain Manufacturing's 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.

8.4 Analysis of Data

St. Vrain Manufacturing determines, collects and analyzes 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. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of the data provides information relating to:

- customer satisfaction survey(see 8.2.1)
- conformance to product requirements on inspection documentation (see 7.2.1)
- characteristics and trends of processes and products including opportunities for preventive action
- supplier on time delivery and quality

8.5 Improvement

8.5.1 Continual Improvement

St. Vrain Manufacturing 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.

St. Vrain Manufacturing monitors the implementation of improvement activities and evaluates the effectiveness of the results.

8.5.2 Corrective Action

St. Vrain Manufacturing 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, AS-QMS-006 Corrective Action, has been established to define 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 actions needed
- records of the results of actions taken (see Section 4.2.4)
- 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
- specific actions where timely and/or effective corrective actions are not achieved
- determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action, when required

8.5.3 Preventive Action

St. Vrain Manufacturing 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, AS-QMS-007 Preventive Action, has been established to define requirements for:

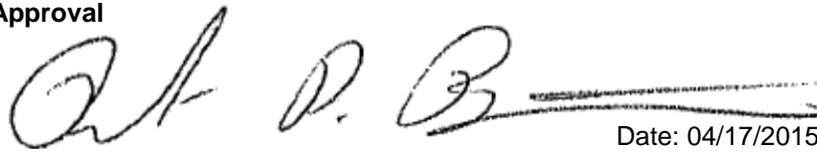
- determining potential nonconformities and their causes
- evaluating the need for action to prevent occurrence of nonconformities
- determining and implementing action needed
- records of results of action taken (see Section 4.2.4)
- reviewing preventive action taken

9 Document Maintenance

Custodian : Quality Assurance Manager
Review Activity : Department Managers
Approval Authority : President
Quality Assurance Manager

10 Document Approval

President
Document Approval
Signature:



Date: 04/17/2015

Quality Manager
Document Approval
Signature:



Date: 04/17/2015
