ST. VRAIN MANUFACTURING

819 S. Lincoln Street
Longmont, CO 80501
(303) 702-1529

I hereby approve the Quality Management System (QMS) described in this Quality Manual (QM), in support of our Quality Policy and Quality Objectives. I am committed to the ongoing development, implementation, and continual improvement of our Quality Management System.

APPROVED BY:	Bob Bergstrom
REVISION:	E
DATE ISSUED:	12/11/2025

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0. Revision History and Approval

Date of Revision	Revision Level	Section Revised	Nature of Revision	Revision Approved by
2/19/2021	A	N/A	Original Issue	B. Bergstrom
3/20/2023	B	8.2.3	Change E2 to JobBOSS2 due to ERP system Change.	Joe Tolbert
2/28/2024	C	8.5.6	Added persons authorized to approve production or service provision changes.	Joe Tolbert
5/15/2024	D	4.2 4.3.2 8.4.1.1	Remove QF-410.03 Opportunities Register and QF-410.04 SWOT Analysis. Remove Wire EDM. Change QF-841.01 Supplier Evaluation Report to Initial Supplier Approval Form.	Joe Tolbert
12/11/2025	E	Page 2, Section 10, 4.3.2,	Remove sections 6.4 and 6.54, Remove QMS from title of section 10, Updated scope in section 4.3.2 to match scope on AS9100 Cert.	Joe Tolbert

1.0 Welcome to St. Vrain Manufacturing

1.1. A strategic decision has been made by senior management to establish a Quality Management System based on AS9100 Revision D, with the aim to support consistent quality management performance outcome, and to provide a sound basis for sustainable processes within our Company. The potential benefits to our Company from implementing a Quality Management System based on AS9100 are:

1.2. The ability to consistently provide products and services that meet or exceed our current and future customer needs and applicable statutory and regulatory requirements;

a) facilitating opportunities to enhance customer satisfaction;

b) addressing risks and opportunities associated with our organizational context and objectives;

c) the ability to demonstrate conformity to all relevant Quality Management System requirements.

1.3. The policies established in this Quality Manual and its scope and purpose are written to conform to the international AS9100 standard as a working document that describes, as a minimum, the Quality Management System to be deployed and at all time maintained at St. Vrain Manufacturing.

1.4. St. Vrain Manufacturing promotes the adoption of a process approach when developing, implementing and improving the effectiveness of the Quality Management System, to ensure to enhance customer satisfaction by meeting customer requirements.

1.5. Management of QMS processes as a whole will be achieved using the PDCA cycle with overall focus on risk-based thinking, aiming to take advantage of opportunities and preventing undesirable results.

1.6. Risk Based Thinking

a) St. Vrain Manufacturing applies the concept of risk-based thinking, as extension of the task known as carrying out preventive action to eliminate potential nonconformities by analyzing any nonconformities that do occur and taking action to prevent recurrence. Risk-based thinking is essential for achieving effective Quality Management System application, as the planning and implementation of actions to address risks and opportunities increases the effectiveness of the Quality Management System, supporting the prevention of negative effects, while leveraging opportunities that can arise as a result of a risk mitigation situations favorable to achieving an intended result within the context of the QMS.

2. Normative References

The following documents are normatively referenced in this document. Only edited content in its latest edition applies including any amendments.

- ISO 9000:2015, Quality Management Systems — Fundamentals and vocabulary
- ISO 9001:2015, Quality Management Systems - Requirements

3. Terms and Definitions

For the purpose of this Quality Manual, the terms and definitions given in ISO 9000:2015 and the following definitions apply to this document:

3.1 Counterfeit Part

An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

3.2 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.3 Key Characteristic

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

3.4 Product Safety

The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

3.5 Special Requirements

Those requirements identified by the customer, or determined by the St. Vrain Manufacturing, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the St. Vrain Manufacturing to be at the limit of its technical or process capabilities.

NOTE: Special requirements (3.5) and critical items (3.2), along with key characteristics (3.3), are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 8.2.2 and 8.2.3). Special requirements can require the identification of critical items. Design output (see 8.3.5) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

4. Context of the Organization

4.1. Understanding the Organization and Its Context

St. Vrain Manufacturing has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company.

4.2. Organizational Context involves:

a) Understanding our core products and services, and scope of management system (see 4.4 below).

b) Identifying "interested parties" (stakeholders) who receive our products, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified in the document ***QF-410.01 List of Interested Parties***.

c) Understanding internal and external issues that are of concern to St. Vrain Manufacturing and its interested parties; also identified in the document ***QF-410.02 Issues List***. Many such issues are identified through an analysis of risks facing either St. Vrain Manufacturing or the interested parties. Such issues are monitored and updated as appropriate and discussed as part of management reviews.

(*QF-410.01 and QF-410.02* is found in the QF-410 Context of the Organization Log)

This information is then used by senior management to determine the company's strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.3. Scope of the Quality Management System

4.3.1 Scope Determination: Our Senior management determines the boundaries and applicability of our Quality Management System to establish its scope by considering:

a) the external and internal issues referred to in clause 4.1 of the AS9100 standard
b) the requirements of relevant interested parties referred to in clause 4.2 of the AS9100 standard
c) to establish consistency in the quality of the applicable products and services of our Company
d) to enhance customer satisfaction through effective application of the QMS

e) all statutory, regulatory and/or legal requirements

f) establishment of suitable processes for improvement of the QMS

4.3.2 Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, St. Vrain Manufacturing has determined the scope of the management system as follows:

Precision Machine Shop Providing CNC Milling, CNC Turning, Manual Machining to Customers in Aerospace, Defense and Commercial Sectors.

4.3.3 The scope of the Quality Management System and the understanding of our core products and services must be also at all time based on our strategic business planning concept outlined within the document.

4.3.4 Facilities Within the Scope

The quality system applies to all processes, activities and employees within the company. The facility is located at:

St. Vrain Manufacturing
819 S. Lincoln Street
Longmont, CO 80501
(303) 702-1529

4.3.5 Permissible Exclusions

The following clauses of AS9100 were determined to be not applicable to St. Vrain Manufacturing:

- 8.3 Design and Development – design activities are performed by the customers and the manufacturing is done in accordance with customer drawings.

4.4 QMS Process Management: St. Vrain Manufacturing has established, implemented, is maintaining and continually improving the Quality Management System, including the processes needed and their interactions, in accordance with the requirements of the AS9100 standard. The processes needed for the Quality Management System have been determined and include business activities and their application throughout the Company.

4.4.1 Process Identification

St. Vrain Manufacturing has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming products discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes. St. Vrain Manufacturing's Quality Management System shall also address customer and applicable statutory and regulatory Quality Management System requirements.

Note: not all activities are considered "processes" – the term "process" in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the

top-level processes identified.

The following top-level processes have been identified for St. Vrain Manufacturing:

- Sales
- Purchasing
- Manufacturing

Each process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of top level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process has a ***Turtle Diagram*** document which defines:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources
- criteria and methods employed to ensure the effectiveness of the process
- Quality Objectives related to that process

The sequence of interaction of these processes is illustrated in Appendix A.

Note: Appendix A represents the typical sequence of processes and may be altered depending on customer or regulatory requirements at the job or contract level, as needed.

4.4.2 Process Controls & Objectives

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one "metric" or key performance indicator (KPI) which is then measured to determine the process' ability to meet the quality objective.

Note: some processes have multiple objectives and multiple metrics. This is determined by the nature of the process, it's impact on products, and associated risks.
Note: Whereas AS9100 discusses process measurements and "Quality Objectives" as separate concepts, St. Vrain Manufacturing combines them; i.e., Quality Objectives are used to control the processes. Additional objectives for products may be assigned, but these will also be used to measure process effectiveness.

Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, to present the data to Senior Management. The data is then analyzed by Senior Management so that they may set goals and adjust for the purposes of long-term continual improvement. The specific Quality Objectives for each process are defined in the applicable ***Process Turtle Diagram***.

Metrics, along with current standings and goals for each objective, are recorded in records of management review.

When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

4.3.3. QMS Process Deployment

4.3.3.1 To establish QMS processes, St. Vrain Manufacturing has created and maintains the Turtle Diagrams that provide the following:

a) determine the inputs required and the outputs expected from each process
b) determine the sequence and interaction of our QMS processes
c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of each process
d) determine the resources needed for each process and ensure their availability
e) assign the responsibilities and authorities for each process
f) address the risks and opportunities for each process as determined in accordance with the requirements of clause 6.1 of the AS9100 standard
g) evaluate each process on effectivity on a regular basis and implement any changes needed to ensure that these processes achieve their intended results, and
h) try to constantly improve all processes and the Quality Management System.

4.3.3.2 St. Vrain Manufacturing will maintain documented information to support the operation of all QMS processes within the Turtle Diagrams to gain confidence that all QMS processes including its businesses activities are being carried out as planned. The documented information includes:

a) a general description of relevant interested parties
b) the scope of the Quality Management System, including boundaries and applicability
c) a description of the processes needed for the Quality Management System and their application throughout St. Vrain Manufacturing
d) the sequence and interaction of these processes
e) assignment of the responsibilities and authorities for these processes

5. Leadership Responsibility

5.1. Quality Commitments: St. Vrain Manufacturing's management must be committed at all time to developing and maintaining an efficient and effective Quality Management System with focus on the following quality management principles**.**

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the Quality Management System by:

a) taking accountability for the effectiveness of the Quality Management System

b) ensuring that the quality policy and quality objectives are established for the Quality Management System and are compatible with the context and strategic direction of the St. Vrain Manufacturing
c) ensuring the integration of the Quality Management System requirements into the St. Vrain Manufacturing 's business processes
d) promoting the use of the process approach and risk-based thinking
e) ensuring that the resources needed for the Quality Management System are available
f) communicating the importance of effective quality management and of conforming to the Quality Management System requirements
g) ensuring that the Quality Management System achieves its intended results
h) engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system
i) promoting improvement
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility

5.1.2 Customer Focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;
b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
c) the focus on enhancing customer satisfaction is maintained*;*
d) product and service conformity and on-time delivery performance are measured, and appropriate action is taken if planned results are not, or will not be, achieved.

5.2 Policy

5.2.1 St. Vrain Manufacturing has established a Quality Policy that provides an overall framework for establishing specific Quality Objectives, and provides direction for the goal of continual improvement and is determined by the following factors:

a) Senior management shall assure that the Quality Policy is appropriate to St. Vrain Manufacturing

b) The Quality Policy shall provide a commitment for product and services to meet the highest quality standards.

c) Continuous improvement is the core of St. Vrain Manufacturing Quality Policy.

d) Review of the Quality Policy will form part of the Quality Management Reviews.

e) The Quality Policy must be communicated to all employees within St. Vrain Manufacturing

f) The Quality Policy will be available to relevant interested parties, as requested

5.2.2 St. Vrain Manufacturing Quality Policy:

"St. Vrain Manufacturing will consistently provide products and services that meet or exceed the requirements and expectations of our customers. We will actively pursue quality improvements through programs that enable each employee to do their job right the first time and every time."

5.3. Roles & Responsibilities: Senior Management is overall responsible for effective deployment, communication and improvement of all matters regarding our QMS, which can be managed by one or more Managers who report directly to the President.

5.3.1. The managers of each department form the senior management staff. They are the key personnel jointly responsible for achieving product and service quality, compliant to the quality system processes and the operating guidelines within this manual.

5.3.2. Engineering, Manufacturing and Production, and Quality departments are jointly responsible for:

a) Supporting the Quality Policy of Continuous Improvement.

b) Creation, implementation and review of quality plans and Quality Objectives.

c) Initiation of corrective action to prevent product, service or any other operational non-conformance within our QMS processes.

d) Identification and recording of product, service or systemic quality problems.

e) Initiation, recommendation and development of risk mitigating preventive measures and solutions.

f) Verification of such preventive measures and solutions.

g) Control of further processing and delivery of non-conforming product until appropriate corrective action of the deficiency.

5.3.3. Personnel who are in charge of inspection, review and testing of products and servicing are responsible for:

a) Identifying and segregating any nonconforming products,

b) Monitoring the production and servicing process on a scheduled basis, and

c) Maintaining manufacturing and inspection plans for all significant process characteristics and parameters (where appropriate).

5.3.4 QMS Management Representative

a) The Quality Manager is designated by the company as the management representative for the quality system.
b) Although senior management is responsible for ensuring that the necessary processes needed

c) for the Quality Management System are established, implemented, and maintained, the Quality Manager has the authority and responsibility to ensure that the daily operation of the quality system is maintained in compliance with AS9100 requirements. The Quality Manager shall have organizational freedom and unrestricted access to top management to resolve any quality management system issues.

d) The Quality Manager is responsible for reporting to senior management on any deviation to this compliance and the performance of the Quality Management System and any needed necessary improvements.

e) The Management Representative may also be the liaison with external parties in relation to the Quality Management System.

6. Planning

6.1. Risks and Opportunities Management

6.1.1. Quality planning must focus on effectively meeting Quality Objectives and customer and legal requirements, as well as try to mitigate all potential operational risks, which includes product risk, service risk, but also all other operational risk, based on the context of the St. Vrain Manufacturing. St. Vrain Manufacturing considers risks and opportunities when taking actions within the Quality Management System, as well as when implementing or improving the Quality Management System; likewise, these risk considerations must be updated within the regular management reviews.

6.1.2. All operational risks and opportunities are managed in accordance with results from risk assessments performed and evaluated in ***QF-610 Risk Assessment Worksheet***.

(The *QF-610 Risk Assessment Worksheet* is found in the QF-410 Context of the Organization Log)

6.2 Quality Objectives and Planning

6.2.1 Senior Management is responsible for quality planning throughout our Company. Inputs of the Quality planning must include:

a) St. Vrain Manufacturing strategies

b) St. Vrain Manufacturing QMS objectives

c) Customer and Regulatory requirements

d) Product and service performance data

e) Risk and Opportunities mitigation strategies

f) Process performance data

g) Lessons learned, Knowledge and Change management

h) Quality Management Review

Outputs Needs of Quality planning shall include:

i) Process improvement plans

j) Necessary skills, resources and knowledge capture

k) Performance metrics

l) Documentation

6.2.2 Quality Objectives, Key Performance Indicators

a) Senior Management determines the Quality Objectives. These objectives must meet the Quality Policy. The Quality Objectives must be at all time established, implemented and maintained as goals to be achieved at relevant functions and levels within the Company.

b) Senior Management ensures that also QMS objectives are established:

c) Quality Objectives must at all time be defined and documented.

d) Quality Objectives will be periodically reviewed on a schedule basis during management review meetings.

e) QMS objectives will be specific, measurable, applicable, reliable and defined within a scheduled achievement time/date.

f) QMS objectives will be tracked.

g) Improvement actions to achieve the Quality Objectives will be implemented based on results of measurements.

6.2.3 The Quality Objectives can include but are not limited to:

a) Customer Satisfaction

b) Process Performance

c) Product Performance

d) On Time Delivery

e) Supplier Performance

f) Overall QMS Performance

6.2.4 Quality Objectives are identified within ***QF-621 Quality Objectives***. The Quality Objectives are reviewed by management and approved by the President.

6.2.5 The specific Quality Objectives for each process are defined in the applicable process activities of each core process, and further described in the ***Turtle Diagrams***. Metrics, along with current standings and goals for each quality objective, are recorded in records (Minutes) of management reviews. When a process does not meet a goal, or an unexpected problem is encountered within a QMS core process, the corrective action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

6.3. QMS Change Management

6.3.1. When the Company determines the need for changes to the Quality Management System and its processes, these changes must be at all times planned, implemented, and then verified for effectiveness; according to the ***QF-641 Change Request Form***. QMS documents are changed also in accordance with the ***Change Request Form***.

7. Support

7.1. Resource Management

7.1.1. Senior management determines and provides the resources necessary to implement, maintain and improve the Quality Management System, including both internal requirements and resources required from external sources.

7.1.2. Senior management determines and provides resources needed to implement and maintain the Quality Management System. Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations. Resources and resource allocation are assessed during management reviews.

7.1.2.1 Resources include:

a) People
b) Facilities
c) Suppliers and supplies
d) Infrastructure
e) Work environment
f) Operational Knowledge capture
g) Natural resources
h) Equipment

7.1.2.2 Senior Management shall at all time ensure the availability of resources. This includes but are not limited to:

a) Adequate staffing
b) Adequate equipment
c) Adequate facilities
d) Adequate tooling
e) Adequate supplies

Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.

7.1.3. Infrastructure: St. Vrain Manufacturing determines, analyzes, provides and maintains the infrastructure to maintain and continuously improve this quality system and ensure that customer requirements are met. This includes the following:

a) Targeted plans for new equipment or new services

b) Product specific requirements

c) Scheduled Preventive Maintenance of equipment

d) Supplier scores\initial and continual supplier performance evaluations

7.1.4. Work Environment: St. Vrain Manufacturing determines, analyses, provides and maintains the work environment to maintain and continuously improve this quality system and ensure that customer requirements are met. This includes the following:

a) Safety training

b) Statutory and regulatory environmental training (as needed)

c) Feedback from employees

d) Environmental controls needed, such as lighting, heat humidity, noise

Human factors are considered to the extent that they directly impact on the quality of products.

Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the management system. Only work environment aspects which can directly affect process efficiency or product and service quality are managed through the management system.

7.1.5 Monitoring and Measuring of Resources

7.1.5.1 St. Vrain Manufacturing determines and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

St. Vrain Manufacturing ensures that the resources provided:

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

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

St. Vrain Manufacturing retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by St. Vrain Manufacturing to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information. A master list of calibrated equipment is maintained ***in the calibration recall system***

a) identified in order to determine their status

b) safeguarded from adjustments, damage or deterioration that would invalidate the

calibration status and subsequent measurement results.

St. Vrain Manufacturing has established, implemented, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.

St. Vrain Manufacturing maintains a register of the monitoring and measuring equipment. The register shall include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

NOTE: Monitoring and measuring equipment can include, but are not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.

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

St. Vrain Manufacturing determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose and shall take appropriate action as necessary.

7.1.6 Organizational Knowledge

St. Vrain Manufacturing determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;

b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained and made available to the extent necessary.

When addressing changing needs and trends, St. Vrain Manufacturing considers its current knowledge and determine how to acquire or access the necessary additional knowledge.

7.2 Competency and Training

Senior management ensures that it provides sufficient staffing for the effective operation of the management system, as well its identified processes.

Staff members performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience, as defined on ***Job Descriptions***. ***The Skills Matrix, form QF-720*** defines these activities in detail.

7.2.1. St. Vrain Manufacturing shall determine the required competence for personnel performing work affecting product and service quality. Consideration will be given to:

a) Future demands

b) Cross training

c) Audit results

d) Statutory and regulatory requirements

e) Promotion of importance of awareness for potential failure of non-active participation within our QMS processes

7.2.2. St. Vrain Manufacturing shall provide training or take other action to satisfy these needs. The objective is to provide people with skills, knowledge and experience that will improve their competence.

7.2.3. St. Vrain Manufacturing shall evaluate the effectiveness of the actions\training taken.

7.2.4. St. Vrain Manufacturing shall ensure its personnel are aware of the relevance and importance of their activities and how they contribute to the quality objectives.

7.2.5. Records of education, training, skills and experience will be maintained.

7.3 Personnel Awareness

7.3.1 St. Vrain Manufacturing selects personnel based on appropriate education, training, skills and experience to perform work that affects product quality. St. Vrain Manufacturing ensures that persons doing work under St. Vrain Manufacturing ’s control are aware of:

a) the Quality Policy;
b) relevant Quality Objectives;
c) their contribution to the effectiveness of the Quality Management System, including the benefits of improved performance;
d) the implications of not conforming with the Quality Management System requirements***;***
e) relevant quality management system documented information and changes thereto;
f) their contribution to product or service conformity;
g) their contribution to product safety;
h) the importance of ethical behavior

7.3.2 St. Vrain Manufacturing encourages the involvement and development of its people by:

a) Ongoing training (***Training Record, QF-720.01***)

b) Establishing responsibilities and authorities

c) Operator certification (***Employee Competency Certification, form QF-720.02***)

d) Establishing Training needs (***Job Descriptions, Skills Matrix***)

7.4 Management of Communication

7.4.1 Senior Management ensures that appropriate communication systems are established within the St. Vrain Manufacturing.

7.4.2 Senior Management must define and implement an effective and efficient communication of the Quality Management System.

7.4.3 Communication parameters of the Quality Management System include:

a) Quality Policy and promotion of Risk Based Thinking
b) QMS Objectives and request for detailed support
c) Results of objective measurements
d) Ongoing improvement projects
e) All QMS Requirements
f) Convey the importance of our applicable Standards
g) All employee accountability for the QMS and Accomplishments

7.4.4 Senior management must also be at all time committed to communicating and meeting all internal and external customer requirements as well as statutory and regulatory requirements by:

a) Continuous training of employees on QMS compliance

b) Detailed documentation of customer and legal requirements

c) Understanding external customer needs and expectations and transferring this information to employees through pertinent disclosure

d) Encouraging all employees to contribute to Risk Based Thinking on all operational processes during regular meetings

e) Understanding and communicating internal customer needs and expectations and transferring this information into documented activities to satisfy these needs

f) Encouraging employees to strive for continuous improvement of customer satisfaction

7.4.5. Methods of communication include:

a) Schedule quality reviews

b) Meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS

c) Performance Boards

d) use of corrective and preventive action processes to report nonconformities or suggestions for improvement

e) use of the results of analysis of data

f) use of the results of the internal audit process

g) regular company meetings with all employees

h) internal emails

i) memos to employees

j) Senior Management's "open door" policy which allows any employee access to Senior Management for discussions on improving the quality system

7.5. Management of Documented Information

7.5.1. Documented and controlled information comprising the QMS includes:

a) Documented statements of the Quality Policy and Quality Objectives.

b) The documented Scope of the QMS and justification of any exclusions.

c) This Quality Manual.

d) Documented procedures relevant to the QMS.

e) All documented information needed to ensure the effective planning, operation and control of the internal and external QMS processes.

f) Records required by AS9100 as being documented information needed to be retained by St. Vrain Manufacturing for the purpose of providing evidence of result achieved

7.5.2. Controlled documented information of Quality Planning can include:

a) Product, Equipment and Process Control documentation

b) Procedures

c) Quality System Documentation

d) Quality Records in hardcopy or any kind of electronic format

e) Documents containing QMS relevant internal communications

f) Any other kind of Test and Inspection Plan, Quality Plan, Risk Plan, Quality Manual, Strategic Plan, Records, or Forms.

7.5.3. Control of Documented Information

7.5.3.1 St. Vrain Manufacturing ensures that all QMS controlled documents are under change and revision control and are maintained on ***QF-753 Master Documents List***. All other documented information necessary to manage the QMS must be kept accessible and preserved at all time during day to day work. Records are controlled per section 7.5.4. St. Vrain Manufacturing has established a documented procedure ***QP-753 Control of Documents*** which defines the controls in place to:

a) Approve documents for adequacy prior to use.

b) Review and update as necessary and re-approve documents

c) Ensure that changes and the current revision of documents is identified.

d) Ensure that relevant versions of documents are available at point of use.

e) Ensure that controlled documents remain legible and readily identifiable.

f) Ensure that documents of external origin and their internal distribution are identifiable and controlled by our QMS within documented filing.

g) Prevent unintended use of obsolete documents and apply suitable identification to them if they are retained for any purpose.

7.5.4. Control of Records

a) St. Vrain Manufacturing establishes and maintains records to provide evidence of conformity to all our legal and customer requirements and establish measurable evidence for effective operations of our Quality Management System.

b) These records will at all time remain legible, easily identifiable, and retrievable either in hardcopy or electronic format. The documented procedure ***QP-754 Control of Records*** defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of the QMS related records.

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

8. Operation

8.1 Operational Planning and Control

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 management system. Such planning considers the information related to the context of the St. Vrain Manufacturing (see section 4.0 above), current resources and capabilities, as well as product and service requirements.

a) Determination of requirements for the products and services should include consideration of:
- personal and product safety;
- producibility and inspectability;
- reliability, availability, and maintainability;
- suitability of parts and materials used in the product;
- selection and development of embedded software;
- product obsolescence;
- prevention, detection, and removal of foreign objects;
- handling, packaging, and preservation;
- recycling or final disposal of the product at the end of its life.

b) Criteria must be established for:
- Processes
- Acceptance of product and services

c) determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;

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

e) determining, maintaining, and retaining documented information to the extent necessary:
1. to have confidence that the processes have been carried out as planned;
2. to demonstrate the conformity of products and services to their requirements*;*

f) determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;

g) engaging representatives of affected St. Vrain Manufacturing functions for operational planning and control

h) determining the process and resources to support the use and maintenance of the products and services;

i) determining the products and services to be obtained from external providers;

j) establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

Customer requirements, and products and services, St. Vrain Manufacturing plans and manages product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.

NOTE: This activity is generally referred to as project planning, project management, or program management. The output of this planning is suitable for St. Vrain Manufacturing's operations. As an output of this planning, documented information specifying the processes of the quality management system and the resources to be applied to a specific product, service, project, or contract can be referred to as a quality plan.

St. Vrain Manufacturing controls planned changes and reviews the consequences of unintended changes, acting to mitigate any adverse effects, as necessary.

St. Vrain Manufacturing ensures that outsourced processes are controlled, as identified in Section 8.4.

St. Vrain Manufacturing has established, implemented, and maintains a process to plan and control the temporary or permanent transfer of work to ensure the continuing conformity of the work to requirements. The process ensures that work transfer impacts and risks are managed.

8.1.1 Operational Risk Management

St. Vrain Manufacturing has planned, implemented, and controls a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the St. Vrain Manufacturing and the products and services:

a. assignment of responsibilities for operational risk management;
b. definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);
c. identification, assessment, and communication of risks throughout operations;
d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;
e. acceptance of risks remaining after implementation of mitigating actions.

8.1.2 Configuration Management

The St. Vrain Manufacturing plans, implements, and controls a process for configuration management as appropriate to the St. Vrain Manufacturing and its products and services to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:

a. control product identity and traceability to requirements, including the implementation of identified changes;
b. ensure that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

8.1.3 Product Safety

St. Vrain Manufacturing plans, implements, and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to St. Vrain Manufacturing and the product.

Examples of these processes include:

- assessment of hazards and management of associated risks;
- management of safety critical items;
- analysis and reporting of occurred events affecting safety;
- communication of these events and training of persons.

8.1.4 Prevention of Counterfeit Parts

St. Vrain Manufacturing has planned, implemented, and controls processes, appropriate to St. Vrain Manufacturing and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

Counterfeit part prevention processes should consider:

- training of appropriate persons in the awareness and prevention of counterfeit parts;
- application of a parts obsolescence monitoring program;
- controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;
- requirements for assuring traceability of parts and components to their original or authorized manufacturers;
- verification and test methodologies to detect counterfeit parts;
- monitoring of counterfeit parts reporting from external sources;
- quarantine and reporting of suspect or detected counterfeit parts

8.2 Requirements for Products and Services

8.2.1 Customer Communication

St. Vrain Manufacturing has implemented effective communication with customers in relation to:

a) providing information relating to products and services;

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

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

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant

8.2.2 Determining the Requirements for Products and Services

Once requirements are identified, St. Vrain Manufacturing reviews the requirements prior to its commitment to supply the product. This review ensures that:

a) product requirements are defined, including statutory or regulatory requirements and any other requirements St. Vrain Manufacturing deems necessary

b) St. Vrain Manufacturing can meet the defined requirements, and/or the claims for the products and services it offers

c) special requirements of the products or services are determined

d) operational risks have been identified and considered

8.2.3 Review of the Requirements for Products and Services

During the review of new customer requirements, St. Vrain Manufacturing ensures they have the ability to meet the customer requirements and shall review the requirements prior to committing to take the order and also review:

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

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

c) statutory and regulatory requirements related to the product;

d) any additional requirements determined by St. Vrain Manufacturing.

e) order requirements that differ from those supplied by the customer or previously identified are resolved

The review shall be coordinated with applicable functions of St. Vrain Manufacturing. If the determination is made that some customer requirements cannot be met or can only partially be met, St. Vrain Manufacturing will negotiate a mutually acceptable requirement with the customer.

The customer requirements shall be confirmed by St. Vrain Manufacturing before acceptance, when the customer does not provide a documented statement of their requirements.

These activities are documented on form ***QF-600 Contract Review, and the Estimating section of JobBOSS2***.

8.2.4 Changes to Requirements for Products and Services

St. Vrain Manufacturing ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed. Changes affecting the Quality Management System are documented on form ***QF-641 Change Request Form***.

8.3. Design and Development - Excluded

8.3.1 General

St. Vrain Manufacturing performs contract manufacturing services to customer designs and performs no design activities. St. Vrain Manufacturing has excluded this clause from the Quality Management System.

8.4. Control of Externally Provided Processes, Products, and Services

8.4.1 General

St. Vrain Manufacturing ensures that externally provided processes, products, and services conform to requirements.

St. Vrain Manufacturing is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

St. Vrain Manufacturing ensures, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.

St. Vrain Manufacturing identifies and manages the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.

St. Vrain Manufacturing requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

St. Vrain Manufacturing determines the controls to be applied to externally provided processes, products, and services when:

a) products and services from external providers are intended for incorporation into St. Vrain Manufacturing ’s own products and services

b) products and services are provided directly to the customer(s) by external providers on behalf of St. Vrain Manufacturing

c) a process, or part of a process, is provided by an external provider because of a decision by St. Vrain Manufacturing.

St. Vrain Manufacturing determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. St. Vrain Manufacturing retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.1 St. Vrain Manufacturing:

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

b) maintains a register of its external providers that includes approval status and the scope of the approval on form ***QF-841 Approved Suppliers List***

c) periodically reviews external provider performance including process, product and service conformity, and on- time delivery performance;

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

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

Procedure ***QP-841 Control of Externally Provided Processes, Products, and Services*** defines the controls in place for approvals and monitoring of suppliers. Supplier approvals are documented on form ***QF-841.01 Initial Supplier Approval Form***.

8.4.2 Type and Extent of Control

St. Vrain Manufacturing ensures that externally provided processes, products and services are controlled to the aspect that they do not adversely affect the ability to consistently deliver conforming products and services to customer requirements. St. Vrain Manufacturing will:

a) Ensure that externally provided processes remain within the control of the QMS
b) Define the controls that it will apply to an external provider and those it intends to apply to the resulting product or service
c) Take into consideration:
    1) The potential impact of the externally provided processes, products and services on the ability to consistently meet customer and any applicable statutory and regulatory requirements
    2) The effectiveness of the controls applied by the external provider
    3) The results of the periodic review of external provider performance
d) Determine the verification or other activities necessary to ensure that the externally provided processes, products and services meet requirements

Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by St. Vrain Manufacturing. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.

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

Verification activities can include:

- review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);
- inspection and audit at the external provider's premises
- review of the required documentation
- review of production part approval process data
- inspection of products or verification of services upon receipt
- review of delegations of product verification to the external provider

When externally provided product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

When St. Vrain Manufacturing delegates verification activities to the external provider, the scope and requirements for delegation shall be defined and a register of delegations shall be maintained. St. Vrain Manufacturing periodically monitors the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, St. Vrain Manufacturing implements a process to evaluate the data in the test reports to confirm that the product meets requirements.

When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), St. Vrain Manufacturing implements a process to validate the accuracy of test reports.

8.4.3. Information for External Providers

St. Vrain Manufacturing ensures the adequacy of requirements prior to their communication to the external provider.

St. Vrain Manufacturing communicates to external providers its requirements for:

a) the processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);
b) the approval of:
    1. products and services;
    2. methods, processes, and equipment;
    3. the release of products and services;
c) competence, including any required qualification of persons;
d) the external providers' interactions with St. Vrain Manufacturing
e) control and monitoring of the external providers' performance to be applied by St. Vrain Manufacturing

f) verification or validation activities that St. Vrain Manufacturing, or its customer, intends to perform at the external providers' premises
g) design and development control
h) special requirements, critical items, or key characteristics
i) test, inspection, and verification (including production process verification)
j) the use of statistical techniques for product acceptance and related instructions for acceptance by St. Vrain Manufacturing
k) the need to:
- implement a quality management system
- use customer-designated or approved external providers, including process sources (e.g., special processes)
- notify St. Vrain Manufacturing of nonconforming processes, products, or services and obtain approval for their disposition
- prevent the use of counterfeit parts (see 8.1.4)
- notify St. Vrain Manufacturing of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain St. Vrain Manufacturing 's approval
- flow down to external providers' applicable requirements including customer requirements;
- provide test specimens for design approval, inspection/verification, investigation, or auditing;
- retain documented information, including retention periods and disposition requirements;

l) the right of access by St. Vrain Manufacturing, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain
m) ensuring that persons are aware of:
- their contribution to product or service conformity
- their contribution to product safety
- the importance of ethical behavior

8.5. Production and Service Provision

8.5.1. Control of Production and Service

St. Vrain Manufacturing management plans and carries out production and service under controlled conditions within planned control points. This includes but is not limited to:

a) availability of documented information that defines:

1. the characteristics of the products to be produced, the services to be provided, or the activities to be performed (drawings, specifications, Bill of Materials)

2. the results to be achieved (production documents, verification documents)

b) the use of suitable equipment and other resources
c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

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

- criteria for acceptance and rejection;
- where in the sequence verification operations are to be performed;

- measurement results to be retained (at a minimum an indication of acceptance or rejection);
- any specific monitoring and measurement equipment required, and instructions associated with their use;

2. ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified based on recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

d) the use of suitable infrastructure and environment for the operation of processes (jigs, fixtures, molds, software);
e) the appointment of competent persons, including any required qualification;
f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement (special processes);
g) the implementation of actions to prevent human error;
h) the implementation of release, delivery, and post-delivery activities;
i) the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
j) accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
k) the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
l) determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
m) the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
n) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
o) the provision for the prevention, detection, and removal of foreign objects;
p) the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);
q) the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

8.5.1.1 Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and is maintained.

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

8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, St. Vrain Manufacturing has established arrangements for these processes including, as applicable:

a) definition of criteria for the review and approval of the processes;
b) determination of conditions to maintain the approval;
c) approval of facilities and equipment;
d) qualification of persons;
e) use of specific methods and procedures for implementation and monitoring the processes;
f) requirements for documented information to be retained.

8.5.1.3 Production Process Verification

St. Vrain Manufacturing has implemented production process verification activities to ensure the production process can produce products that meet requirements. These activities can include risk assessments, first article inspection, capability studies, and control plans.

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 can produce parts and assemblies that meet requirements. This activity shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).

St. Vrain Manufacturing retains documented information on the results of production process verification.

8.5.2 Identification and Traceability

St. Vrain Manufacturing uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

St. Vrain Manufacturing maintains the identification of the configuration of the products and services to identify any differences between the actual configuration and the required configuration.

St. Vrain Manufacturing identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

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

St. Vrain Manufacturing controls the unique identification of the outputs when traceability is a requirement and retains the documented information necessary to enable traceability.

Traceability requirements can include:

a) the identification to be maintained throughout the product life;
b) the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);
c) for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;

d) for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.

8.5.3 Property Belonging to Customers or External Providers

St. Vrain Manufacturing exercises care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

St. Vrain Manufacturing identifies, verifies, protects, and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, St. Vrain Manufacturing reports this to the customer or external provider and retains documented information on what has occurred.

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

8.5.4 Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

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

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

a) cleaning;

b) prevention, detection, and removal of foreign objects (FOD);

c) special handling and storage for sensitive products;

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

e) shelf life control and stock rotation;

f) special handling and storage for hazardous materials.

8.5.5 Post-Delivery Activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements;

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

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

d) customer requirements;

e) customer feedback;

f) collection and analysis of in-service data (e.g., performance, reliability, lessons learned);

g) control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;

h) controls required for work undertaken external to the organization (e.g., off-site work);

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

When problems are detected after delivery, St. Vrain Manufacturing takes appropriate action including investigation and reporting to the interested parties.

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

St. Vrain Manufacturing does not conduct any activities which are considered post-delivery activities.

8.5.6 Control of Changes

St. Vrain Manufacturing reviews and controls changes for production or service provisions, to the extent necessary to ensure continuing conformity with requirements. Persons authorized to approve production or service provision changes are identified as follows.

a) President/Owner
b) Estimator
c) Office Manager
d) Manufacturing Process Planner
e) Shipping and Receiving Manager
f) Shop Floor Manager
g) Quality Manager

Production or service provision changes may include the changes affecting processes, production equipment, tools, or software programs.

St. Vrain Manufacturing retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of Products and Services

St. Vrain Manufacturing implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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

St. Vrain Manufacturing retains documented information on the release of products and services. The documented information shall include:

a) evidence of conformity with the acceptance criteria;
b) traceability to the person(s) authorizing the release.

When required to demonstrate product qualification, St. Vrain Manufacturing ensures that retained documented information provides evidence that the products and services meet the defined requirements. St. Vrain Manufacturing ensures that all documented information required to accompany the products and services are present at delivery.

8.7 Control of Nonconforming Outputs

8.7.1 St. Vrain Manufacturing ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

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

St. Vrain Manufacturing takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

St. Vrain Manufacturing 's nonconformity control process shall be maintained as documented information in procedure ***QP-870 Nonconforming Product*** and documented on form ***QF-870 Corrective/Preventive Action Request*** and includes provisions for:

- defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
- taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;
- timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
- defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts

St. Vrain Manufacturing deals with nonconforming outputs in one or more of the following ways:

a) correction;
b) segregation, containment, return, or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:

- after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;
- after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

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

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

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

8.7.2 St. Vrain Manufacturing retains documented information on form ***QF-870 Corrective/Preventive Action Request*** that:

a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action in respect of the nonconformity.

9. QMS Performance Evaluation

9.1.1 Monitoring, Measurement, Analysis, and Evaluation: St. Vrain Manufacturing determines:

a) what information or processes need to be monitored or measured

b) what methods will be used to ensure valid results

c) when monitoring and measuring will be performed and when the results will be analyzed and evaluated

The performance of the Quality Management System will be evaluated, and records maintained in the Management Review Meeting and on the Data Analysis Reports.

9.1.2 Monitoring and Measurement of Customer Satisfaction

St. Vrain Manufacturing shall monitor information relating to customer perception as to whether the St. Vrain Manufacturing has met customer satisfaction. The Customer Satisfaction System includes methods for obtaining and using this information. Methods include:

a) Customer complaints

b) On Time Delivery data

c) Product returns

d) Customer feedback

Customer Satisfaction results and analysis are documented on the Data Analysis Reports and the Quality Score Card and discussed during Management Review Meetings. Management shall develop plans of action if there is analysis that does not meet objectives or indicate deficiencies.

9.1.3 St. Vrain Manufacturing realizes that measurement data is important for making evidence-based decisions. To ensure St. Vrain Manufacturing performance and customer satisfaction, effective and efficient measurement, collection, and validation of data is necessary. Examples of process performance measurables include:

a) Conformity of products, services and processes

b) Customer Satisfaction

c) Performance and effectiveness of the Quality Management System

d) Planning effectiveness

e) Effectiveness of actions taken to address risks and opportunities

f) Performance of external providers

g) Need for improvements to the Quality Management System

A broad range of data is collected and acted upon. This measurement data is converted to information and knowledge that benefits St. Vrain Manufacturing. Data collection and analysis is documented on the ***Data Analysis Reports*** and reviewed with the management.

9.2. Internal Audit

9.2.1. Internal Audits are conducted at planned intervals to determine whether the Quality Management System conforms and is effectively implemented and maintained to:

a) Planned arrangements

b) Requirements of the AS9100 standard

c) Requirements established by this Quality Manual

d) Customer, statutory, and regulatory Quality Management System requirements

9.2.2 St. Vrain Manufacturing:

a) plan, establish, implement, and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements, and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

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

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process (auditors may be qualified suppliers or contractors);

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

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

f) retain documented information as evidence of the implementation of the audit program and the audit results.

9.3. Management Review

9.3.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization.

9.3.2 Management Review Inputs

The management review shall be planned and carried out taking into consideration:

a) the status of actions from previous management reviews;

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

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

1. customer satisfaction and feedback from relevant interested parties;

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

3. process performance and conformity of products and services;

4. nonconformities and corrective actions;

5. monitoring and measurement results;

6. audit results;

7. the performance of external providers;

8. on-time delivery performance;

d) the adequacy of resources;

e) the effectiveness of actions taken to address risks and opportunities (see 6.1);

f) opportunities for improvement.

9.3.3 Management Review Outputs

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

a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs;

d) risks identified.

Records from quality management reviews are maintained on form ***QF-930 Management Review Template***.

10. Improvement

10.1 General

St. Vrain Manufacturing determines and selects opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

Opportunities for improvement include:

a) improving products and services to meet requirements as well as to address future needs and expectations;
b) correcting, preventing, or reducing undesired effects;
c) improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, St. Vrain Manufacturing will:

a) react to the nonconformity and, as applicable:
   1. act to control and correct it;
   2. deal with the consequences;
b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   1. reviewing and analyzing the nonconformity;
   2. determining the causes of the nonconformity, including, as applicable, those related to human factors;
   3. determining if similar nonconformities exist, or could potentially occur;
c) implement any action needed;
d) review the effectiveness of any corrective action taken;
e) update risks and opportunities determined during planning, if necessary;
f) make changes to the quality management system, if necessary***;***
g) flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
h) take specific actions when timely and effective corrective actions are not achieved.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

St. Vrain Manufacturing maintains documented information that defines the nonconformity and corrective action management processes in procedure ***QP-1020 Corrective/Preventive Action***.

10.2.2 St. Vrain Manufacturing retains documented information on form ***QF-870 Corrective/Preventive Action Request*** as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;
b) the results of any corrective action.

10.3 Continual Improvement

St. Vrain Manufacturing continually improves the suitability, adequacy, and effectiveness of the quality management system.

St. Vrain Manufacturing considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

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

There is also opportunity to document continual improvement activities on form ***QF-1010 Continual Improvement Project Log*** or on form ***QF-870 CPAR*** to identify QMS improvement activities.

Appendix A: Overall Process Sequence & Interaction