



**MACHINING - FABRICATION - WELDING**

# RiAlto Manufacturing, Inc.

**Marion, OH**

## **Quality Policy Manual**

## **FOREWORD**

RiAlto Manufacturing started in 1981 as RiAlto Welding and was located on the property of RiAlto Farms in New Bloomington, OH. RiAlto Welding was a general repair shop for local farmers, truckers and for state and local government. RiAlto Welding started working for the Automotive business in 1984. The official name was changed to RiAlto Manufacturing in 1992. During the 1990's and early 2000's RiAlto Manufacturing grew the business to over 24,000 sq. ft. RiAlto's specialty was manufacturing assembly line fixtures, carts and racks. RiAlto outgrew their facility in 2014 and moved to the current location in Marion, OH with over 42,000 sq. ft. RiAlto Manufacturing now specializes in machining and metal fabrication utilizing laser cutting, metal forming and welding for industrial and commercial industries.

The documented business management system in place at RiAlto Manufacturing was implemented on March 1, 2020 in accordance with the requirements of ISO 9001. The RiAlto Manufacturing business processes and their interactions are defined in the Process Interaction Diagram. Prior to system implementation, RiAlto Manufacturing vendors were evaluated by the General Manager and grandfathered based on past quality performance. Also, existing RiAlto Manufacturing employees were evaluated by the General Manger against position-specific training records and qualified based upon past experience, education and training.

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**1.0 Revision Control Sheet**

DATE	REV.	DESCRIPTION OF REVISION	WRITTEN BY	APPROVED BY
3/1/2020	01	Initial document preparation	Josh Obenour	Rick Mattix
4/15/2021	02	Revised Organization Chart to add Quality & Safety Supervisor	Josh Obenour	Rick Mattix
7/2/2024	03	Added to section 4.1 consideration of Climate Change on the QMS; Updated Org. Chart	Josh Obenour	Rick Mattix

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## **3. Manual Administration**

The Quality Policy Manual is subject to amendments as a result of changes to working practices and is reviewed periodically for adequacy. Requests for revision shall be submitted to the Management Representative. Final approval of the Quality Policy Manual is by the President of RiAlto Manufacturing, Inc. (RiAlto Manufacturing) .

The administration, control, and issue of this manual are the responsibility of the Management Representative.

The information contained in this document is the property of RiAlto Manufacturing and cannot be distributed or reproduced without the approval of the Management Representative.

Controlled copies of this Quality Policy Manual will be listed on the RiAlto Manufacturing Document Masterlist, they are current when issued and will be subject to automatic update when parts of the manual are revised. Uncontrolled copies will not be updated.

## **4. Context of the organization**

### **4.1 Understanding the organization and its context**

RiAlto Manufacturing has determined the external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system as part of initial system setup and includes items such as, work load, competition, exposure to new markets, customer relationships, customer requirements, scheduling, business financial/operational needs, employee development, etc. Note: Climate change was considered as part of this review and determined not to have any impact on the QMS.

RiAlto Manufacturing monitors and reviews information about external and internal issues as part of Management meetings, customer meetings, employee communication, ongoing improvement efforts. etc.

### **4.2 Understanding the needs and expectations of interested parties**

Due to their effect or potential effect on RiAlto Manufacturing's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, RiAlto Manufacturing has determined:

- a) the interested parties that are relevant to the quality management system including customers, suppliers and employees and ownership;
- b) the requirements of these interested parties that are relevant to the quality management system.

RiAlto Manufacturing monitors and reviews information about these interested parties and their relevant requirements through Management meetings, customer communications, employee communication/feedback, etc.

### **4.3 Determining the scope of the quality management system**

RiAlto Manufacturing has determined the boundaries and applicability of the quality management system to establish its scope. **RiAlto Manufacturing specializes in machining and metal fabrication utilizing laser cutting, metal forming and welding for industrial and commercial industries.**

RiAlto Manufacturing applies the requirements of the ISO 9001:2015 Standard to the QMS, excluding the requirements of 8.3 Design and Development of Products and Services as design requirements are provided by RiAlto Manufacturing's customers.

When determining this scope, RiAlto Manufacturing considered:

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- a) the external and internal issues referred to in 4.1;
- b) the requirements of relevant interested parties referred to in 4.2;
- c) the products and services provided by RiAlto Manufacturing.

### **4.4 Quality management system and its processes**

**4.4.1** RiAlto Manufacturing has established, implemented, maintains and continually improves a quality management system, including the processes needed and their interactions, in accordance with the requirements of the ISO 9001:2015 Standard without Design.

RiAlto Manufacturing has determined the processes needed for the quality management system and their application throughout RiAlto Manufacturing (see Appendix B), and has:

- a) determined the inputs required and the outputs expected from these processes;
- b) determined the sequence and interaction of these processes;
- c) determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determined the resources needed for these processes and ensures their availability;
- e) assigned the responsibilities and authorities for these processes;
- f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) evaluates these processes and implements any changes needed to ensure that these processes achieve their intended results;
- h) improves the processes and the quality management system.

**4.4.2** To the extent necessary, RiAlto Manufacturing:

- a) maintains documented information to support the operation of its processes;
- b) retains documented information to have confidence that the processes are being carried out as planned.

## **5. Leadership**

### **5.1 Leadership and commitment**

#### **5.1.1 General**

RiAlto Manufacturing's top management demonstrates 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 RiAlto Manufacturing;
- c) ensuring the integration of the quality management system requirements into RiAlto 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**

RiAlto Manufacturing's top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;



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- 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.

## **5.2 Policy**

### **5.2.1 Establishing the quality policy:**

**RiAlto Manufacturing is committed to customer satisfaction through the continual improvement of our products, processes and services.**

RiAlto Manufacturing's top management has established, implemented and maintains this quality policy and ensures that it:

- a) is appropriate to the purpose and context of RiAlto Manufacturing and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the quality management system.

### **5.2.2 Communicating the quality policy**

The quality policy is:

- a) available and be maintained as documented information;
- b) communicated, understood and applied within RiAlto Manufacturing;
- c) available to relevant interested parties, as appropriate.

## **5.3 Organizational roles, responsibilities and authorities**

RiAlto Manufacturing's top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within RiAlto Manufacturing (see Appendix A).

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RiAlto Manufacturing's President has assigned the General Manager the responsibility and authority for:

- a) ensuring that the quality management system conforms to the requirements of the ISO 9001:2015 Standard;
- b) ensuring that the processes are delivering their intended outputs;
- c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1);
- d) ensuring the promotion of customer focus throughout RiAlto Manufacturing;
- e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

## **6. Planning**

### **6.1 Actions to address risks and opportunities**

**6.1.1** When planning for the quality management system, RiAlto Manufacturing considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that needed to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effects;
- d) achieve improvement.

**6.1.2** RiAlto Manufacturing plans:

- a) actions to address risks and opportunities;
- b) how to:
  - 1) integrate and implement the actions into its quality management system processes (see 4.4);
  - 2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

### **6.2 Quality objectives and planning to achieve them**

**6.2.1** RiAlto Manufacturing has established quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives are:

- a) consistent with the quality policy;
- b) measurable;
- c) take into account applicable requirements;

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- d) relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) monitored;
- f) communicated;
- g) updated as appropriate.

RiAlto Manufacturing maintains documented information on the quality objectives.

**6.2.2** When planning how to achieve its quality objectives, RiAlto Manufacturing determines:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

### **6.3 Planning of changes**

When RiAlto Manufacturing determines the need for changes to the quality management system, the changes are carried out in a planned manner (see [4.4](#)).

RiAlto Manufacturing considers:

- a) the purpose of the changes and their potential consequences;
- b) the integrity of the quality management system;
- c) the availability of resources;
- d) the allocation or reallocation of responsibilities and authorities.

## **7. Support**

### **7.1 Resources**

#### **7.1.1 General**

RiAlto Manufacturing determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

RiAlto Manufacturing considers:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

#### **7.1.2 People**

RiAlto Manufacturing has determined and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

#### **7.1.3 Infrastructure**

RiAlto Manufacturing has determined, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

#### **7.1.4 Environment for the operation of processes**

RiAlto Manufacturing determined, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

#### **7.1.5 Monitoring and measuring resources**

##### **7.1.5.1 General**

RiAlto Manufacturing has determined 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.

RiAlto Manufacturing ensures that the resources provided:

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

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

RiAlto 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 RiAlto Manufacturing to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:

- a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- b) identified in order to determine their status;
- c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

RiAlto 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 takes appropriate action as necessary.

## **7.1.6 Organizational knowledge**

RiAlto Manufacturing determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

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

When addressing changing needs and trends, RiAlto Manufacturing considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

## **7.2 Competence**

RiAlto Manufacturing:

- a) determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

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- b) ensures that these persons are competent on the basis of appropriate education, training, or experience;
- c) where applicable, takes actions to acquire the necessary competence, and evaluates the effectiveness of the actions taken;
- d) retains appropriate documented information as evidence of competence.

### **7.3 Awareness**

RiAlto Manufacturing ensures that persons doing work under RiAlto 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.

### **7.4 Communication**

RiAlto Manufacturing determines the internal and external communications relevant to the quality management system, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

### **7.5 Documented information**

#### **7.5.1 General**

RiAlto Manufacturing's quality management system includes:

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- a) documented information required by the ISO 9001:2015 Standard;
- b) documented information determined by RiAlto Manufacturing as being necessary for the effectiveness of the quality management system.

### **7.5.2 Creating and updating**

When creating and updating documented information, RiAlto Manufacturing ensures appropriate:

- a) identification and description (e.g. a title, date and reference number);
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.

### **7.5.3 Control of documented information**

**7.5.3.1** Documented information required by the quality management system and by the ISO 9001:2015 Standard is controlled to ensure:

- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

**7.5.3.2** For the control of documented information, RiAlto Manufacturing addresses the following activities, as applicable:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

Documented information of external origin determined by RiAlto Manufacturing to be necessary for the planning and operation of the quality management system is identified as appropriate, and controlled.

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



## **8. Operation**

### **8.1 Operational planning and control**

RiAlto Manufacturing plans, implements and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

- a) determining the requirements for the products and services;
- b) establishing criteria for:
  - 1) the processes;
  - 2) the acceptance of products and services;
- c) determining the resources needed to achieve conformity to the product and service requirements;
- 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.

The output of this planning is suitable for RiAlto Manufacturing's operations.

RiAlto Manufacturing controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

RiAlto Manufacturing ensures that outsourced processes are controlled (see 8.4).

### **8.2 Requirements for products and services**

#### **8.2.1 Customer communication**

Communication with customers includes:

- a) providing information relating to products and services;
- b) handling enquiries, contracts or orders, including changes;

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- 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**

When determining the requirements for the products and services to be offered to customers, RiAlto Manufacturing ensures that:

- a) the requirements for the products and services are defined, including:
  - 1) any applicable statutory and regulatory requirements;
  - 2) those considered necessary by the organization;
- b) the organization can meet the claims for the products and services it offers.

### **8.2.3 Review of the requirements for products and services**

**8.2.3.1** RiAlto Manufacturing ensures that it has the ability to meet the requirements for products and services to be offered to customers. RiAlto Manufacturing conducts a review before committing to supply products and services to a customer, to include:

- 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 the specified or intended use, when known;
- c) requirements specified by RiAlto Manufacturing;
- d) statutory and regulatory requirements applicable to the products and services;
- e) contract or order requirements differing from those previously expressed.

RiAlto Manufacturing ensures that contract or order requirements differing from those previously defined are resolved.

The customer's requirements are confirmed by RiAlto Manufacturing before acceptance, when the customer does not provide a documented statement of their requirements.

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**8.2.3.2** RiAlto Manufacturing retains documented information, as applicable:

- a) on the results of the review;
- b) on any new requirements for the products and services.

## **8.2.4 Changes to requirements for products and services**

RiAlto 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.

## **8.3 Design and development of products and services – NA – See Section 4.3**

## **8.4 Control of externally provided processes, products and services**

### **8.4.1 General**

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

RiAlto 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 the organization's own products and services;
- b) products and services are provided directly to the customer(s) by external providers on behalf of RiAlto Manufacturing;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by RiAlto Manufacturing.

RiAlto 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. RiAlto Manufacturing retains documented information of these activities and any necessary actions arising from the evaluations.

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## **8.4.2 Type and extent of control**

RiAlto Manufacturing ensures that externally provided processes, products and services do not adversely affect RiAlto Manufacturing's ability to consistently deliver conforming products and services to its customers.

RiAlto Manufacturing:

- a) ensures that externally provided processes remain within the control of its quality management system;
- b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) takes into consideration:
  - 1) the potential impact of the externally provided processes, products and services on RiAlto Manufacturing's ability to consistently meet customer and applicable statutory and regulatory requirements;
  - 2) the effectiveness of the controls applied by the external provider;
- d) determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

## **8.4.3 Information for external providers**

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

RiAlto Manufacturing communicates to external providers its requirements for:

- a) the processes, products and services to be provided;
- 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;

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- d) the external providers' interactions with CBC Connect;
- e) control and monitoring of the external providers' performance to be applied by RiAlto Manufacturing;
- f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

## **8.5 Production and service provision**

### **8.5.1 Control of production and service provision**

RiAlto Manufacturing has implemented production and service provision under controlled conditions. Controlled conditions include, as applicable:

- a) the 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;
  - 2) the results to be achieved;
- b) the availability and use of suitable monitoring and measuring 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;
- d) the use of suitable infrastructure and environment for the operation of processes;
- 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;
- g) the implementation of actions to prevent human error;
- h) the implementation of release, delivery and post-delivery activities.

### **8.5.2 Identification and traceability**

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

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

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

### **8.5.3 Property belonging to customers or external providers**

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

RiAlto 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, RiAlto Manufacturing reports this to the customer or external provider and retains documented information on what has occurred.

### **8.5.4 Preservation**

RiAlto Manufacturing preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

### **8.5.5 Post-delivery activities**

RiAlto Manufacturing meets requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, RiAlto Manufacturing considers:

- 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;

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- e) customer feedback.

## **8.5.6 Control of changes**

RiAlto Manufacturing reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

RiAlto 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**

RiAlto Manufacturing has 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 does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

RiAlto Manufacturing retains documented information on the release of products and services. The documented information include:

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

## **8.7 Control of nonconforming outputs**

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

RiAlto 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.

RiAlto 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.

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

**8.7.2** RiAlto Manufacturing retains documented information 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 Performance evaluation**

### **9.1 Monitoring, measurement, analysis and evaluation**

#### **9.1.1 General**

RiAlto Manufacturing determines:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) when the monitoring and measuring is performed;
- d) when the results from monitoring and measurement are analyzed and evaluated.

RiAlto Manufacturing evaluates the performance and the effectiveness of the quality management system.

RiAlto Manufacturing retains appropriate documented information as evidence of the results.

#### **9.1.2 Customer satisfaction**

RiAlto Manufacturing monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. RiAlto Manufacturing determines the methods for obtaining, monitoring and reviewing this information.

#### **9.1.3 Analysis and evaluation**



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RiAlto Manufacturing analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

## **9.2 Internal audit**

**9.2.1** RiAlto Manufacturing conducts internal audits at planned intervals to provide information on whether the quality management system:

- a) conforms to:
  - 1) RiAlto Manufacturing's own requirements for its quality management system;
  - 2) the requirements of the ISO 9001:2015 Standard;
- b) is effectively implemented and maintained.

**9.2.2** RiAlto Manufacturing:

- a) plans, establishes, implements and maintains an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the importance of the processes concerned, changes affecting RiAlto Manufacturing, and the results of previous audits;
- b) defines the audit criteria and scope for each audit;
- c) selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

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- d) ensures that the results of the audits are reported to relevant management;
- e) takes appropriate correction and corrective actions without undue delay;
- f) retains documented information as evidence of the implementation of the audit program and the audit results.

### **9.3 Management review**

#### **9.3.1 General**

RiAlto Manufacturing's top management reviews 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 is planned and carried out taking into consideration:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the quality management system;
- c) information on the performance and effectiveness of the quality management system, including trends in:
  - 1) customer satisfaction and feedback from relevant interested parties;
  - 2) the extent to which quality objectives have been met;
  - 3) process performance and conformity of products and services;
  - 4) nonconformities and corrective actions;
  - 5) monitoring and measurement results;
  - 6) audit results;
  - 7) the performance of external providers;
- d) the adequacy of resources;

## *RiAlto Manufacturing, Inc. Quality Policy Manual*

- 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 includes decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the quality management system;
- c) resource needs.

RiAlto Manufacturing retains documented information as evidence of the results of management reviews.

## **10 Improvement**

### **10.1 General**

RiAlto Manufacturing determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These 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, RiAlto Manufacturing:

- a) reacts to the nonconformity and, as applicable:
  - 1) takes action to control and correct it;
  - 2) deals with the consequences;

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- b) evaluates 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;
  - 3) determining if similar nonconformities exist, or could potentially occur;
- c) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) updates risks and opportunities determined during planning, if necessary;
- f) makes changes to the quality management system, if necessary.

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

**10.2.2** RiAlto Manufacturing retains documented information 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**

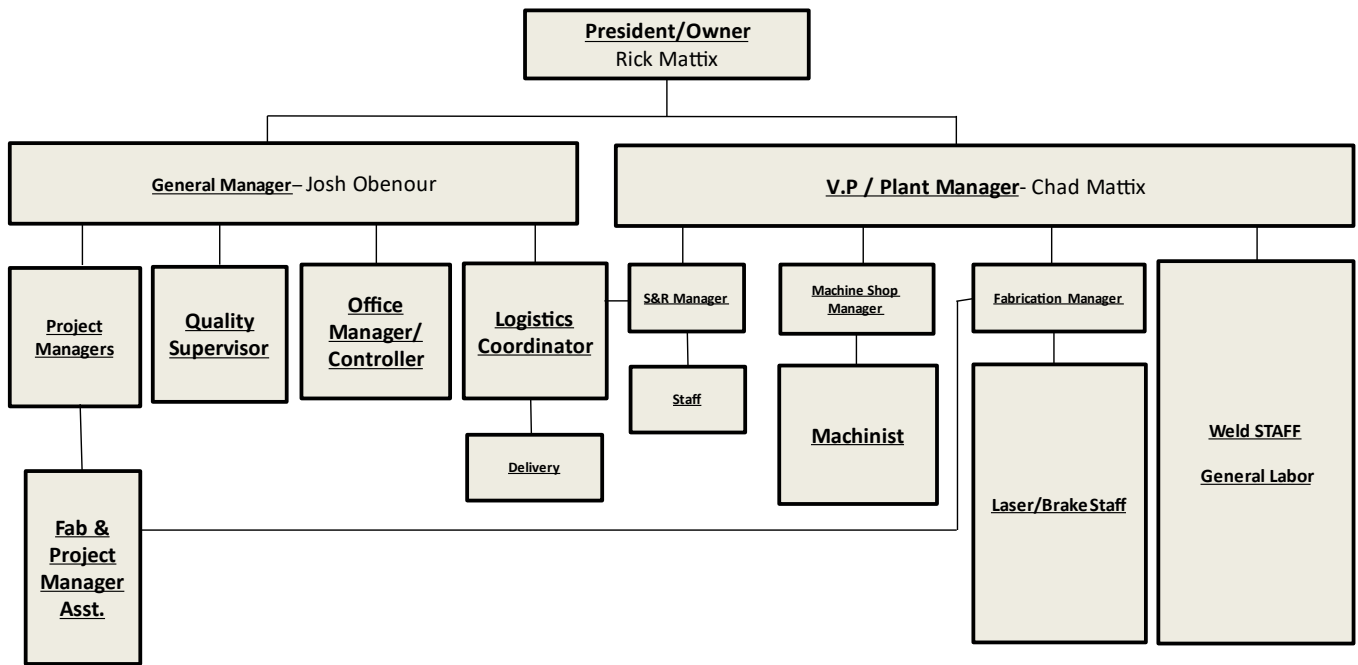
RiAlto Manufacturing continually improves the suitability, adequacy and effectiveness of the quality management system.

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

Appendix A. – Organizational Chart

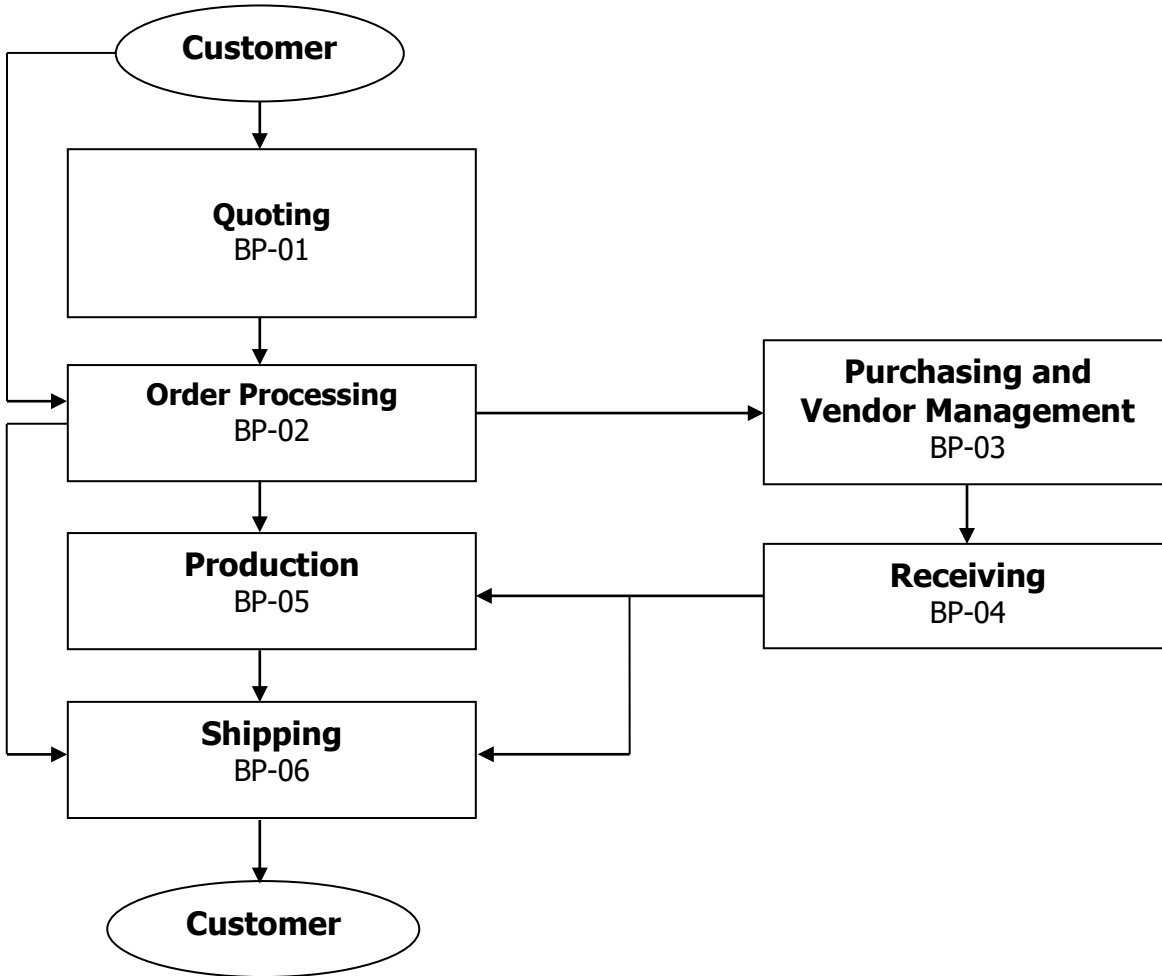


RiAlto Manufacturing Inc.  
Organizational Chart – 6/10/2024



**Appendix B. – Process Interaction Diagram**

**Core Business Processes:**



**Management/Support Processes:**

Competency and Training BP-09

Information Management

Control of Documents BP-10

Control of Records BP-11

Monitoring and Measurement

Calibration BP-08

Control of Nonconforming Product BP-12

Internal Audits BP-13

Corrective Action BP-14

Preventive Action BP-15

Management Review BP-16