QUALITY	QUALITY SYSTEM		
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RBR Machine

ISO 9001:2015
AS9100 Rev D

QUALITY ASSURANCE MANUAL

Revision 4 FEB 2018

1.0 RECORD OF CHANGES

Change No.	Date of Change	Description of change	Paragraph / Appendix
0	Nov 2015	Issued	
1	Jan 2016	Corrected to read does not design and develop parts	1.2, 5.4.1
2	Mar 2016	Revised RBR process map	Appendix 1
3	Feb 2018	AS 9100D Rewrite	All

1.1 INTRODUCTION AND SCOPE

RBR Machine has developed and implemented a Quality Management System (QMS) based upon the requirements of API Specification Q1, AS9100D and ISO 9001 in order to guide the processes and actions of our employees in machining parts to external customers in a consistent, reliable, and repeatable manner. This document is considered as the RBR Machine's quality manual, which includes reference to required documented procedures and other references to meet the requirements of API Specification Q1, AS9100D and ISO 9001 Quality Management System standards. All employees of RBR Machine are responsible for compliance to established requirements.

The scope of certification is; *Custom Machining Services*, the scope applies to all applicable activities at the company.

1.2 APPLICATION AND EXCLUSIONS

API Specification Q1, AS9100D and ISO 9001 applies to the production of our parts, with the exception of the following:

- RBR Machine does not design and develop parts. Our customers or their representatives provide product design specifications and configurations. As such, API Specification Q1 clause 5.4, ISO 9001:2015 clause 8.3, and AS9100D clauses 7.1.a, 7.1.3, 7.3 are not applicable to RBR Machine's QMS.

- RBR Machine claims an exclusion to API Specification Q1 Annex A, as RBR Machine does not currently monogram products.

2.0 NORMATIVE REFERENCE

The latest versions of the following documents are used as reference for the proper development and implementation of our QMS:

a) API Specification Q1 Ninth Edition June 2013, Specification for Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industry.

b) AS9100D Jan 2016 Quality Management System Requirements for Aviation, Space and Defense Organizations.

c) ISO 9000, Quality management systems - Fundamentals and Vocabulary.

3.0 TERMS AND DEFINITIONS

See Appendix 2 Terms and Definitions

4 QUALITY MANAGEMENT SYSTEM.

4. Context of RBR Machine.

4.1 Understanding RBR Machine and Its Context

RBR Machine determines 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.

RBR Machine monitors and reviews information about these external and internal issues and this documented in the Management Review Report.

4.2 Understanding the Needs and Expectations of Interested Parties

Due to their effect or potential effect on RBR Machine ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, RBR Machine determines:

a) the interested parties that are relevant to the quality management system
b) the requirements of these interested parties that are relevant to the quality management system

RBR Machine monitors and review information about these interested parties and their relevant requirements.

Interested Party	**What is the interest**
Customer	Maintain ISO/AS Certification to demonstrate an effective QMS
Owners / Stakeholders	Maintain ISO/AS Certification to satisfy customer requirements and corporate strategy to be a good corporate citizen.
Management	Maintain ISO/AS Certification to satisfy corporate strategy
Regulatory Bodies	To meet regulations and Maintain ISO/AS Certification in lieu of site inspections / visits
Employees	To help the company maintain ISO/AS Certification and therefore interested to understand what they are required to do

Feedback, if any, from Interested Parties is documented in the Management Review.

4.3 Determining the Scope of the Quality Management System

RBR Machine has determined the boundaries and applicability of the quality management system to establish its scope.

The scope of certification at RBR Machine is; *Custom Machining Services* and this scope of certification applies to all applicable activities with the exception of Section 8.3 Design and Development which is not applicable and has been claimed as an exclusion.

4.4 Quality Management System and Its Processes

RBR Machine has established, implemented, maintains, and continually improves its quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard and as shown in *Appendix 1* of this Quality Manual.

RBR Machine quality management system addresses customer and applicable statutory and regulatory quality management system requirements.

RBR Machine manages these processes in accordance with the requirements of the ISO 9001:2015 and AS9100D.

5. LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General

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 RBR Machine;
c) ensuring the integration of the quality management system requirements into RBR Machine 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 demonstrates leadership and commitment with respect to customer focus by ensuring that: customer and applicable statutory and regulatory requirements are determined, understood, and consistently met; the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; the focus on enhancing customer satisfaction is maintained***;*** 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 Establishing the Quality Policy

Top management has established, implemented, and maintains a quality policy as identified in Document QMS-001 which states:

“The Management and Employees of RBR Machine are committed to provide products that meet requirements and continually improve the effectiveness of our quality management system (QMS). In an effort to achieve this purpose, the company has established a formal QMS known as the RBR Machine QMS. The quality policy is the basis for the development of our quality objectives, which are monitored through the following:

- Management Reviews,
- Internal / External Audits, and
- Feedback from Customers and Employees

RBR Machine is committed to produce products that meets customer requirements. The quality of our products are controlled through the purchase of quality material, inspections and quality control procedures. Employees that impact quality are required to familiarize themselves with appropriate parts of the QMS that impacts their work and implement the same. RBR Machine's Management is committed to comply with API Specification Q1, AS9100 and ISO 9001 requirements.

The quality policy is communicated to employees that impact the quality of our products to enhance their understanding of how they impact the company’s quality management system. These employees have a responsibility for the quality of their work as part of the final product we offer to our Customers. Employees at all relevant functions and levels of the organization are empowered to participate in the continual improvement of the quality management system to maintain its effectiveness. The quality policy is reviewed for continuing suitability”.

5.3 Organizational Roles, Responsibilities, and Authorities

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within RBR Machine.

Top management assigns the responsibility and authority for:

a) ensuring that the quality management system conforms to the requirements of this International 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), in particular to top management;
d) ensuring the promotion of customer focus throughout RBR Machine;
e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

See QMS-008 for the current organization chart.

Top management has appointed the Quality Manager as the management representative, who has the responsibility and authority for oversight of the above requirements.

The management representative has RBR Machine freedom and unrestricted access to top management to resolve quality management issues.

6. PLANNING

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the quality management system, RBR Machine considers the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need 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 RBR Machine plans:

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

RBR Machine maintains QMS-013 Risk Identification, Control and Contingency Planning procedure to identify and control risk associated with impact on delivery and meeting product quality requirements. Risk that impact delivery and product quality requirements are registered on QMS-F21 Risk Register in a preventive and corrective action approach. QMS-F21 identifies the techniques, tools and application for risk identification, assessment and mitigation. Risk assessment associated with product delivery includes, but is not limited to:

a) facility/equipment availability and maintenance; and
b) supplier performance and material availability/supply.

Risk assessment associated with product quality includes but is not limited to, as applicable:

c) delivery of nonconforming product (see 5.10.1);
d) availability of competent personnel.

QMS-F21, which records risk assessment and management including actions taken is maintained per QMS-004 Control of Records.

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 RBR Machine establishes quality objectives at relevant functions, levels, and processes needed for the quality management system.

The quality objectives shall:

a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction; e. be monitored;
e) be communicated;
f) be updated, as appropriate.

RBR Machine maintains documented information on the quality objectives. See QMS-009, Quality Objectives for additional information and details.

6.2.2 When planning how to achieve its quality objectives

RBR Machine 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 RBR Machine determines the need for changes to the quality management system, the changes are carried out in a planned manner (see 4.4).

RBR Machine 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

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

RBR Machine considers:

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

7.1.2 People

RBR Machine determines 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

RBR Machine determines, 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

RBR Machine determines, 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

RBR Machine 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.

RBR Machine 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.

RBR Machine 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 RBR Machine to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

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 is 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.

RBR Machine has established, implements, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification. RBR Machine maintains a register of the monitoring and measuring equipment. The register includes the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria. Calibration or verification of monitoring and measuring equipment is carried out under suitable environmental conditions as applicable.

RBR Machine 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

RBR Machine 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, RBR Machine considers its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

RBR Machine:

a) determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
b) ensures that these persons are competent on the basis of appropriate education, training, or experience;
c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
d) retains appropriate documented information as evidence of competence.

See Procedure QMS-010 Personnel Training and Competency for additional information and details.

7.3 Awareness

The organization shall ensure that persons doing work under the organization'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.

Training requirements and their frequencies are defined using QMS-F07 Training and Competency Matrix. Training requirements include the following as a minimum:

a) QMS training;
b) job training;
c) customer-specified training and/or customer-provided training, when required.

7.4 Communication

RBR Machine 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

RBR Machine quality management system includes:

a) documented information required by this International Standard;
b) documented information determined by RBR Machine as being necessary for the effectiveness of the quality management system.

RBR Machine has established a documentation structure that is comprised of four levels. The levels consist of the following:

a) Level 1 – Policies,
b) Level 2 – Processes and Procedures,
c) Level 3 – Records and Forms and
d) Level 4 – References

7.5.2 Creating and Updating

When creating and updating documented information, RBR Machine ensures appropriate:

a) identification and description (e.g., a title, date, author, or 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 this International Standard are 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, RBR Machine 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***;***
e) prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

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

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

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

See Procedures Control of Documents QMS-003 and Control of Records QMS-004 for additional information and details.

8. OPERATION

8.1 Operational Planning and Control

RBR Machine 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:
c) the processes;
d) the acceptance of products and services;
e) determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;
f) implementing control of the processes in accordance with the criteria;
g) determining, maintaining, and retaining documented information to the extent necessary:
h) to have confidence that the processes have been carried out as planned;
i) to demonstrate the conformity of products and services to their requirements;
j) determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;
k) engaging representatives of affected organization functions for operational planning and control;
l) determining the process and resources to support the use and maintenance of the products and services;
m) determining the products and services to be obtained from external providers;
n) establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

As appropriate to RBR Machine, customer requirements, and products and services, RBR Machine 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. The output of this planning is suitable for RBR Machine operations. RBR Machine controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. RBR Machine ensures that outsourced processes are controlled.

RBR Machine 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

RBR Machine plans, implements, and controls a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to RBR Machine and the products and services: a. assignment of responsibilities for operational risk management;

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

See Procedure QMS-013 Risk Identification, Control and Contingency Planning for additional information and details.

8.1.2 Configuration Management

RBR Machine plans, implements, and controls a process for configuration management as appropriate to RBR Machine and its products and services in order 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

RBR Machine plans, implements, and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to RBR Machine and the product.

8.1.4 Prevention of Counterfeit Parts

RBR Machine plans, implements, and controls processes, appropriate to RBR Machine and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

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;
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, RBR Machine ensures that:

a) the requirements for the products and services are defined, including:
b) any applicable statutory and regulatory requirements;
c) those considered necessary by RBR Machine;
d) RBR Machine can meet the claims for the products and services it offers;
e) special requirements of the products and services are determined;
f) operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.

8.2.3 Review of the Requirements for Products and Services

8.2.3.1 RBR Machine ensures that it has the ability to meet the requirements for products and services to be offered to customers. RBR Machine conducts a review before committing to supply products and services to the 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 RBR Machine;
c) statutory and regulatory requirements applicable to the products and services;
d) contract or order requirements differing from those previously expressed.

This review is coordinated with applicable functions of RBR Machine.

If upon review RBR Machine determines that some customer requirements cannot be met or can only partially be met, RBR Machine negotiates a mutually acceptable requirement with the customer.

RBR Machine ensures that contract or order requirements differing from those previously defined are resolved.

The customer requirements are confirmed by RBR Machine before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2 RBR Machine 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

RBR Machine 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.

See Procedure QMS-012 Review of Requirements for additional information and details.

8.3 Design and Development of Products and Services – sub – clause not applicable

8.4 Control of Purchasing Activities

8.4.1 General

RBR Machine ensures that externally provided processes, products, and services conform to requirements.

RBR Machine is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer. RBR Machine ensures, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.

RBR Machine 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.

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

RBR Machine 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 RBR Machine own products and services;
b) products and services are provided directly to the customer(s) by external providers on behalf of RBR Machine;
c) a process, or part of a process, is provided by an external provider as a result of a decision by RBR Machine.
d) RBR Machine determines and applies criteria for the evaluation, selection, monitoring of performance, and reevaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. RBR Machine retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.1 RBR Machine shall:

a) define 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) maintain a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);
c) periodically review external provider performance including process, product and service conformity, and on time delivery performance;
d) define the necessary actions to take when dealing with external providers that do not meet requirements;
e) define the requirements for controlling documented information created by and/or retained by external providers.

8.4.2 Type and Extent of Control

RBR Machine ensures that externally provided processes, products, and services do not adversely affect RBR Machine ability to consistently deliver conforming products and services to its customers.

RBR Machine:

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) take into consideration:

    1) the potential impact of the externally provided processes, products, and services on RBR Machine ability to consistently meet customer and 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) determines 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 are performed according to the risks identified by RBR Machine. These include inspections or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.

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

When RBR Machine delegates verification activities to the external provider, the scope and requirements for delegation are defined and a register of delegations is maintained. RBR Machine periodically monitors the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, RBR Machine 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), RBR Machine implements a process to validate the accuracy of test reports.

8.4.3 Information for External Providers

RBR Machine ensures the adequacy of requirements prior to their communication to the external provider.

RBR Machine 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 RBR Machine;
e) control and monitoring of the external providers' performance to be applied by RBR Machine;

RBR Machine communicates to external providers its requirements for:

a) verification or validation activities that RBR Machine, or its customer, intends to perform at the external providers' premises;
b) design and development control;
c) special requirements, critical items, or key characteristics;
d) test, inspection, and verification (including production process verification);
e) the use of statistical techniques for product acceptance and related instructions for acceptance by RBR Machine;

The need to:

a) implement a quality management system;
b) use customer-designated or approved external providers, including process sources (e.g., special processes);
c) notify RBR Machine of nonconforming processes, products, or services and obtain approval for their disposition;
d) prevent the use of counterfeit parts (see 8.1.4);

e) notify RBR Machine of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain RBR Machine approval;
f) flow down to external providers applicable requirements including customer requirements;
g) provide test specimens for design approval, inspection/verification, investigation, or auditing;
h) retain documented information, including retention periods and disposition requirements;
i) the right of access by RBR Machine, 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:
j) their contribution to product or service conformity;
k) their contribution to product safety;
l) the importance of ethical behavior.

See Procedures QMS-015 Purchasing Products and Services and QMS-015FC New Vendor Process Flowchart for additional information and details.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

RBR Machine maintains QMS-017 Control of Production, Inspection and Testing procedure to describe the controls associated with production of products.

RBR Machine implements production and service provision under controlled conditions.

Controlled conditions include, as applicable:

a) the availability of documented information that defines:
b) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
c) the results to be achieved;
d) the availability and use of suitable monitoring and measuring resources;
e) 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;
f) ensuring that documented information for monitoring and measurement activity for product acceptance includes:
g) criteria for acceptance and rejection;
h) where in the sequence verification operations are to be performed;
i) measurement results to be retained (at a minimum an indication of acceptance or rejection);
j) any specific monitoring and measurement equipment required and instructions associated with their use;
k) ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).
l) the use of suitable infrastructure and environment for the operation of processes;
m) the appointment of competent persons, including any required qualification;
n) 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;
o) the implementation of actions to prevent human error;
p) the implementation of release, delivery, and post-delivery activities;
q) the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);

r) the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
s) the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;

Controlled conditions include, as applicable:

a) the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
b) the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
c) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
d) the provision for the prevention, detection, and removal of foreign objects;
e) 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);
f) 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 are 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, RBR Machine establishes 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

RBR Machine implements production process verification activities to ensure the production process is able to produce products that meet requirements.

RBR Machine uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity is repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).

RBR Machine retains documented information on the results of production process verification.

See Procedure QMS-019 Validation of Processes for Production for additional information and details.

8.5.2 Identification and Traceability

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

RBR Machine maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

RBR Machine 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), RBR Machine establishes controls for the media. RBR Machine controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

See Procedure QMS-020 Identification and Traceability of Products for additional information and details.

8.5.3 Property Belonging to Customers or External Providers

RBR Machine exercises care with property belonging to customers or external providers while it is under RBR Machine control or being used by RBR Machine. RBR Machine 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, RBR Machine reports this to the customer or external provider and retain documented information on what has occurred.

8.5.4 Preservation

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

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

a) cleaning;
b) prevention, detection, and removal of foreign objects;
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.

See Procedure QMS-022 Safeguarding and Preservation for additional information and details.

8.5.5 Post-Delivery Activities

RBR Machine meets the requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, RBR Machine 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;
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 RBR Machine (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, RBR Machine takes appropriate action including investigation and reporting.

8.5.6 Control of Changes

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

Persons authorized to approve production or service provision changes are identified.

RBR Machine 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

RBR Machine implements 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.

RBR Machine retains documented information on the release of products and services.

The documented information includes:

a) evidence of conformity with the acceptance criteria;
b) traceability to the person(s) authorizing the release.
c) When required to demonstrate product qualification, RBR Machine ensures that retained documented information provides evidence that the products and services meet the defined requirements.

RBR Machine 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 RBR Machine ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery, see procedure QMS-006.

RBR Machine 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

8.7 Control of Nonconforming Outputs - continued

services. RBR Machine nonconformity control process is maintained as documented information including the provisions for:

a) defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
b) taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;
c) timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
d) defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).

RBR Machine 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 is only implemented:

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

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

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

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

8.7.2 RBR Machine 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

RBR Machine has determined:

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 shall be performed;
d) when the results from monitoring and measurement are analyzed and evaluated.

RBR Machine evaluates the performance and the effectiveness of the quality management system.

RBR Machine retains appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

RBR Machine monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. RBR Machine determines the methods for obtaining, monitoring, and reviewing this information. Information to be monitored and used for the evaluation of customer satisfaction include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. RBR Machine develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

See Procedure QMS-028 Measurement of Customer Satisfaction for additional information and details.

9.1.3 Analysis and Evaluation

RBR Machine 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.

See Procedure QMS-029 Analysis of Data Regarding Effectiveness of QMS for additional information and details.

9.2 Internal Audit

9.2.1 RBR Machine conducts internal audits at planned intervals to provide information on whether the quality management system conforms to:

a) RBR Machine own requirements for its quality management system;
b) the requirements of this International Standard;
c) is effectively implemented and maintained.

9.2.2 RBR Machine shall:

a) plan, establish, implement, and maintain 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 RBR Machine, 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;
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.

See Procedure QMS-005 Internal Audits for additional information and details.

9.3 Management Review

9.3.1 General

Top management reviews RBR Machine quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of RBR Machine.

9.3.2 Management Review Inputs

The management reviews are 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:
d) customer satisfaction and feedback from relevant interested parties;
e) the extent to which quality objectives have been met;
f) process performance and conformity of products and services;
g) nonconformities and corrective actions;
h) monitoring and measurement results;
i) audit results;
j) the performance of external providers***;***
k) on-time delivery performance;
l) the adequacy of resources;
m) the effectiveness of actions taken to address risks and opportunities;
n) 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;
d) risks identified.

RBR Machine retains documented information as evidence of the results of management reviews.

10. IMPROVEMENT

10.1 General

RBR Machine determines and selects opportunities for improvement and implement 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, RBR Machine shall:

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

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

RBR Machine maintains documented information that defines the nonconformity and corrective action management processes, see procedure Corrective and Preventative Actions QMS-007.

10.2.2 RBR Machine retains documented information as evidence of:

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

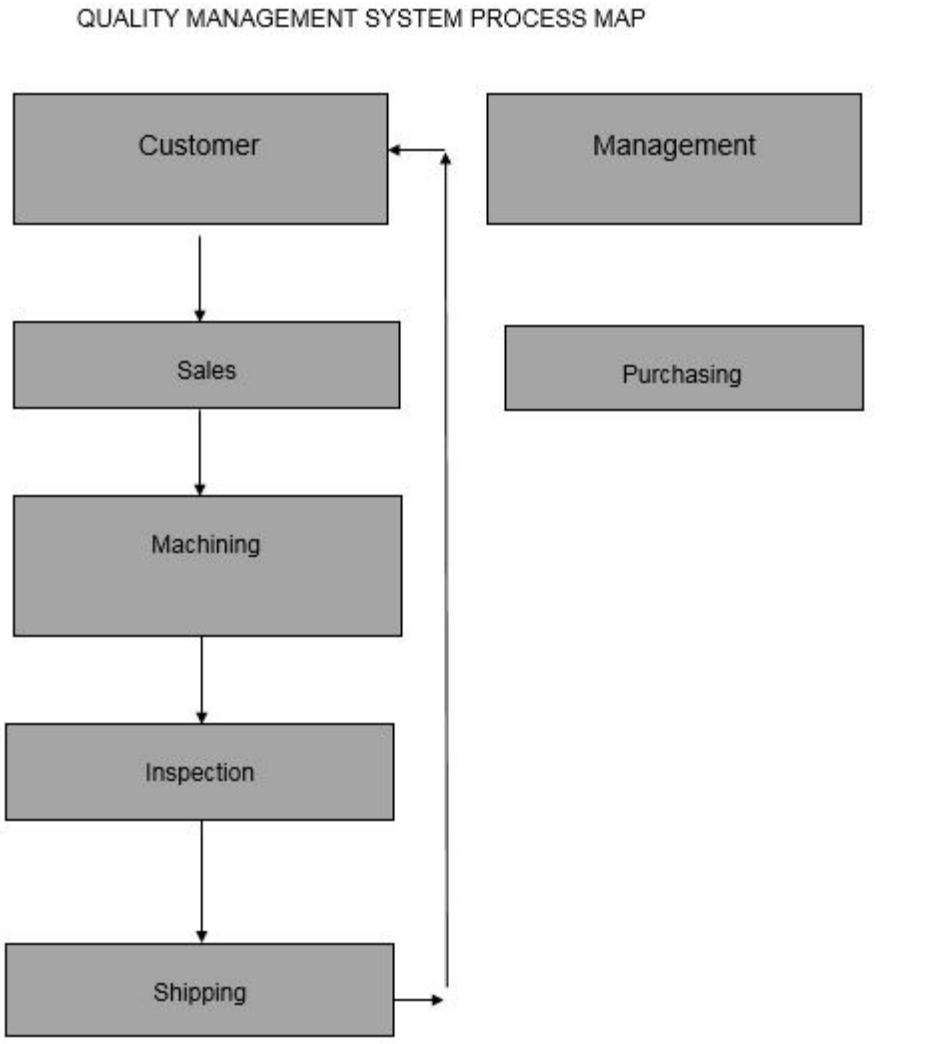
10.3 Continual Improvement

RBR Machine continually improves the suitability, adequacy, and effectiveness of the quality management system.

RBR Machine 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.

RBR Machine monitors the implementation of improvement activities and evaluate the effectiveness of the results.

Appendix 1 RBR Machine Process Model



Notes – the key processes are machining and Purchasing; purchasing interacts with all process

Key Process Control Criteria					
Process	**Input**	**Output**	**Criteria for Success**	**Measured By**	**Responsibilities and Authorities**
Purchasing	**"Work Order" (Includes customer requirements, drawings, Specifications);** **Sales Order;** **Material and Outside Process Prices and Lead times;** **Approved Suppliers;** **Receiving: Materials and tooling;** **Provides input to all departments**	**Purchase order / confirmation Completed;** **"Work Order" (Includes customer requirements, drawings, Specifications);** **Raw Material PO;** **OSV Purchase Orders;** **Data to all departments**	**Accurate information;** **Trained personnel;** **Quality Vendors;** **Adequate infrastructure & environment;** **C.O.C.'s Adherence to quality standards**	**Customer Satisfaction Data,** **Non-Conformances ≤ 5%** **Supplier Performance ≥ 95%**	**Purchasing Manager**
Machining	**"Work Order" (Includes customer requirements, drawings, Specifications);** **Raw Materials;** **Machines;** **Plant & Support Group schedules,** **Control Plans**	**Completed Machined parts;** **Paperwork;** **Quality Control Inspection Data.**	**Accurate information;** **Trained personnel;** **Suitable machines and equipment = calibrated as required;** **Quality Material Vendors;** **Control Plans;** **Adequate infrastructure & environment;** **Adherence to 9001:2015 ISO and AS9100 standards**	**Customer Satisfaction Data:** **Non-Conformances ≤ 5%** **On-time delivery ≥ 95%**	**Shop Manager**

Support Processes

Accounting \ Finance
*Coating
Human Resources
Management
Purchasing
Safety
Training
Warehouse
*Calibration
Equipment Maintenance
*Inspection (NDE)
*Production
Quality
Sales
Transportation

**** - Potentially Outsourced***

Appendix 2 - Terms and Definitions

Acceptance Criteria - Specified limits of acceptability applied to process or product characteristics.

Acceptance Inspection - Demonstration through monitoring or measurement that the product complies with specified requirements.

API - American Petroleum Institute

Audit - The on-site verification activity, such as inspection or examination, of a process or quality system, to ensure compliance to requirements. An audit can apply to an entire organization or might be specific to a function, process or production step.

Calibration - The comparison of a measurement instrument or system of unverified accuracy to a measurement instrument or standard of known accuracy to detect any variation from the required performance specification.

Collection - Process of obtaining, assembling, and/or organizing applicable information with the intent of meeting the requirements of 4.5.

Control Feature - Organization's documented method to perform an activity under controlled conditions to achieve conformity to specified requirements.

Competence - The ability for an employee to perform a job properly.

Compliance - Act or process of satisfying the legal and other applicable requirements of a regulation or regulatory body.

Continuous Improvement - Sometimes called continual improvement. The ongoing improvement of products, services or processes through incremental and breakthrough improvements.

Corrective Action – The identification and elimination of the root causes of a problem thus preventing their recurrence.

Critical - That deemed by the organization, product specification, or customer as mandatory, indispensable or essential, needed for a stated purpose or task, and requiring specific action.

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

Customer – A Customer is one who receives products (in terms of specified requirements), and gives the final verdict on the same. This in turn acts as a hidden feedback, which can be implemented leading to improvement to all the parameters of the process. Customers can be internal or external.

Customer Supplied Property – Any property or material, such as product, provided or obtained by RBR Machine on behalf of the Customer, as an input to be managed by RBR Machine's internal processes.

Delivery - Point in time and physical location at which the agreed transfer of ownership takes place.

Design Acceptance Criteria - Defined limits placed on characteristics of material, products or services established by the organization, customer, and/or applicable specifications to achieve conformity to the product design.

Design Validation - Process of proving a design by testing to demonstrate conformity of the product to design requirements.

Design Verification - process of examining the result of a given design or development activity to determine conformity with specified requirements.

Document – A document is a collection of information or instructions presented to perform some activity in a process or procedure. A document is an output of manual or electronic

documentation of data or information used for documenting events, processes, procedures or activities and utilized as a testimony to verify performance.

Field Nonconformity - Product nonconformity that is detected after delivery or use has started.

First Article - Representative sample of product, component, or output from a process used to verify that prescribed activities have satisfied the requirements as specified by the organization.

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.

Key Performance Indicator - Quantifiable measure that an organization uses to gauge or compare performance.

Legal requirement - Obligation imposed on an organization, including those that are statutory or regulatory.

Management - Person or group of people, as defined by the organization, who directs and controls all or part of a facility, location, department, or other function; has the fiscal responsibility for the organization, and is accountable for ensuring compliance with legal and other applicable requirements.

Manufacturing Acceptance Criteria - Defined limits placed on characteristics of materials, products and services established by the organization to achieve conformity to the manufacturing or service requirements.

Outsource - Function or process that is performed by an external supplier on behalf of the organization.

Preventive action - Action taken to remove or improve a process to prevent potential future occurrences of a nonconformance.

Procedure - Organization's documented method for performing an activity under controlled conditions to achieve conformity to specified requirements.

Process - A series of steps or actions that lead to a desired result or output. A set of common tasks that create a product, services, process, or plan that will satisfy a customer or group of customers. A sequential series of steps leading to a desired outcome. Processes are largely affected by one or more of the following factors: a) personnel who operate the processes b) materials which are used as inputs (including information) c) machines or equipment being used in the process (in process execution or monitoring/measurement) d) methods (including criteria and various documentations used along the process) e) work environment. Understanding how these factors interact and affect processes is a key consideration in process management.

Product Realization - All phases of the planning, organizing, resourcing, and delivery of products.

Quality Assurance – A concept that covers all policies and systematic activities implemented within an organization.

Record – A document recording specific information that relates to a process, procedure, or work instruction. They serve as evidence of conformity to requirements and of the effective operation of the QMS.

Risk - Situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

Service - Performance of an activity by one function or organization for another.

Servicing - Product maintenance, adjustment, repair, and/or on-site installation when installation is required by applicable product specifications.

Standard - The metric, specification, gauge, statement, category, segment, grouping, behavior, event or physical product sample against which the outputs of a process are compared and declared acceptable or unacceptable.

Special Requirements - Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements

include product or process complexity, past experience and product or process maturity. 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 organization to be at the limit of its technical or process capabilities.

Subcontractor – A junior or secondary contractor who contracts with a prime contractor (and not the principal or owner of the project) to perform some or all of the prime contractor's contractual obligations under the prime contract. A subcontractor is also a supplier.

Supplier – An external entity that supplies relatively common, off the shelf, or standard goods or services, as opposed to a contractor or subcontractor who commonly adds specialized input to deliverables. Also called a vendor.

Supporting Documentation - Supporting Documentation includes work instructions, practices, procedures, forms, and industry reference manuals, which are used by staff to perform work affecting the organization's ability to provide high quality products, which meet with Customer and organization requirements. Supporting Documentation also includes those records, which Management uses to gauge the effectiveness of our QMS.

Tender - Offer made by an organization in response to an invitation to provide a product.

Top Management - a person or group of people who directs and controls an organization at the highest level.

Traceability - The ability to verify the history, location, or application of an item by means of documented recorded identification.