ACCUTECH MACHINE, Inc.

ISO 9001:2015
Quality Manual

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(A)
Revision and Approval Log

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(B)

Our QUALITY POLICY

Accutech Machine is committed to manufacture the highest quality products that satisfy or exceed our Customer needs and requirements while effectively utilizing every employee and their skills to achieve the goal. Accutech Machine is dedicated to continually improve the Quality Management System.

(0) INTRODUCTION

0.1 General

The company's quality management system (QMS) specifies requirements for the company to consistently:

- provide products and services that meet Customer and applicable statutory and regulatory requirements,
- facilitate opportunities to enhance Customer satisfaction,
- address risks and opportunities associated with its context and objectives, and
- allow the ability to demonstrate conformity to all controlled QMS requirements.

0.2 Quality Management Principles

The direct link between this QMS and ISO 9000 are these 7 quality principles:

1. Customer focus
2. Leadership
3. Engagement of People
4. Process Approach
5. Improvement
6. Evidence-Based Decision Making
7. Relationship Management

0.3 Process Approach

The company has adopted two linked process approaches to quality management. These approaches, followed throughout the company's processes, include the ***P-D-C-A (Plan-Do-Check-Act)*** and ***Risk-Based Thinking*** methodologies.

The process approach involves the systematic definition, planning and management of processes and their interactions to achieve the intended results in accordance with the quality policy and strategic direction of the company.

The PDCA cycle enables the company to ensure that the processes are adequately resourced and managed, and that opportunities for improvement have been determined and are acted on. It is applied to all processes and to the entire QMS.

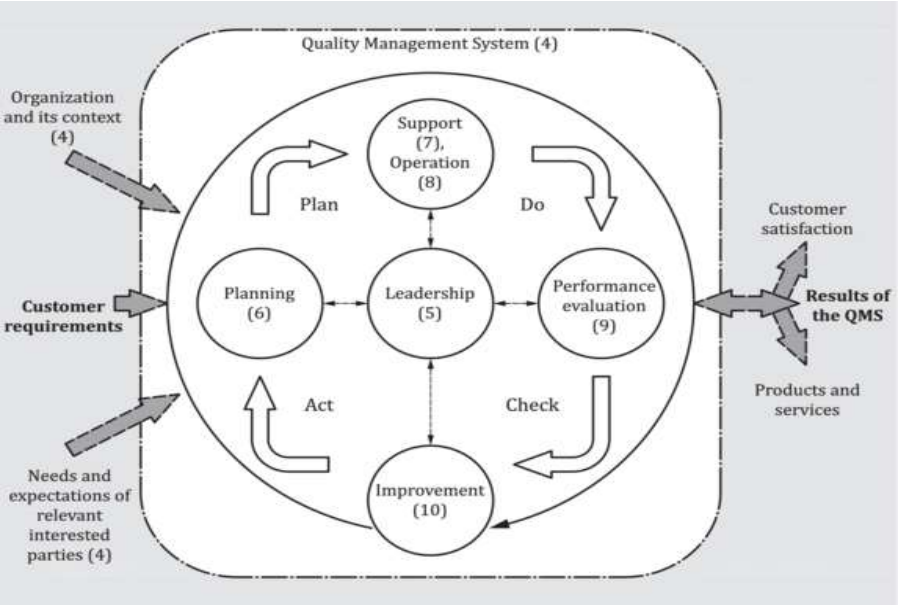
The P-D-C-A cycle is briefly described as:

PLAN – establishing the objectives of the system, its processes and the resources needed to deliver the results to meet all Customer requirements as well as the company's policies and identify and address risk and opportunities.

DO – implement what was planned.

CHECK – monitor and measure processes and the resulting products and services vs. policies, objectives, requirements and other planned activities and report on these results.

ACT – take the necessary action to improve performance.

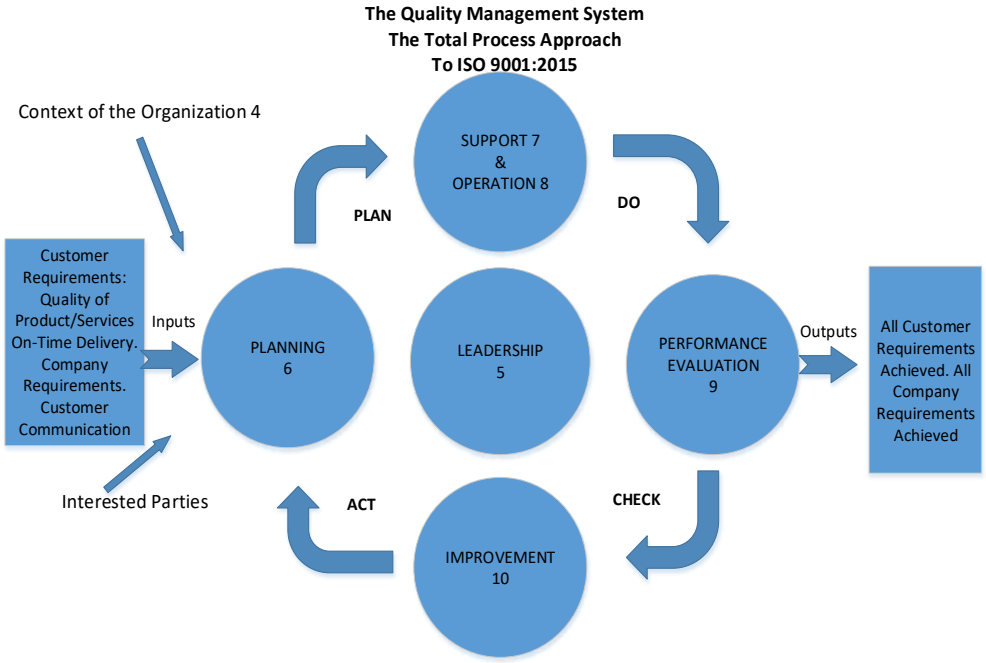


Imported from ISO9001:2015, fifth edition 2015-09-15, pg. viii

Risk-based thinking enables the company to determine the factors that could cause processes and the quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise.

The company plans and implements actions to address risks and opportunities. In addressing risks and opportunities the company establishes a basis for increasing the effectiveness of the QMS, achieves improved results and prevents negative results.

The company has designed and utilizes schematic representations, diagrams, and databases to define the process approaches to achieving objectives and meeting all Customer requirements. The following represents processes and the interaction of elements, known as the *Total Process Approach*.



1 SCOPE (of the QMS)

1.1 General

Documented information that devises the company's QMS specifies requirements for a quality management system when the company: a) demonstrates its ability to provide consistent products and service that meets Customer and applicable statutory and regulatory requirements, and b) addresses Customer satisfaction through the effective application of
The system, including processes for improvement and assurance of conformity to Customer and applicable statutory and regulatory requirements and c) 8.3, Design and development of products and services and 8.5.5 Post-delivery activities are not applicable to the company.

2 NORMATIVE REFERENCE

Standards

ISO9001 Fifth Edition 2015-09-15(ISO 9001:2015(E))

3 TERMS AND DEFINITIONS

*"**Product and Service**" includes all outputs.*

***"Documented Information**" includes all* "Documents" and "Records"

"Continual Improvement" *is to improve the "effectiveness" of the QMS though it also now improves "**suitability**" and "**adequacy**" of the QMS.*

"Monitoring and Measuring Resources" *references calibration devices used to measure product compliance.*

*The terms "supplier" and "vendor" are also now known as "**external provider**" and therefore "purchased product or service" is also now known as "**externally provided products and services**".*

Risk-based thinking *enables the company to determine issues and opportunities that could cause processes and the QMS to deviate from what has been planned and to put in place preventive controls to minimize the negative effects and to make maximum use of opportunities as they* arise.

Additional terms and definitions in ISO9001:2015 apply within the company's quality management system.

4 Context of the Organization

4.1 Understanding the organization and its context

The company has determined external and internal issues that are relevant to our purpose and our strategic direction and that they affect our ability to achieve the intended results of our quality management system.

The company monitors and reviews information about these external and internal issues.

External issues include tangible factors such as the ability for all levels of the supply chain to meet all company requirements, including quality of product/services and delivery commitments, as follows:

1. **Internal issues** include (but are not limited to):
    - Manufacturing/engineering challenges
    - Internal communication
    - Equipment & Infrastructure
    - Effectiveness of actions (following the P-D-C-A cycle and application of RBT)

2. **External issues** include (but are not limited to):
    - Customer perception and satisfaction
    - Competitive sector strengths
    - Supply chain management
    - Industry and Customer specific requirements

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the company's ability to consistently provide products and services that meet Customer and applicable statutory and regulatory requirements, the company determines:

a) The interested parties that are relevant to the QMS, and
b) The requirements of these interested parties that are relevant to the QMS.

The company monitors and reviews information about these interested parties and their relevant requirements.

Interested parties include both internal (all company personnel; the reliance of one individual's or department's ability to meet requirements to ensure the success and operational flow of each additional downstream individuals/departments to meet external Customer requirements related to product and service and external Customers. Other interested parties include external providers also referred to as suppliers or individuals or companies that render product and/or services, considered on the company's supply-chain to meet all Customer requirements. These Interested Parties may include, but are not limited to:

- Company Employees
- Company Owners
- Customers
- Suppliers
- Regulatory Agencies
- Internal Auditors
- Third Party Auditors

4.3 Determining the scope of the QMS

The company determines the boundaries and applicability of the QMS in the establishment of our scope. The company has considered:

a) The external and internal issues referred to 4.1, above,
b) The requirements of relevant interested parties referred to 4.2, above, and
c) The products and services of the company.

The company applies all the requirements of ISO 9001:2015 as they apply within the determined scope of our QMS. The scope of our QMS is available and maintained as documented information. The scope states all products and services covered and provides justification for any requirement of the standard that we have determined is not applicable to the scope of our QMS.

Conformity to the ISO 2015 standard is maintained with 8.3, design/development not being applicable. Additionally, all aspects of 8.5.5 are also not applicable as the company does not perform post-delivery activities. In the case where non-complaint product or services are released to the Customer, the company will issue a return materials authorization and support the nonconformity with applicable requirements to

ensure compliance is achieved. This has no adverse effect on the company's ability or responsibility to ensure the conformity of our products and services and the enhancements of Customer satisfaction.

Our corporate scope is stated as follows:

ACCUTECH MACHINE was established in 2005 and is located in Danvers, Massachusetts. The company's scope is to offer superior product and services as a contract machining manufacturer.

4.4 QMS and its processes.

4.4.1 The company has established, implemented, maintains, and continually improves our QMS, including all the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015.

The company has determined the processes needed for the QMS and their application throughout the company, 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 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 of Planning,
g) Evaluated these processes and implement, accordingly, and changes needed to ensure that these processes achieve their intended results, and
h) And continues to improve the processes and the overall QMS.

4.4.2 To the extent necessary, the company:

a) Maintains documented information to support the operation of its processes; and
b) Retains documented information to ensure confidence that the processes are being carried out as planned.

A controlled list of all company documented information is maintained. This includes what are both maintained (formally known as "documents") and what are retained (formally known as "records").

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 QMS,
b) Ensures the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the company,
c) Ensures the integration of the QMS requirements into the company business processes,
d) Promotes the use of the process approach and risk-based thinking,
e) Ensures that the resources needed for the QMS are available,
f) Communicates the importance of effective quality management and of conforming to the QMS requirements,
g) Ensures that the QMS achieves its intended results,
h) Engages, directs, and supports people to contribute to the effectiveness of the QMS,
i) Promotes improvement, and
j) Supports other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

The leadership team of the company is defined as a select group who converse, meet, discuss, determine, and implement all aspects of the company quality management system which includes the company's focus on the Customer.

5.1.2 Customer Focus

Top Management demonstrates leadership and commitment with respect to Customer focus by ensuring that:

a) The Customer and applicable statutory and regulatory requirements that are determined are also understood and consistently met,
b) The risks and opportunities that can affect conformity of products and services and the ability to enhance Customer satisfaction have been determined and addressed, and
c) The focus on enhancing Customer satisfaction is maintained.

Documented information, including processes, have been developed to ensure that the needs and requirements of all Customers can and shall be achieved through effective planning, support, and overall operations. All developed documented information and processes are measured for effectiveness and the need, where applicable, to implement improvements. Each has a level of risk management applied to ensure that, what may go wrong prior to implementation is addressed, suitable changes are made to mitigate or eliminate risk and then execution occurs.

5.2 Policy

5.2.1 Establishing the quality policy:

Top management has established, implemented, and maintains a quality policy that:

a) Is appropriate to the purpose and context of the company and supports its strategic direction,
b) Provides a framework for setting quality objectives,
c) Includes a commitment to satisfy applicable requirements, and
d) Incudes a commitment to continual improvement of the QMS.

The company's quality policy is:

Accutech Machine is committed to manufacture the highest quality products that satisfy or exceed our Customer needs and requirements while effectively utilizing every employee and their skills to achieve the goal. Accutech Machine is dedicated to continually improve the Quality Management System.

5.2.2 Communicating the quality policy

The quality policy is:

a) Available and maintained as documented information,
b) Communicated, understood, and applied companywide, and
c) Available to relevant interested parties, as appropriate.

The policy is posted companywide and is continually promoted with company staff during meetings, evaluations, audits and whenever there is an appropriate opportunity.

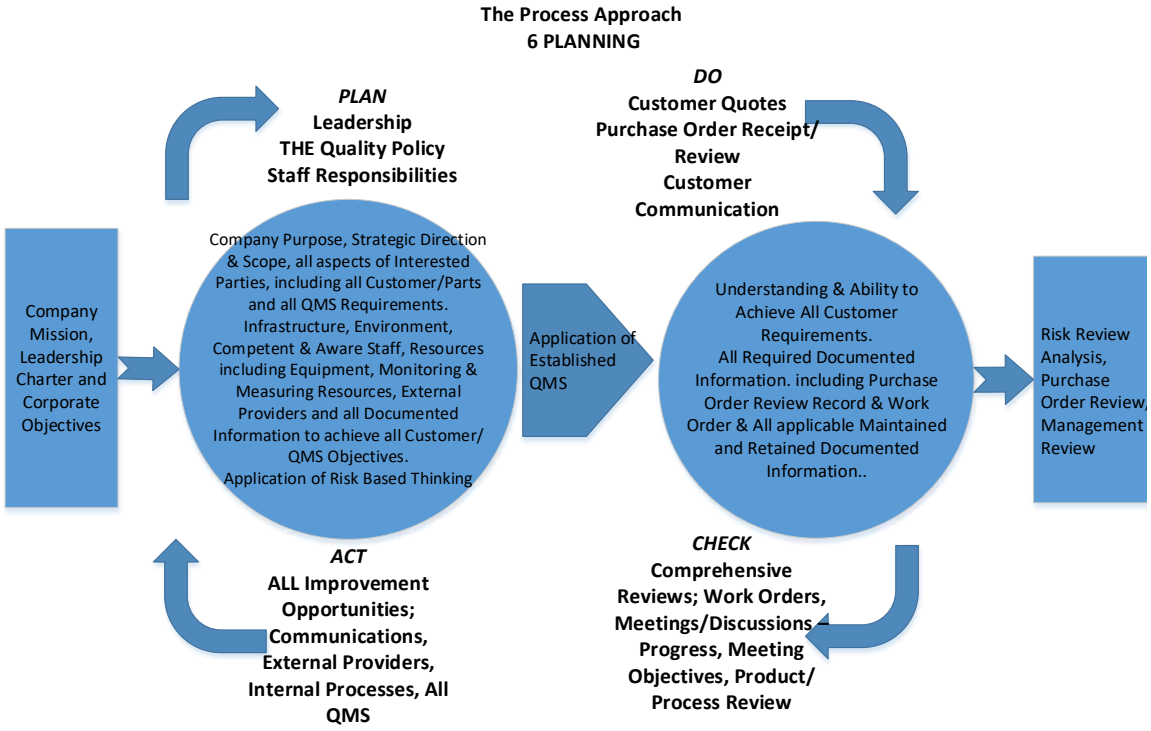
5.3 Organizational roles, responsibilities, and authorities

Top Management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the company. Top management has assigned responsibilities and authorities to:

a) Ensure that the QMS conforms to the requirements of ISO 9001:2015,
b) Ensures that the processes are delivering their intended outputs,
c) Reports on the performance of the QMS and on opportunities for improvement, in particular to top management,
d) Ensures the promotion of Customer focus throughout the company, and
e) Ensures that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

All positions, as defined on the company's organizational chart have a controlled corresponding job description that are identified and managed electronically. The current controlled Organizational Chart is noted on the company's ***Master List of QMS Documented Information, 7.5.1-4-1.***

6 Planning



6.1 Actions to address risk and opportunities

6.1.1 When planning for the QMS, the company 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 QMS can achieve its intended results,
b) Enhances desirable effects,
c) Prevents and/or reduces undesired effects, and
d) Achieve improvement.

6.1.2 The company plans:

a) Actions to address the risks and opportunities, and
b) How it:
    1) Integrates and implements the actions into the QMS processes, and
    2) Evaluates 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.

The company has planned and implements actions to address risks and opportunities (*Risk-based thinking)*. These actions enable the company to determine issues and opportunities that could cause processes and the QMS to deviate from what has been planned. And to put in place preventive controls to minimize/ prevent negative effects while ensuring that the QMS is effective, that the company achieves improved results, and that the company maximizes the use of opportunities.

The concept of risk-based thinking is applied to the company's various processes and basically asks the question "What can go wrong?" as a preventive tool and applies the answer to that question with actions that are preventive in nature.

The Total Process Approach, under 0.3, above, is a schematic representation of the process flow and interactions.

Risk-Based Thinking is applied to these processes:

- The process approach to planning,
- The process approach to support and operation,
- Personnel; Use of job descriptions, training, evaluation and assessing competence, awareness, and training needs & effectiveness,
- Operational capacity, personnel, and infrastructure planning,
- Product compliance,
- Preventive maintenance process to determine adequate machine PM frequency, actions to ensure appropriate operations and follow-up actions,
- Measurement and monitoring resources & documented information, process, process for in-house calibration/verification and M&M resource data including tolerances and resource frequency,
- Supplier (externally provided processes, products, and services), meeting requirements of 8.4,
- Customer related processes: value added services, quote of product and services,
- The order process for defining processes and job-flow and traveler process entailing applicable nonconforming issues,
- In-process quality of product inspection,
- Purchase order related items (Customer requirement review/risk level assignment),
- On-time order delivery,
- Internal Audit,
- Management Review,
- Corrective Actions Reports,
- Safety process and practices.

The company continually verifies that risk-based thinking and risk controls and mitigations are effective and functionally applied throughout the various processes, use of documented information and in maintaining full compliance to its quality management system. Documented information is utilized, as appropriate, to ensure this compliance,

determine need for corrective action, seek continual improvement and ensure that all risk measures are applied, implemented and are effective.

The company continually reviews, assesses, and evaluates all applicable internal and external factors that impact the company's ability to meet its objectives and will record these upon determination while applying risk-based thinking.

6.2 Quality objectives and planning to achieve them

6.2.1 The company has established quality objectives at relevant function, levels and processes needed for the QMS. The quality objectives:

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

The company maintains documented information on the quality objectives.

As quality objectives are corporate goals that are maintained and reviewed in management review and linked directly to the company's quality policy and overall understanding the context of the organization, the company performs its due diligence to ensure that these are achieved.

The two defined quality objectives include 1) Providing Consistent Quality Product, and 2) On-Time Delivery Performance of This Product to Customers.

6.2.2 When planning how to achieve its quality objectives, the company defines:

a) What is done,
b) What resources are required,
c) Who is responsible,
d) When they will be completed, and
e) How the results are evaluated.

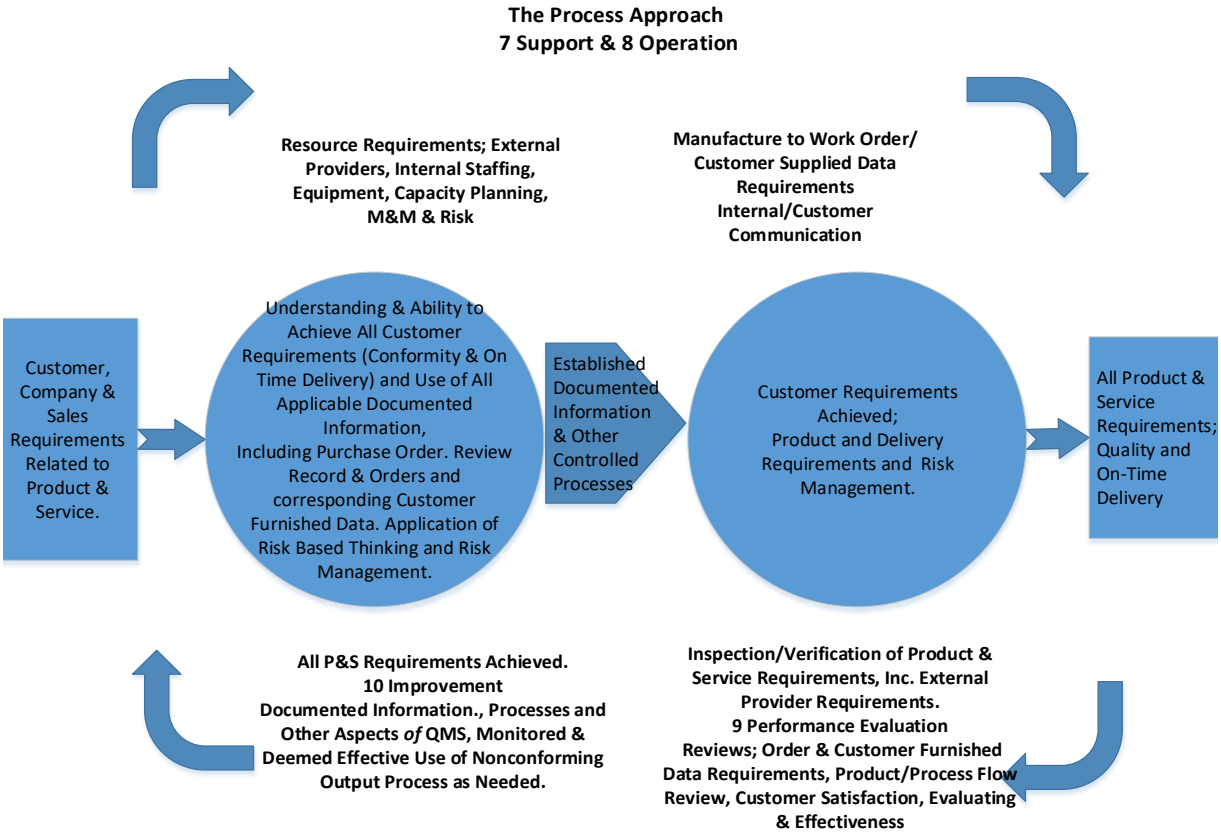
6.3 Planning of changes

When the company has determined the need for changes to the QMS, these changes are carried out in a planned manner. The company considers:

a) The purpose of the changes and their potential consequences,
b) The integrity of the QMS,
c) The availability of resources, and
d) The allocation/reallocation of responsibilities and authorities.

All changes that are made within the QMS, including all additions, revisions/changes, or deletions, are recorded. Determination is made if training is required related to any change, and this is recorded on this form. This form is utilized as training and effectiveness documented information.

7 Support



7.1 Resources

7.1.1 General

The company has determined and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the QMS. The company considers:

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

The company has and continually monitors the need for resources and defines that as a) the resources currently available are suitable and adequate to achieve Customer requirements, and b) additional resources needed to meet the same objective. Resources are generally defined as equipment, including tools, external providers who are relied

upon for product, service, and transportation of product to Customers, staff, and overall infrastructure, including peripheral requirements such as packing, packaging and any applicable consumable items.

7.1.2 People

The company has determined and provides the people necessary for the effective implementation of its QMS and for the operation and control of its processes. Controlled ***Job Descriptions*** have been created that define areas of responsibilities for all positions within the company. These positions correspond directly with the company's controlled organizational chart. These are controlled as ***7.1.2-4-X***.

7.1.3 Infrastructure

The company has determined, provides, and maintains the infrastructure *(includes building, utilities, equipment, hardware, software, transportation, information/communication technology)* necessary for the operation of its processes and to achieve conformity of products and services.

The company has developed and has implemented a preventive maintenance program to ensure the availability of internal process equipment as this equipment is needed to meet product and service requirements. The processes and corresponding documented information are controlled as "Machine Maintenance". Data includes both scheduled preventive maintenance and any maintenance performed outside the PM process. All data ais maintained and evaluated.

7.1.4 Environment for the operation of processes

The company has determined, provides, and maintains the environment *(includes: a combination of human and physical factors such as social {e.g., non-discriminatory, calm & non-confrontational}, psychological {e.g., stress-reducing, burnout prevention & emotionally protective}, physical {e.g., temperature, heat, humidity, light, airflow, hygiene & noise}* 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

The company 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. The company ensures that the resources provided:

a) Are suitable for the specific type of monitoring and measurement activities being undertaken, and
b) Are maintained to ensure their continuing fitness for their purpose.

The company retains appropriate documented information as evidence of fitness for the purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is considered by the company 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 is retained as documented information,
b) Identified in order to determine their status, and
c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

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

All company calibrated equipment are recorded and controlled on ***Monitoring and Measuring Resources Log, 7.1.5-4-1***. This log notes the unique "Tool/Resource" identification number, a description of what the monitoring and measurement resource is, the most recent date of the calibration, the next due date for calibration and any other applicable data such as location, owner, etc.

All monitoring and measuring resources have corresponding calibration certificates.

The process for managing the company's monitoring and measurement resources program, including all applicable documented information, is shown as including the technician, date, resource number, location, frequency, procedure, as applicable.

7.1.6 Organizational knowledge

The company determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge is maintained and made available to the extent necessary.

When addressing changing needs and trends, the company considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates. *(Organizational knowledge is knowledge specific to the company and is generally gained by experience. It is information that is used and shared to achieve the company's objectives. This knowledge is based on Internal Sources: lessons learned from failures/successes, capturing/sharing undocumented knowledge/experience, the results of improvements in processes, products, and services. External Sources: standards, academia, conferences, gathering knowledge form Customers or external suppliers.)*

7.2 Competence

The company:

a) Determines the necessary competence of people doing work under its control that affects the performance and effectiveness of the QMS,
b) Ensures that these people are competent based on appropriate education, training, or experience,
c) Where applicable, takes actions to acquire the necessary competence, and evaluates the effectiveness of the actions taken, and
d) Retains the appropriate documented information as evidence of competence.

Training events include various levels of awareness (7.3) and communication (7.4). All training is recorded on controlled ***Training Record, 7.2-4-1***. Competence is ensured daily with all personnel and captured formally within the evaluation process on ***Employee Evaluation, 7.1.6-4-1***. Within this process, positive activities/performances and opportunities for improvements are discussed from both the perspective of the company and those of the employee. All data is captured as documented information, maintained by both employee and company, and utilized as a tool/plan for actions and activities in the coming cycle.

7.3 Awareness

The company ensures that people doing work under the company's control are aware of:

a) The quality policy,
b) Relevant quality objectives,
c) Their contribution to the effectiveness of the QMS, including the benefits of improved processes, and
d) The implications of not conforming with the QMS requirements.

7.4 Communication

The company determines the internal and external communications relevant to the QMS, including:

a) On what it communicates,
b) When to communicate,
c) With whom to communicate,
d) How to communicate, and
e) Who communicates.

Various methods of communication are performed by the company to communicate all aspects of the QMS; including verbal one-on-one or is group settings, depending on the nature/intent of the message. Additional methods include the use of bulletin-boards, postings, action-team meetings, management review, etc. Where appropriate and when actions are determined/needed, corresponding documented information is maintained and retained.

7.5 Documented information

7.5.1 General

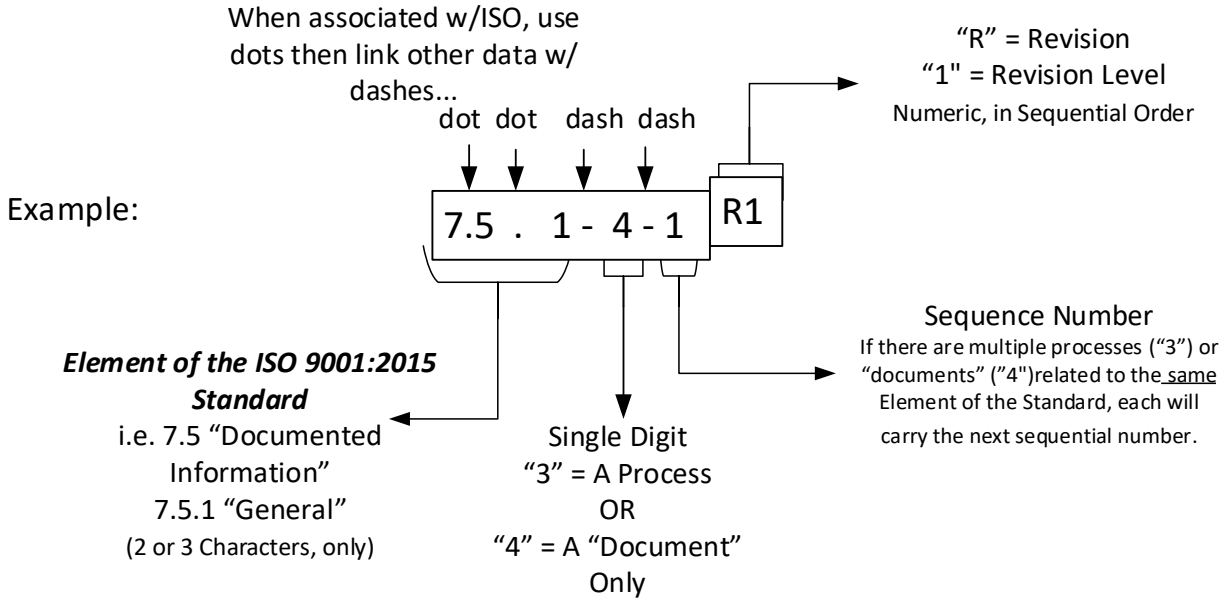
The company's QMS includes:

a) Documented information required by ISO 9001:2015, and
b) Documented information determined by the company as being necessary for the effectiveness of the QMS.

Controlled list of all company documented information is maintained on ***Master List of QMS Documented Information, 7.5.1-4-1.***

The following diagram defines how all documented information; documents (previously known as documents and records) or processes (all processes, procedures, and work instructions) have control numbers and revision levels assigned when new documented information is implemented within the QMS or when current documented information is revised within the QMS.

- Applies to ALL "Documented Information" (previously known as documentation, quality manual, procedures, work-instructions, records, etc.) that comprise your Quality Management System.
- ALL included on the company's ***Master List of QMS Documented Information.***
- ALL include a "Control Number" and "Revision Level"



7.5.2 Creating and updating

When creating and updating documented information, the company ensures appropriate:

a) Identification and description *(e.g., title, date, author, or reference number),*
b) Format *(e.g., language, software versions, graphics)* and the media *(e.g., paper, electronic), and*
c) Review and approval for suitability and adequacy.

All changes, including additions and deletions, in documented information are recorded on controlled, ***QMS Change Form, 7.5.3-4-2***.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the QMS and by ISO 9001:2015 is controlled to ensure:

a) It is available and suitable for use, where and when it is needed, and
b) It is adequately protected *(from, for example, loss of confidentiality, improper use, or loss of integrity).*

7.5.3.2 For the control of documented information, the company 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., revision control*) and
d) Retention and disposition.

Documented information of external origin determined by the company to be necessary for the planning and operation of the QMS is identified as appropriate and is controlled. Documented information retained as evidence of conformity is protected from unintended alterations.

All documented information is maintained electronically by the company. All is controlled with a unique control number and revision level. Each is recorded on the controlled ***Master List of QMS Documented Information***. Each is maintained electronically within a sign database and on a server both internally and externally as a back-up. Each originates as a Microsoft WORD, EXCEL, or VISIO document. All are available to all company personnel as a PDF document. All desktops have a complete PDF copy of the current QMS. The "originals" are protected against intentional or accidental changes or deletions.

All changes, including the addition of anything new or deletions and/or revisions are managed electronically by the director. All applicable previous documented information is maintained by the QMS Administrator in an electronic "Obsolete" folder.

Any applicable or determined necessary information furnished by any external provider is managed by the director and filed appropriately and electronically by the company's ISO delegates.

All documentation is maintained for a minimum of seven years and is only superseded by the requirements, as applicable, by external Customers who may require additional/other retention requirements.

8 Operation

8.1 Operational planning and control

The company has planned, implemented, and controls the processes 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, and
    2. The acceptance of products and services,
c) Determining the resources needed to achieve conformity to the products 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, and
    2. To demonstrate the conformity of products and services to their requirements.

The output of this planning is suitable for the company's operation.

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

The company ensures that outsourced processes are controlled.

The company plans all its resources (7.1); personnel (7.1.2), infrastructure (7.1.3) while considering environmental (7.1.4) factors that may impact operations.

8.2 Requirements for product and services

8.2.1 Customer communication

Communication with Customers includes:

a) Providing information relating to products and services,
b) Handling inquires, contracts/orders, including changes,
c) Obtaining Customer feedback relating to products and services, including Customer complaints,
d) Handing or controlling Customer property, and
e) Establishing specific requirements for contingency action, 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, the company ensures that:

a) The requirements for the products and services are defined, including:
    1. Any applicable statutory and regulatory requirements, and
    2. Those considered necessary by the company.
b) The company meets the claims for products and services.

Controlled ***Customer Requirements Review form, 8.2.2-4-2***, is an additional application of risk-based thinking to ensure all Customer Requirements will be achieved.

8.2.3 Review of the requirements for products and services

8.2.3.1 The company ensures that it can meet requirements for products and services offered to Customers. The company 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 the company,
d) Statutory and regulatory requirements applicable to the products and services, and
e) Contract or order requirements differing from those previously expressed.

The company ensures that contract or order requirements differing from those previously defined are resolved.

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

(In some situations, e.g., a formal review is impractical for each order. In such cases, a "review" can cover relevant product and service information).

8.2.3.2 The company retains documented information, as applicable:
a) On the results of the review, and
b) On any new requirements for products and services.

8.2.4 Changes to the requirements for products and services

The company ensures that relevant documented information is amended, and that relevant people are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of product and services

This element of the standard is not applicable to the company.

8.4 Control of externally provided processes, products, and services

8.4.1 General

The company ensures that externally provided processes, products and services conform to requirements.

The company 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 company's own products and services,
b) Product and services are provided directly to the Customer by external providers on behalf of the company, and
c) A process, or part of a process, is provided by an external provider as a result of a decision by the company.

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

The company monitors quality of product and services and overall delivery performance of suppliers of required externally provided product, including components. The nonconformity and corrective action processes comprise the function to record adverse supplier activities. The company verifies that all product and hard resources purchased meet purchase order requirements and that all are determined to meet compliance, quantity, type, proper identification, and technical requirements, as applicable.

8.4.2 Type and extent of control

The company ensures that externally provided process, products and services do not adversely affect the company's ability to consistently deliver conforming products and services to our Customers.

The company:

a) Ensures that externally provided processes remain within the control of our QMS,
b) Defines both the controls that we intend to apply to an external provider and those we intend to apply to the resulting output,
c) Take into consideration:
    1. The potential impact of the externally provided processes remain within the control of our QMS, and
    2. The effectiveness of the controls applied by the external suppliers.
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

The company ensures the adequacy of requirements prior to their communication to the external provider.

The company communicates to external providers the requirements for:

a) The processes, products, and services provided,
b) The approval of;
    1. Products and services,
    2. Methods, processes, and equipment, and
    3. The release of products and services.
c) Competence, including any required qualification of people,
d) The external providers' interactions with the company,
e) Control and monitoring of the external providers' performance applied by the company, and
f) Verification or validation activities that the company, or our Customer, intends to perform at the external providers' premises.

8.5 Production and service provision

8.5.1 Control of production and service provision

The company has implemented production and service provisions under controlled conditions.

These controlled conditions include, as applicable:

a) The availability of documents that define;
    1. The characteristics of the products to be produced, the services to be provided and the activities to be performed, and
    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 the 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 people, 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, and
h) The implementation of release, delivery, and post-delivery activities.

The process for creating a production order and correlating all applicable technical data is defined.

8.5.2 Identification and traceability

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

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

The company controls the unique identification of the outputs when traceability is a requirement and retains the documented information necessary to enable traceability.

All product: raw material, work-in-process (WIP), Customer owned/supplied and finished goods are consistently identified through all stages, as applicable.

8.5.3 Property belonging to Customers or external providers

The company exercises care with property belonging to Customers or external providers while it is under our control or being used by the company. *(This property includes materials, components, tools, equipment, premises, intellectual property, and personal data.)*

The company identifies, verifies, protects, and safeguards Customers' or external providers' property provided for use or incorporation into the products and services.

If the property of a Customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, the company reports this to the Customer or external provider and retains documented information on what had occurred.

8.5.4 Preservation

The company preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. *(Preservation includes, as appropriate, identification, handling, contamination control, packaging, storage, transmission, transportation, and protection.)*

8.5.5 Post-delivery activities

This element of the standard is not applicable to the company. See 4.3, above.

8.5.6 Control of changes

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

The company retains documented information describing the results of the review of changes, the people (or person) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

The company implements planned arrangement, at appropriate stages, to verify that the product and service requirements have been met.

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

The company retains documented information on the release of products and services. The documented information includes:

a) Evidence of conformity with the acceptance criteria, and
b) Traceability to the people authorizing the release.

No product will be released for shipment to Customers until verification of all requirements, as defined by the Customer, have been performed.

8.7 Control of nonconforming outputs

8.7.1 The company ensures that the outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The company 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.

The company 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, and
d) Obtaining authorization for acceptance under concession.

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

8.7.2 The company retains documented information that:

a) Describes the nonconformity,
b) Describes the actions taken,
c) Describes any concessions obtained, and
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

The company 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 monitoring and measuring will be performed, and
d) When the results from monitoring and measuring will be analyzed and evaluated.

The company evaluates the performance and the effectiveness of the QMS.

The company retains appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction

The company monitors Customer's perceptions *(examples may include Customer surveys, Customer feedback on delivered product and services, meetings with Customers, market-share analysis, and complaints.)* of the degree to which their needs and expectations have been fulfilled. The company determines the methods for obtaining, monitoring, and reviewing this information.

9.1.3 Analysis and evaluation

The company 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 QMS,
d) If planning is effectively implemented,
e) The effectiveness of actions taken to address risks and opportunities,
f) The performance of external providers and
g) The need for improvement to the QMS.

The company evaluates the performance and the effectiveness of the QMS.

9.2 Internal audit

9.2.1 The company conducts internal audits at planned intervals to provide information on whether the QMS:

a) Conforms to:
    1. The company's own requirements for our QMS, and
    2. The requirements of ISO 9001:2015.
b) Is effectively implemented and maintained.

9.2.2 The company has:

a) Planned, established, implemented, and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the importance of the processes concerned, changes affecting the company and the results of previous audits,
b) Defined the audit criteria and scope for each audit,
c) Selected the auditor and conducts audit to ensure objectivity and the impartiality of the audit process,
d) Ensured that the results of the audits are reported to relevant management,
e) Taken appropriate correction and corrective actions without undue delay, and
f) Retained and retains for all internal audits documented information as evidence of the implementation of the audit program and the audit results.

The internal audit process is performed following the ***Internal Audit Process & Schedule, 9.2.1-4-1*** at a minimum of one full system internal audit within its 3rd-party audit cycle. This also defines the process to meet all the requirements of 9.2 and records the month and year each clause of the QMS was/to be audited. All outputs of the internal audit process are recorded on an ***Internal Audit Outputs Report***, controlled by the Internal Auditor. Depending upon the scope of the I.A., with each finding being noted with applicable documented information, noted as an "observation" or a "nonconformity" as applicable, whether a ***Corrective Action Report, 10.2.1-4-1*** (CAR) is issued, and any applicable/corresponding comments/details noted. All findings determined to be nonconforming, minor, or major in nature, will have a corresponding documented information. If an IA CAR is issued all applicable CAR processes and D.I. will be completed with a recording of the finding, the action taken to control and correct the nonconformity, the cause(s), and the corrective action. The auditor will determine the adequacy and effectiveness of corrective action(s) and if any changes will be made to the QMS. The auditor has the exclusive authority to determine that the IA CAR responses meet compliance and, in turn, are closed.

An ***Audit of the Internal Audit Process*** form is controlled by the Internal Auditor. This form verifies the effective auditing of element 9.2, Internal Audit, ensuring objectivity in the I.A. process.

9.3 Management Review

9.3.1 General

The company reviews the QMS at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with our strategic direction.

A review of the company's QMS and to meet at the required inputs, below is performed at minimum, one time per audit cycle. This includes the "leadership" of the organization who conduct the management review in the form of a meeting. The QMS Director is responsible for planning, scheduling, executing, facilitating, and capturing all applicable data, as records of management review.

All outputs are achieved as noted below and any action items that result from management review are assigned to a specific individual or individuals with a clear path to meet the objectives of the action items, including the due date.

The agenda of management review is controlled as ***Management Review Inputs/Agenda, 9.3-4-1***.

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 QMS,
c) Information on the performance and effectiveness of the QMS, 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, and
    7. The performance of external providers.
d) The adequacy of resources,
e) The effectiveness of actions taken to address risks and opportunities, and
f) Opportunities for improvement.

9.3.3 Management review outputs

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

a) Opportunities for improvement,
b) Any need for changes to the QMS, and
c) Resource needs.

The company retains documented information as evidence of the results of management review.

10 Improvement

10.1 General

The company determines and selects opportunities for improvement *(examples include correction, corrective action, continual improvement, breakthrough change, innovation, and re-organization))* 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, and reducing undesired effects, and
c) Improving the performance and effectiveness of the QMS.

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, the company:

a) Reacts to the nonconformity and, as applicable:
    1. Takes action to control and correct it, and
    2. Deals with the consequences.

All issues of nonconformity, product, service or otherwise, are recorded. The specific issue, root-cause finding and all applicable actions to control and correct the issue are recorded on this MRR. If it is deemed necessary, a controlled ***Corrective Action Report, 10.2.1-4-1***, will be generated. All nonconformities and corrective actions are recorded/tracked on the controlled, ***NC/CA Log, 10.2.1-4-2***. The corrective action process is closed-looped as all corrective actions proposed by the recipient are verified as effective prior to the corrective action being considered "closed".

b) Evaluates the need for action to eliminate causes 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, and
    3. Determining if similar nonconformities exist or could potentially occur.
c) Implements any action needed,
d) Reviews the effectiveness of any corrective action taken, and
e) Update risks and opportunities determined during planning, as necessary, and
f) Makes changes to the QMS, if necessary.

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

10.2.2 The company retains documented information as evidence of:

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

10.3 Continual improvement

The company continually improves the suitability, adequacy, and effectiveness of the QMS. The company considers the results of analysis and evaluation, and the outputs for management review, to determine if there are needs and opportunities that should be addressed as part of continual improvement.