Quality Management System Manual

Manual No. - eQMS Distribution

Unless otherwise indicated by a RED “Controlled” stamp, printed copies of this document are considered to be uncontrolled.

Document:	**MSA 9100**
Revision:	**K**
Date:	**March 27, 2018**

M.S. Aerospace, Inc.
13928 Balboa Blvd.
Sylmar, CA 91342

Phone (818) 833-9095
Fax (818) 833-9525
CAGE Code: 0UCY9

www.msaerospace.com

&

A. S. Aerospace, Inc.
21095 Centre Pointe Pkwy.
Santa Clarita, CA 91350

Phone (661) 964-3760
CAGE Code: 80JT2

www.asaerospace.com

This manual defines the policy for the development, implementation and continual improvement of the M.S. Aerospace, Inc. and A.S. Aerospace quality management system (QMS).

The QMS manual is endorsed and evidenced by a signature record maintained in hard copy that is available at M.S. Aerospace for review. A signature and approval record shall be maintained that supports current Top Management awareness, support and approval of policies defined in this manual.

Original QMS Release Date: April 30, 2003

REV. LEVEL	REV. DATE	DETAILS		DESCRIPTION OF CHANGE
		SEC.	PARA	
0	April 30, 2003	All	All	Original Issue to ISO 9001:2000 / AS9100A.
A	September 15, 2003	3.0 5.5 7.3	All	Sect. 3.0: Deleted Sales graph and references to new facility; Sect. 5.5: Added para. 3.1.2.7 – Mfg. Support Mgr. and updated responsibilities and authorities to match updated Org. Chart. Sect. 7.3: Deleted (excluded from the Quality Management System). (Ref. ISO CAR 02/PA1/TA and 07/PA1/TA).
B	July 22, 2004	1.1 2.0 3.0 4.2 5.5	All	Sect. 1.1: Revision Change to B and Date to July 22, 2004; Sect. 2.0: Address Change to 13928 Balboa Blvd. & Date Change to July 22, 2004; Sect. 3.0: Added 2 paragraphs…"In 2004, M.S. Aerospace,… through "We are more prepared…" Sect. 4.2: Added paragraph 3.3.10.1; Sect. 5.5: Changed Materials Manager to Production Control Manager and removed raw material administration from the responsibilities; Changed Director of Finance to Administrative & Finance Manager; Changed Administrative Manager to Human Resources Manager; Purchasing Manager now reports to Administrative & Finance Manager; Adjusted Organizational Chart to align with these changes; Title corrections of MSAP 5.1 & 7.5 throughout manual; Incorporated AS9100B; Changes are due to annual review per Section 4.1, paragraph 3.1.5.
C	July 29, 2005	1.1 1.3 1.4 4.2 7.3	All	Sect. 1.1: Revision Change to C and Date to July 29, 2005; Sect. 1.3, 1.4: Adjusted Table of Contents and Cross-Reference to accommodate addition of Section 7.3; Sect. 4.2: Para. 3.1: Changed number of procedures - 25 to 26; Re-paginate as necessary; Changes are due to annual review per Section 4.1, paragraph 3.1.5.
D	August 12, 2008	All	All	Completely revised, restructured and rewritten to more accurately reflect requirements of AS9100, and to more accurately reflect business structure and process at MS Aerospace. DNV Audit # PR-29930
E	January 12, 2010	All	All	Updated document references for ISO9000:2008
F	May 01, 2010	All	All	Revised and restructured to align with and incorporate the requirements AS9100 Revision C
G	March 01, 2012	0.2 4.0 5.0	All	Removed Signature/Title List – that had directed user to review hard copy version. New statement inserted Revised Table 1 & Figure 1: Consolidated MSA processes from 7 to 5 major QMS processes (A – G). Title added: Director of Mfg. Title added: Director of Eng. & Mfg Support Title removed: Director of Lean, Plant Manager from section.
H	April 24, 2015	7.0	All	Added: MSAP 8.12 F.O.D; MSAP 8.13 Counterfeit Parts Prevention & MSAP 8.14 MRB NCR and Disposition – to MSA's QMS Authorized Procedures

REV. LEVEL	REV. DATE	DETAILS		DESCRIPTION OF CHANGE
		SEC.	PARA	
J	February 07, 2018	All	All	Revised: Full re-write to comply with ISO / AS9100 Rev. D Add: A. S. Aerospace to scope
K	March 27, 2018	0.5 1.0 3.2 4.1 4.0	0.5 1.0 3.2 4.1 4.2	Updated: Table of Contents for Sec. 8.5.5 Post Delivery Support Revised: Scope to include Mfger. of high strength fasteners Removed: Exclusion in scope for Section 8.5.5 - Post Delivery Support. Updated: Verbiage for Sec. 8.3 Design / Development exclusion Updated: QMS Interaction Table to include 8.5.5 Post Delivery Activities Updated: MSA's external / internal issues Updated: MSA's interested parties

M.S. Aerospace, Inc. was established as a start-up company on June 1st, 1992. The original facility was located on Foothill Boulevard in Sylmar, California.

The Company's long term strategy was to position itself as a niche player in high temperature, high strength aerospace bolts, studs, pins, and screws, serving the jet engine and rocket engine industry, as well as customers demanding superior quality high strength fasteners.

In the short term, the depressed aerospace market in 1992 and 1993 forced the company to distinguish itself by concentrating on these core strengths: unrivaled quality, significantly shorter lead times and superior service. This dedication and integrity allowed the company to grow even in an industry recession.

M.S. Aerospace, Inc. soon gained a formidable reputation as a manufacturer capable of producing consistent world-class fasteners offering impressive lead times, with the integrity and documentation required by an increasingly demanding marketplace.

By the end of 1993, M.S. Aerospace, Inc. had grown to 48 employees and was doing significant business with jet engine manufacturers through distribution.

In January of 1994, the Northridge Earthquake destroyed the company's building on Foothill Boulevard. Although a profound blow to the fledging company, M.S. Aerospace, Inc. secured a building in Burbank and was back in full production by the beginning of February 1994, just two weeks after the earthquake, and just four days after moving into the new building.

The process of rebuilding the company began immediately and was successful beyond expectations, so that by the end of 1994, M.S. Aerospace, Inc. had 73 employees and had a secured General Electric Aircraft Engines approval with a 100% zero defect rating.

This impressive growth continued through 1995 and 1996, and the most significant factor in this development was attributable to the company providing Pratt and Whitney and General Electric Aircraft Engines with impeccable quality fasteners in very short lead times. In a genuine commitment to continuous improvement, M.S. Aerospace, Inc. has implemented full SPC Controls, has automated much of the machinery and equipment, has added significant CNC capability, and has achieved ISO9001/AS9100 and Nadcap Accreditation.

In 1998, M.S. Aerospace, Inc. moved to a brand new, purpose-built facility in a new business park in Sylmar, which, at 46,000 square feet, tripled the manufacturing floor space and provided significantly greater capability.

By 2004, M.S. Aerospace had once again outgrown floor space and, looking to increase capacity, moved into our current location – a 100,000 square foot, purpose-built facility. The new building is only 1000 feet from our previous building, and we are again in the wonderful setting of the Cascade Business Park. In addition to adding manufacturing capability, the move also allowed the addition of a full heat-treatment operation, increased testing and NDT capacity, as well as cleaning, Chemical Processing and Lube.

As M. S. Aerospace celebrated 25 years of existence in 2017, the volume of specialty nuts had grown to the point where M.S. Aerospace proudly announced the creation of a new subsidiary, A. S. Aerospace. This exciting new manufacturing entity, A.S. Aerospace, was developed to specialize in internally threaded fasteners such as self-locking nuts, barrel nuts, nut sleeves, jam nuts and other critical fasteners manufactured to the same exacting standards as the aerospace bolts, screws, studs and pins manufactured so successfully by M. S. Aerospace. A. S. Aerospace builds on the engineering and quality experience of M. S. Aerospace to create a new standard in internally threaded fasteners.

We are more prepared than ever to meet the demands of an ever-increasing compliance, and a challenging marketplace. We look forward to serving our customers with consistent reliability, quality, integrity, and service, building on our knowledge and experience in the high strength, close tolerance and high temperature fastener market.

Unless otherwise indicated on the front cover page, this document is a controlled copy of M.S. Aerospace, Inc.'s (MSA's) Quality Management System (QMS) Manual. The manual number identified is registered with and controlled by MSA's Quality Assurance.

For controlled copies, changes and additions to this manual will be forwarded to the recipient as they are incorporated. Recipients of uncontrolled copies will not receive any updates.

This manual and individual procedures or documents referenced throughout are considered company proprietary and confidential and are not to be loaned, duplicated or distributed externally except when duly authorized by MSA management.

The recipient's acceptance of a controlled copy of the QMS Manual indicates that you will read and acknowledge all requirements set forth therein. Further, you will make every effort to ensure your personal compliance with the stated requirements and their references.

In addition, it is the recipient's personal responsibility to continually promote and work to improve the QMS defined by this document.

If the controlled manual is recalled or otherwise becomes obsolete it is the responsibility of the manual holder to make the necessary substitution of revised pages as instructed, return the copy to MSA or destroy the copy & notify MSA of its destruction.

Table of Contents (Cross Reference)

1.0 Scope

This manual applies to the following sites:

M.S. Aerospace, Inc.
13928 Balboa Blvd.
Sylmar, CA 91342

Phone (818) 833-9095
Fax (818) 833-9525

CAGE Code: 0UCY9

www.msaerospace.com

A. S. Aerospace, Inc.
21095 Centre Pointe Pkwy.
Santa Clarita, CA 91350

Phone (661) 964-3760
CAGE Code: 80JT2

www.asaerospace.com

M.S. Aerospace, Inc., is a manufacturer of quality high strength fasteners, (i. e. - nuts, bolts, pins, studs & screws. This manual serves as the policy for the development, implementation and continual improvement of the M.S. Aerospace, Inc. (MSA) quality management system. This manual establishes MSA Management policy concerning quality and refers to Quality Management Procedures and Work Instructions. These procedures and instructions have been developed to ensure the quality of deliverables in strict accordance with contractual, jurisdictional, and regulatory requirements. The policies contained herein, and the methodologies defined by each referenced procedure and instruction are applicable to all contracts performed by MSA. MSA procedures and instructions shall act as supplements to all industry specifications, drawings, standards, contractual requirements, and statutory or regulatory requirements, and shall not supersede the aforementioned documents.

Nothing in this manual relieves MSA of the responsibility for the conformity of all products to all customers, statutory and regulatory requirements, including work performed by customer-designated and MSA suppliers.

QMS Exclusions

Based on the justifications provided below, two Quality Management System requirements which are defined within the ISO 9000 / AS9100 Standard do not apply to our type of operation and have been excluded from our Quality Management System and this manual:

Section 8.3: Design and Development: M.S. Aerospace, Inc. does not perform design or development activity at this time. All products are manufactured in accordance with customer design and customer supplied drawings / specifications.

2.0 Normative References

The quality management system defined herein is derived from the requirements of the following documents, either in whole or in part.

Appendix QX	Supplier Quality Requirements (Lockheed)
AS9100	Quality Management Systems – Requirements for Aviation, Space and Defense Organizations
ASQR-01	Supplier Quality System Requirements (UTC)
CFR 14	Code of Federal Regulations - Subpart K §21.301 – §21.303
ISO 9000	Quality management Systems – Fundamentals and Vocabulary
ISO 9001	Quality management Systems – Requirements
ISO 9004	Managing for the Sustained Success of an Organization – A Quality Management Approach
ISO 10012	Measurement Management Systems – Requirements for Measurement Processes and Measuring Equipment
ISO/IEC 17025	General Requirements for the Competence of Testing and Calibration Laboratories
QSLM	Class 3 Threaded Fasteners – Qualified Supplier List for Manufacturers (DoD)
S-1000	Quality System Requirements for Suppliers (GE Aviation)

3.0 Terms and Definitions

Unless otherwise specified, all terms and definitions used herein are as defined by ISO9001:2015 and AS9100D.

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.

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

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

customer: organization or person that receives a product.

Note 1: A customer can be internal or external to the organization.
Note 2: The term customer also relates to applicable legal and regulatory agencies (e.g., FAA).

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

process: set of interrelated or interacting activities which transforms inputs into outputs.

Note 1: Inputs to a process are generally outputs of other processes.
Note 2: processes in an organization are generally planned and carried out under controlled conditions to add value.
Note 3: a process where the conformity of the resulting product cannot be readily or economically verified is frequently referred to as a “special process”.

product: result of a process.

product safety: the state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk or harm to persons or damage to property

risk: an undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

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 performance requirements imposed by the customer that are at the limit of its technical or process capabilities.
Note: Special requirements and critical items, along with key characteristics, are interrelated. Special requirements are identified when determining and reviewing requirements related to the product. Special requirements can require the identification of critical items. Design output can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to be controlled.

3.1 Plan-Do-Check-Act Cycle

The PDCA cycle can be applied to all key processes and to MSA's quality management system as a whole.

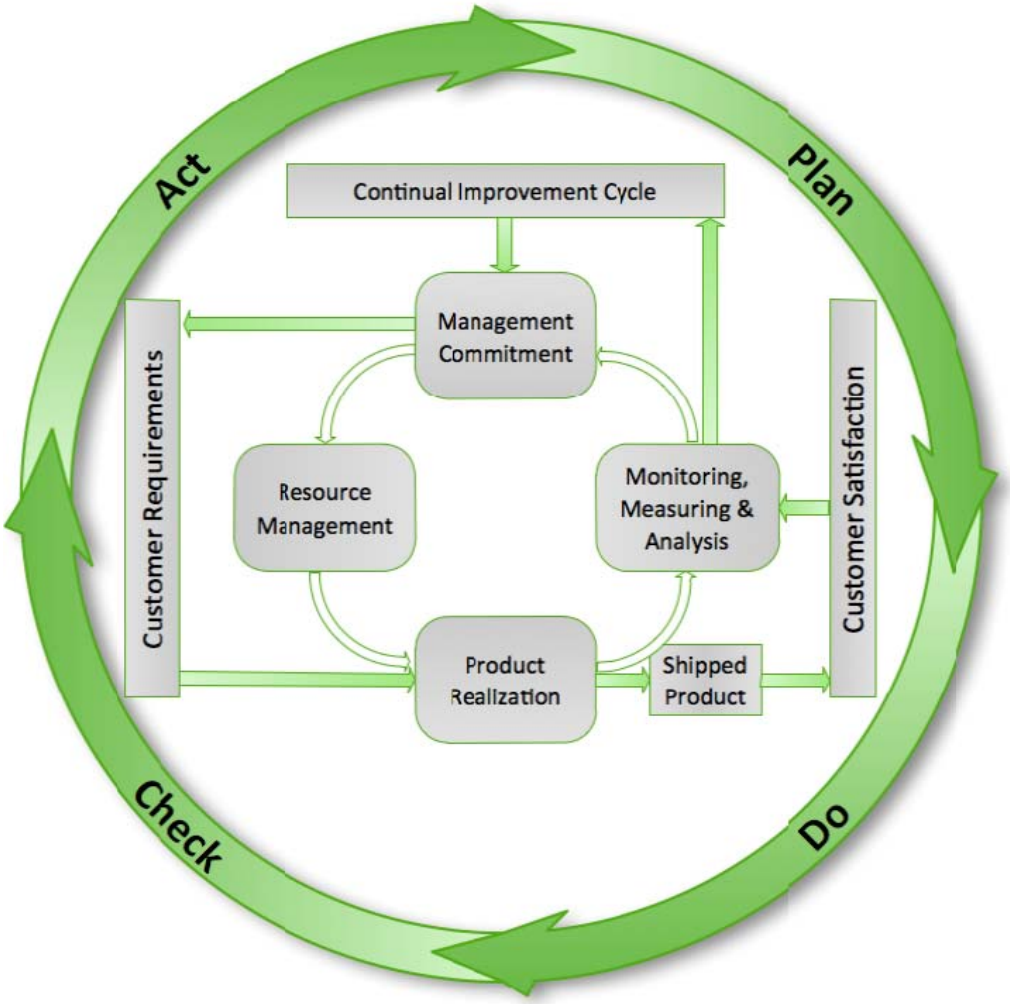
The PDCA cycle can be briefly described as follows:

Plan: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;

Do: implement what was planned;

Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements, and planned activities, and report the results;

Act: take actions to continually improve performance, as necessary.



3.2 QMS Process Interaction – Table 1

AS9100 QMS		QMS Process Codes				
Clause	**Description**					
4	**Context of the Organization**	**A**	**B**	**C**	**D**	**E**
4.1	Understanding the Organization and its Context	X				
4.2	Understanding the Needs and Expectations of Interested Parties	X				
4.3	Determining the Scope of the Quality Management System	X				
4.4	Quality Management System and its Processes	X				
5	**Leadership**	**A**	**B**	**C**	**D**	**E**
5.1	Leadership and Commitment	X				
5.1.1	General	X				
5.1.2	Customer Focus	X	X	X		X
5.2	Policy					X
5.2.1	Establishing the Quality Policy	X				X
5.2.2	Communicating the Quality Policy					X
5.3	Organizational Roles, Responsibilities and Authorities	X				
6	**Planning**	**A**	**B**	**C**	**D**	**E**
6.1	Actions to Address Risks and Opportunities	X	X	X	X	X
6.2	Quality Objectives and Planning to Achieve Them	X	X			X
6.3	Planning of Changes	X	X	X		X
7	**Support**	**A**	**B**	**C**	**D**	**E**
7.1	Resources	X		X	X	X
7.1.1	General	X		X	X	X
7.1.2	People	X	X	X		X
7.1.3	Infrastructure	X		X		X
7.1.4	Environment for the Operation of Processes	X		X		X
7.1.5	Monitoring and Measuring Resources					X
7.1.6	Organizational Knowledge	X		X	X	X
7.2	Competence	X		X	X	X
7.3	Awareness	X	X	X	X	X
7.4	Communication	X	X	X	X	X
7.5	Documented Information	X				X
7.5.1	General	X				X
7.5.2	Creating and Updating		X			X
7.5.3	Control of Documented Information	X	X	X	X	X
8	**Operation**	**A**	**B**	**C**	**D**	**E**
8.1	Operational Planning and Control	X		X	X	X
8.1.1	Operational Risk Management	X	X	X	X	X
8.1.2	Configuration Management	X		X		X
8.1.3	Product Safety	X	X	X	X	X
8.1.4	Prevention of Counterfeit Parts	X	X	X	X	X
8.2	Requirements for Products and Services		X			X
8.2.1	Customer Communication	X	X			X
8.2.2	Determining the Requirements for Products and Services	X	X			X
8.2.3	Review of the Requirements for Products and Services		X			X

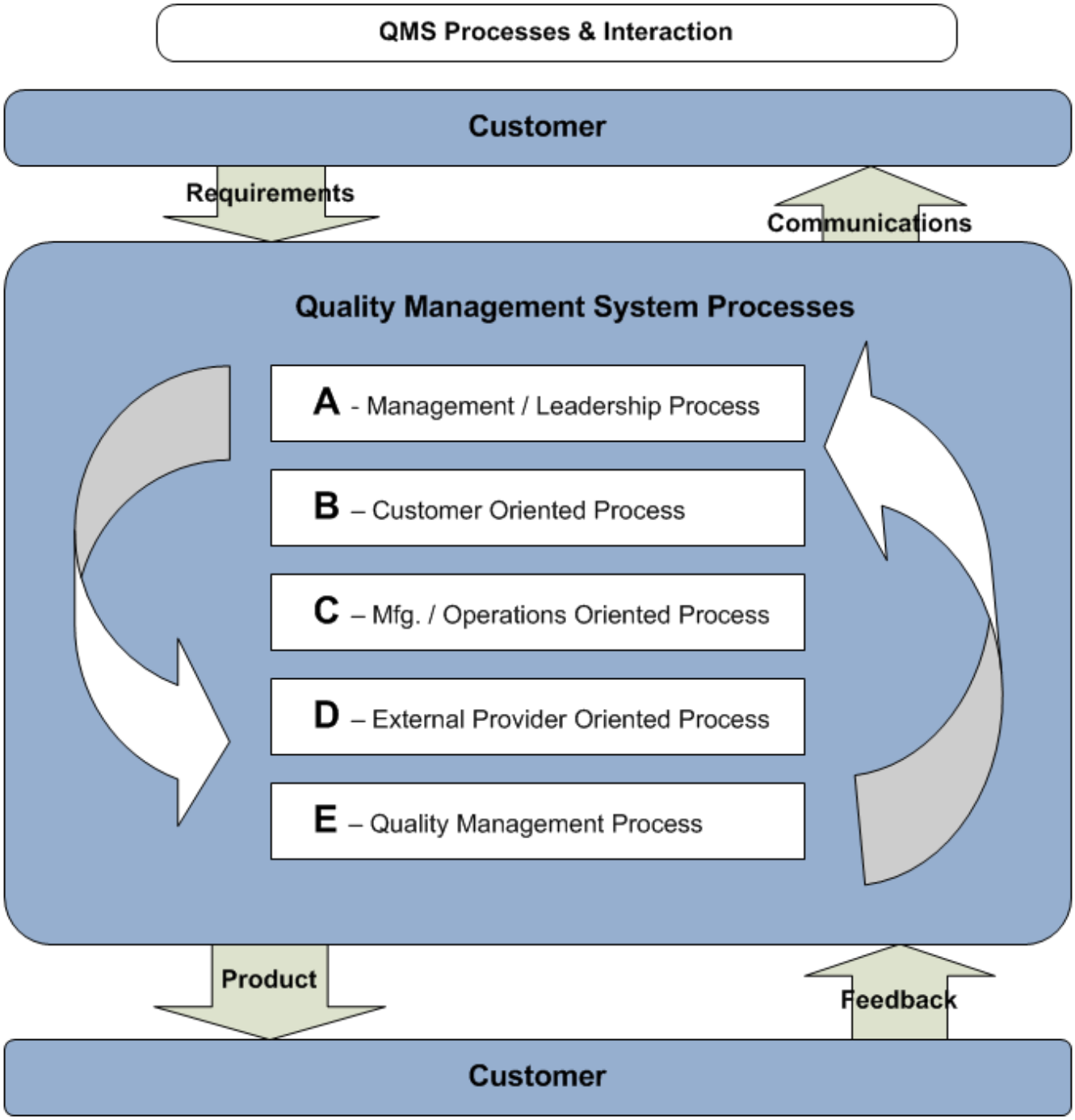
8.2.4	Changes to Requirements for Products and Services		X			X
8.3 – 8.3.6	Design and Development of Products and Services (QMS Exclusion)					
8.4	Control of Externally Provided Processes, Products and Services				X	
8.4.1	General				X	
8.4.2	Type and Extent of Control				X	
8.4.3	Information for External Providers				X	
8.5	Production and Service Provision	X		X		X
8.5.1	Control of Production and Service Provision	X		X		X
8.5.2	Identification and Traceability	X		X		X
8.5.3	Property Belonging to Customers or External Providers		X	X	X	X
8.5.4	Preservation			X	X	X
8.5.5	Post-Delivery Activities		X			X
8.5.6	Control of Changes	X	X	X	X	X
8.6	Release of Products and Services					X
8.7	Control of Nonconforming Outputs	X		X	X	X
9	**Performance Evaluation**	**A**	**B**	**C**	**D**	**E**
9.1	Monitoring, Measurement, Analysis and Evaluation	X			X	X
9.1.1	General	X				X
9.1.2	Customer Satisfaction	X	X			X
9.1.3	Analysis and Evaluation	X	X		X	X
9.2	Internal Audit	X				X
9.3	Management Review	X				
9.3.1	General	X				
9.3.2	Management Review Inputs	X				
9.3.3	Management Review Outputs	X				
10	**Improvement**	**A**	**B**	**C**	**D**	**E**
10.1	General	X		X	X	X
10.2	Nonconformity and Corrective Action	X		X	X	X
10.3	Continual Improvement	X	X	X	X	X

* QMS Process Interaction Table 1 has been shaded to indicate which AS9100 clause is audited within the applicable (5) key QMS process checklists. The shading insures all clauses are audited annually and avoids duplication of audit activities.

QMS Process Codes

A Management Process (Leadership)
B Customer Oriented Process (Sales / Quotation)
C Mfg. / Operation Oriented Process (Planning / Mfg.)
D External Provider Process (Supplier Control)
E Quality Management Process (QMS)

Figure 1


QMS Processes & Interaction
Customer
Requirements
Communications
Quality Management System Processes
A - Management / Leadership Process
B – Customer Oriented Process
C – Mfg. / Operations Oriented Process
D – External Provider Oriented Process
E – Quality Management Process
Product
Feedback
Customer

4.0 Context of the Organization

4.1 Understanding Organization and its Context

MSA has determined external & internal issues that are relevant to our purpose and our strategic direction that affect the organizations ability to achieve the intended result(s) of the quality management system. External issues may include but are not limited to regulatory agencies, customer needs, external providers, 3rd party registrars and natural disasters. Internal issues may include but are not limited to our employees, capacity, quality, compliance, communication and equipment.

MSA monitors and reviews the information about these external and internal issues at Mgmt. Review meetings.

Note 1: Issues can include positive and negative factors or conditions for consideration.

Note 2: Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional, or local.

Note 3: Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge, and performance of MSA.

4.2 Understanding the Needs and Expectations of Interested Parties

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

a. the interested parties that are relevant to MSA's quality management system; may include but is not limited to: employees, customers, external providers, investors, internal / external stake holders, statutory and regulatory agencies and 3rd party registrars

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

MSA monitors and reviews information about these interested parties and their relevant requirements at Mgmt. review meetings.

4.3 Determining the Scope of the Quality Management System

MSA determines the boundaries & applicability of the quality management system to establish its scope.

When determining this scope, MSA considers:

a. the external and internal issues referred to in Para 4.1;
b. the requirements of relevant interested parties referred to in Para 4.2;

c. the products and services of MSA.

MSA applies all the requirements of AS9100 if they are applicable within the determined scope of MSA's quality management system.

The scope of MSA's quality management system is available and maintained as documented information. The scope states the types of products and services covered, and provide justification for any requirement of AS9100D that MSA determines is not applicable to the scope of its quality management system.

Conformity to AS9100D may only be claimed if the requirements determined as not being applicable do not affect MSA's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.4 Quality Management System and its Processes

4.4.1 MSA establishes, implements, maintains, and continually improves a quality management system, including the processes needed and their interactions, in accordance with the requirements of AS9100D.

MSA's quality management system also addresses customer and applicable statutory and regulatory quality management system requirements.

MSA determines the processes needed for the quality management system and their application throughout MSA, and shall:

a. determine the inputs required and the outputs expected from these processes;

b. determine the sequence and interaction of these processes;

c. determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d. determine the resources needed for these processes and ensure their availability;

e. assign the responsibilities and authorities for these processes;

f. address the risks and opportunities as determined in accordance with the requirements of Para 6.1;

g. evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h. improve the processes and the quality management system.

4.4.2 To the extent necessary, MSA:

a. maintains documented information to support the operation of its processes;

b. retains documented information to have confidence that the processes are being carried out as planned.

MSA establishes and maintains documented information that includes:

- a general description of MSA's relevant interested parties include but is not limited to: employees, customers, external providers, investors, internal / external stake holders, statutory and regulatory agencies and 3rd party registrars.

- the scope of the quality management system;

- a description of the processes needed for the quality management system and their application throughout MSA;

- the sequence and interaction of these processes;

- assignment of the responsibilities and authorities for these (5) key processes via MSA's organizational chart.

5.0 Leadership

5.1 Leadership and Commitment

5.1.1 General

MSA's top management demonstrates leadership and commitment with respect to the quality management system by:

a. taking accountability for the effectiveness of the quality management system;

b. ensuring the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

c. ensuring the integration of the quality management system requirements into MSA's business processes;

d. promoting the use of the process approach and risk-based thinking;

e. ensuring the resources needed for the quality management system are available;

f. communicating the importance of an effective quality management and for conforming to the quality management system requirements;

g. ensuring 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

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

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

b. the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c. the focus on enhancing customer satisfaction is maintained;

d. product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.

5.2 Policy

5.2.1 Establishing the Quality Policy

MSA's top management establishes, implements and maintains a quality policy that:

a. is appropriate to the purpose and context of MSA and supports its strategic direction;

b. provides a framework for setting quality objectives

c. includes a commitment to satisfy applicable requirements;

d. includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy

The quality policy shall:

a. be available and maintained as documented information;

b. be communicated, understood and applied within MSA;

c. be available to relevant interested parties, as appropriate.

5.3 Organizational Roles, Responsibilities and Authorities

MSA's Top management shall ensure the responsibilities and authorities for relevant roles are assigned, communicated and understood within MSA.

Top management shall assign the responsibility and authority for:

a. Ensuring the quality management system conforms to the requirements of AS9100D;

b. Ensuring the processes are delivering their intended outputs;

c. Reporting on the performance of the quality management system and on opportunities for improvement (see Para 10.1), in particular to top management;

d. Ensuring the promotion of customer focus throughout the organization;

e. Ensuring the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Top management has appointed the director of Quality who is identified as the management representative, who shall have organizational freedom and unrestricted access to top management to resolve quality management issues.

MSA's management representative has the organizational freedom and unrestricted access to top management to resolve quality management issues. NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

6.0 Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the quality management system, MSA shall consider the issues referred to in Para 4.1 and the requirements referred to in Para 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 undesirable effects;

d. Achieve improvement.

6.1.2 MSA plans:

a. actions to address these risks and opportunities;

b. how to:

1. integrate and implement the actions into its quality management system processes (see Para 4.4);

2. evaluate the effectiveness of these actions.

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

Note 1: Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

Note 2: Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address MSA's or its customers' needs.

6.2 Quality Objectives and Planning to Achieve Them

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

The quality objectives are:

a. consistent with the quality policy;

b. measurable;

c. taking into account applicable requirements;

d. relevant to conformity of products and services and to enhancement of customer satisfaction;

e. monitored

f. communicated

g. updated, as appropriate.

MSA maintains documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, MSA 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 MSA determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see Para 4.4).

MSA 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.

7.0 Support

7.1 Resources

7.1.1 General

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

MSA considers:
a. the capabilities of, and constraints on, existing internal resources;

b. what needs to be obtained from external providers.

7.1.2 People

MSA 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

MSA determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of of products and services.

Note: Infrastructure may include:

a. buildings and associated utilities;

b. equipment, including hardware and software;

c. transportation resources;

d. information and communication technology.

7.1.4 Environment for the Operation of Processes

MSA determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of the products and services.

Note: A suitable environment can be a combination of human and physical factors, such as:

a. social (e.g., non-discriminatory, calm, non-confrontational);

b. psychological (e.g., stress-reducing, burnout prevention, emotionally protective);

c. physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

MSA 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.

MSA 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.

MSA retains the 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 MSA 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;

c. safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

MSA establishes, implements and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification.

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

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

Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions (see Para 7.1.4).

MSA 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

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

Note 1: Organizational knowledge is knowledge specific to MSA; it is generally gained by experience, it is information that is used and shared to achieve MSA's objectives.

Note 2: Organizational knowledge can be based on:

a. Internal sources (e.g., intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b. External sources (e.g., standards; academia; conferences; gathering knowledge from customers or external providers).

7.2 Competence

MSA:

a. determines the necessary competence of persons 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.

Note: Consideration is given for the periodic review of the necessary competence.

Note: Applicable actions may include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness

MSA ensures that persons doing work under MSA's control are aware of:

a. the quality policy;

b. relevant quality objectives

c. their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

d. the implications of not conforming with the quality management system requirements;

e. relevant quality management system documented information and changes thereto;

f. their contribution to product or service conformity;

g. their contribution to product safety;

h. the importance of ethical behavior.

7.4 Communication

MSA 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.

Note: Communication should include internal and external feedback relevant to the quality management system.

7.5 Documented Information

7.5.1 General

MSA's quality management system includes:

a. documented information required by AS9100 Rev. D;

b. documented information determined by MSA as being necessary for the effectiveness of the quality management system.

Note: The extent of documented information for a quality management system can differ from one organization to another due to:

- the size of the organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

7.5.2 Creating and Updating

When creating and updating documented information, MSA 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.

Note: Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by MSA.

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the quality management system and AS9100 Rev. D is controlled to ensure:

a. it is available and suitable for use, where and when it is needed;

b. it is adequately protected (e.g., from loss of confidentiality, improper use or loss of integrity).

7.5.3.2 For the control of documented information, MSA 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 MSA 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).

Note: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

8.0 Operation

8.1 Operational Planning and Control

MSA plans, implements and controls the processes (see Para 4.4) needed to meet the requirements for the provision of products and services and to implement the actions determined in Para 6.0, by:

a. determining the requirements for the product and services;

Note: Determination of requirements for the products and services should include consideration of:

- personal and product safety;
- producibility and inspectability;
- reliability, availability, and maintainability;
- suitability of parts and materials used in the product;
- selection and development of embedded software;
- product obsolescence;
- prevention, detection, and removal of foreign objects;
- handling, packaging, and preservation;
- recycling or final disposal of the product at the end of its life.

b. establishing criteria for:

1. the processes;
2. the acceptance of products and services;

Note: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:

- design verification (e.g., reliability, maintainability, product safety);
- process control
    - selection and verification of key characteristics;
    - process capability measurements;
    - statistical process control
    - design of experiments;

- verification;
- failure mode, effects, and criticality analysis.

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

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

e. determining, maintaining, and retaining documented information to the extent necessary;

1. to have confidence that the processes have been carried out as planned;
2. to demonstrate the conformity of products and services to their requirements;

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

g. engaging representatives of affected organization functions for operational planning and control;

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

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

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

Note: One method to achieve operational planning and control can be through using integrated phased processes.

As appropriate to MSA, customer requirements, and products and services MSA shall plan and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.

Note: This activity is generally referred to as project planning, project management, or program management.

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

Note: As an output of this planning, documented information specifying the processes of the quality management system and the resources to be applied to a specific product, service, project, or contract can be referred to as a quality plan.

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

MSA ensures that outsourced processes are controlled (see Para 8.4).

MSA establishes, implements, 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 shall ensure that work transfer impacts and risks are managed.

Note: For the control of work transfer from MSA to an external provider, or from an external provider to another external provider, see Para 8.4. For the control of work transfer from one MSA facility to another, or from an external provider to MSA, see Para 8.5.

8.1.1 Operational Risk Management

MSA plans, implements, & controls a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to MSA and the products and services:

a. assignment of responsibilities for operational risk management;

b. definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);
c. identification, assessment, and communication of risks throughout operations;

d. identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

e. acceptance of risks remaining after implementation of mitigating actions.

Note 1: While Para 6.1 addresses the risks and opportunities when planning for the quality management system of MSA, the scope of this paragraph (8.1.1) is limited to the risks associated to the operational processes needed for the provision of products and services (Para 8).

Note 2: Within the aviation, space and defense industry, risk is generally expressed in terms of the likelihood of occurrence and the severity of the consequences.

8.1.2 Configuration Management

MSA plans, implements, and controls a process for configuration management as appropriate to MSA 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

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

Note: Examples of these processes include:
- assessment of hazards and management of associated risks (se Para 8.1.1);

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

8.1.4 Prevention of Counterfeit Parts

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

Note: Counterfeit part prevention processes should consider:

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

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with customers includes:

a. providing information relating to products and services, including customer complaints;
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, MSA shall ensure that:

a. the requirements for the products and services are defined, including:

   1. any applicable statutory and regulatory requirements;

   2. those considered necessary by MSA;

b. MSA can meet the claims for products and services MSA that offers;

c. special requirements of the products and services are determined;

d. operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame, tight dimensional tolerances) have been identified.

8.2.3 Review of the Requirements for Products and Services

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

   a. requirements specified by 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 MSA

   d. statutory and regulatory requirements applicable to the products and services;

   e. contract or order requirements differing from those previously expressed.

   This review is coordinated with applicable functions of MSA.

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

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

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

8.2.3.2 MSA shall retain documented information, as applicable:

a. on the results of the review;
b. on any new requirements for the product and services.

8.2.4 Changes to Requirements for Products and Services

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

8.3 Design and Development of Products and Services

MSA does not perform any design or development at this time. The 8.3 series sections are included in this manual to preserve the numbering scheme established by AS9100.

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General

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

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

MSA 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.

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

MSA 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 MSA's own products and services;

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

c. a process, or part of a process, is provided by an external provider as a result of a decision by MSA.

MSA 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. MSA retains documented information of these activities and any necessary actions rising from the evaluations.

Note: During external provider evaluation and selection, MSA may use quality data from objective and reliable external sources, as evaluated by MSA (e.g., information from accredited quality management system or process certification bodies, external provider approvals from government authorities or customers). Use of such data would only be one element of MSA's external provider control process and MSA remains responsible for verifying that externally provided processes, products, and services meet specified requirements.

8.4.1.1 MSA:

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

b. maintains a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);

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

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

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

8.4.2 Type and Extent of Control

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

MSA:

a. ensures that externally provided processes remain within the control of its quality management system;

b. defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c. takes into consideration:

1. the potential impact of the externally provided processes, products, and services on MSA's 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 (see Para 8.4.1.1 c);

d. determines the verification, or other activities, necessary to ensure that 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 MSA. These shall include inspection or periodic testing, as applicable, when there is a high risk of nonconformities including counterfeit parts.

Note 1: Customer verification activities performed at any level of the supply chain does not absolve MSA of it responsibility to provide acceptable processes, products, and services and to comply with all the requirements.

Note 2: Verification activities may include:

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

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

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

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

8.4.3 Information for External Providers

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

MSA 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 MSA;

e. control and monitoring of the external providers' performance to be applied by MSA;

f. verification or validation activities that MSA or its customer, intends to perform at the external providers' premises;

g. design and development control;

h. special requirements, critical items or key characteristics;
i. test, inspection, and verification (including production process verification);

j. the use of statistical techniques for product acceptance and related instructions for acceptance by MSA;

k. the need to:

- implement a quality management system;

- use customer-designated or approved external providers, including process sources (e.g., special processes);

- notify MSA of nonconforming processes, products, or services and obtain approval for their disposition;

- prevent the use of counterfeit parts (see Para 8.1.4);

- notify MSA of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain MSA's approval;

- flow down to external providers applicable requirements including customer requirements;

- provide test specimens for design approval, inspection/verification, investigation or auditing;

- retain documented information, including retention periods and disposition requirements;

l. the right of access by MSA, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;

m. ensuring that persons are aware of:

- their contribution to product or service conformity;
- their contribution to product safety;
- the importance of ethical behavior.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

MSA implements production and service provision under controlled conditions. Controlled conditions include, as applicable:

a. the availability of documented information that defines:

1. the characteristics of the product to be produced, the services to be provided, or the activities to be performed;
2. the results to be achieved;

Note 1: Documented information that defines characteristics of products and services may include digital product definition data, drawings, parts lists, materials and process specifications.

Note 2: Documented information for activities to be performed and results to be achieved may include process flow charts, control plans, production documents, (e.g., manufacturing plans, travelers, routers, work orders, process cards), and verification documents.

b. the availability and use of suitable monitoring and measuring resources;

c. the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met;

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

- criteria for acceptance and rejection;
- where in the sequence verification operations are to be performed;
- measurement results to be retained (at a minimum an indication of acceptance or rejection);

- any specific monitoring and measurement equipment required and instructions associated with their use;

2. ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified 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).

d. the use of suitable infrastructure and environment for the operation of processes;

Note: Suitable infrastructure can include product specific tools(e.g., jigs, fixtures, molds) and software programs.

e. the appointment of competent persons, including any required qualification;

f. the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

Note: These processes can be referred to as special processes(see Para 8.5.1.2).

g. the implementation of actions to prevent human error;

h. the implementation of release, delivery and post-delivery activities;

i. the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);

j. the accountability for all products during production (e.g., part quantities, split orders, nonconforming product);

k. the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;

l. the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);

m. the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;

n. the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;

o. the provision for the prevention, detection, and removal of foreign objects;

p. the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements;

q. the identification and recording of products released for subsequent production use pending

completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

8.5.1.1 Control of Equipment, Tools, and Software Programs

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

Storage requirements are defined for production equipment or tooling in storage including any necessary periodic preservation of 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, MSA 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

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

Note: These activities may include risk assessments, capacity studies, capability studies and control plans

MSA utilizes 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).

Note: This activity can be referred to as First Article Inspection (FAI).

MSA retains documented information of the results from production process verifications.

8.5.2 Identification and Traceability

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

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

MSA 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), MSA establishes controls for the media.

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

Note: Traceability requirements may include:

- the identification to be maintained throughout the product life;
- the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);
- for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;
- for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.

8.5.3 Property Belonging to Customers or External Providers

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

MSA 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, MSA shall report this to the customer or external provider and retain documented information on what has occurred.

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

8.5.4 Preservation

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

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

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

a. cleaning;

b. prevention, detection, and removal of foreign objects

c. special handling and storage for sensitive products;

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

e. shelf life control and stock rotation;

f. special handling and storage for hazardous materials.

8.5.5 Post-Delivery Activities

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

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

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

8.5.6 Control of Changes

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

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

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

MSA 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

MSA 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 do not proceed until planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

MSA retains documented information on the release of products and services. The documented information shall include:

a. evidence of conformity with the acceptance criteria;

b. traceability to the person(s) authorizing the release.

When required to demonstrate product qualification, MSA ensures that retained documented information provides evidence that the products and services meet the defined requirements.

MSA 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 MSA ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

Note: The term “nonconforming outputs” includes nonconforming product or service generated

internally, received from and external provider, or identified by a customer.

MSA 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.

MSA nonconformity control process is maintained as documented information including the provisions for:

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

Note: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory agencies.

MSA deals with nonconforming outputs in one or more of the following ways:

a. correction;

b. segregation, containment, return or suspension 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 are only implemented:

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

Product dispositioned for scrap is 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 is verified when nonconforming outputs are corrected.

8.7.2 MSA retains documented information that:

a. describes the nonconformity;

b. describes the action taken;

c. describes any concessions obtained;

d. identifies the authority deciding the action in respect of the nonconformity.

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

MSA determines:

a. what needs to be monitored

b. the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results

c. when the monitoring and measuring is to be performed;

d. when the results from monitoring and measurement are to be analyzed and evaluated.

MSA evaluates the performance and the effectiveness of the quality management system.

MSA retains the appropriate documented information as evidence of the results.

9.1.2 Customer Satisfaction

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

Note: Examples of monitoring customer perceptions may include customer surveys, customer feedback on delivered products and services, meeting with customers, market-share analysis, compliments, warranty claims and dealer reports.

Information to be monitored and used for evaluation of customer satisfaction includes, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. MSA develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

9.1.3 Analysis and Evaluation

MSA analyzes and evaluates the appropriate data and information arising from monitoring and measurement.

Note: Appropriate data can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisories).

The results of the analysis are utilized 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 system.

Note: Methods to analyze data can include statistical techniques.

9.2 Internal Audit

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

a. conforms to:

1. MSA's own requirements for its quality management system;

Note: MSA's own requirements should include customer and applicable statutory and regulatory quality management system requirements.

2. the requirements of AS9100 Revision D.

b. is effectively implemented and maintained.

Note: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.

9.2.2 MSA:

a. plans, establishes, implements, 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 MSA, and results of previous audits;

b. defines the audit criteria and scope for each audit;

c. selects auditors and conduct audits to ensure objectivity and impartiality of the audit process;

d. ensures that results of the audits are reported to relevant management;

e. takes appropriate correction and corrective actions without undue delay;

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

Note: See ISO 19011 for guidance.

9.3 Management Review

9.3.1 General

MSA's top management reviews MSA's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction.

9.3.2 Management Review Inputs

MSA's management review is planned and carried out taking into consideration:

a. the status of actions from previous management reviews;

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

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

1. customer satisfaction and feedback from relevant interested parties;
2. the extent to which quality objectives have been met
3. process performance and conformity of products and services;
4. nonconformities and corrective action;
5. monitoring and measurement results;
6. audit results;
7. the performance of external providers;
8. on-time delivery performance;

d. the adequacy of resources;

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

f. opportunities for improvement

9.3.3 Management Review Outputs

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

a. opportunities for improvement;

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

c. resource needs;

d. risks identified.

MSA retains documented information as evidence of the results of management reviews.

10.0 Improvement

10.1 General

MSA 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.

Note: Examples of improvements may include correction, corrective action, continual improvement, breakthrough change, innovation and reorganization.

10.2 Nonconformity and Corrective Action

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

a. Reacts to the nonconformity and, as applicable:

1. takes action to control and correct it;

2. deals with the consequences;

b. evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1. reviewing and analyzing the nonconformity;

2. determining the causes of the nonconformity, including, as applicable, those related to human factors;

3. determining if similar nonconformities exist, or could potentially occur;

c. implements any action needed;

d. reviews the effectiveness of any corrective action taken;

e. updates risks and opportunities determined during planning, if necessary;

f. makes changes to the quality management system, if necessary;

g. flows down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;

h. takes specific actions when timely and effective corrective actions are not achieved.

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

MSA maintains documented information that defines the nonconformity and corrective action management processes.

10.2.2 MSA 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

MSA continuously improves the suitability, adequacy, and effectiveness of the quality management system.

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

MSA monitors the implementation of improvement activities and evaluate the effectiveness of the results.

Note: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.