

QUALITY ASSURANCE MANUAL



AS9100D & ISO9001:2015 Quality Management System

Revision History

Date	Change Description
1/5/15	Initial release in accordance with AS9100C
4/30/15	Clarified the exceptions on section 1.2
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Introduction


M K Services, Inc's goal is to supply precision machining assembly of products for customers while meeting and all customer expectations. We are committed to actively pursuing and offering the best solutions and services to the variety of customers' needs.

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This Quality Manual specifies requirements that M K Services, Inc. (MKS) uses to address customer satisfaction, to meet customer and applicable regulatory and statutory requirements, ISO 9001:2015 and AS 9100D requirements, and is supported by additional procedures where necessary. The Quality Management principles state in ISO 9000 and ISO 9004, have been taken in to consideration during the development of this Quality Manual.

This Quality Manual specifies requirements that MKS' competence towards a management system for quality, administrative, and technical operations.

1 Scope

This Quality manual includes ISO 9001:2015 quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes.

It is emphasized that the requirements specified in this standard are complementary (not alternative) to customer and applicable statutory and regulatory requirements.

If there is a conflict between the requirements of this standard and customer or applicable statutory or regulatory requirements, the latter shall take precedence.

This Quality Manual specifies requirements for a quality management system where MKS:

- a) Needs to demonstrate its ability to consistently provide product and services that meet customer and applicable statutory and regulatory requirements, and
- b) Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this AS9100D are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides;

2 Normative References

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO9001:2015	Quality management systems – Requirements
AS9100D	Quality Management Systems Requirements for Aviation, Space and Defense Organizations

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following apply.

3.1 Counterfeit Part

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

3.2 Critical Items

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

3.3 Key Characteristic

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

3.4 Product Safety

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

3.5 Special Requirements

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

4 Context of the Organization

4.1 Understanding the Organization and its Context

MKS has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. (See [P-022](#))

MKS monitors and reviews information about these external and internal issues.

4.2 Understanding the Needs and Expectations of Interested Parties

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

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

MKS monitors and reviews the information about these interested parties and their relevant requirements.

4.3 Determining the Scope of the Quality Management System

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

When determining this scope, MKS considered:

- a) The external and internal issues referred to in [4.1](#);
- b) The requirements of relevant interested parties referred to in [4.2](#);
- c) The products and services of MKS

MKS applies all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of MKS' quality management system is available and maintained as documented information. The scope states the types of products and services covered, and provides justification for any requirements that MKS has determined is not applicable to the scope of its quality management system.

Conformity to this international standard are only claimed if the requirements determined as not being applicable do not affect MKS' ability to ensure the conformity of its product and services and the enhancement of customer satisfaction.

Scope of Registration

The Scope associated with MKS activities and registration is:

Precision Machining and Assembly of products to customer specifications for various industries.

4.4 Quality Management System and its Processes

- 4.4.1 MKS has established, implemented, maintains, and continually improves a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

MKS' quality management system has addressed customer and applicable statutory and regulatory quality management system requirements.

MKS has determined the processes needed for the quality management system and their application throughout MKS, and

- a) Determined the inputs required and the outputs expected from these processes;
- b) Determined the sequence and interaction of these processes;

- c) Determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
 - d) Determined the resources needed for these processes and ensure their availability;
 - e) Assigns the responsibilities and authorities for these processes;
 - f) Addresses the risks and opportunities as determined in accordance with the requirements of [6.1](#);
 - g) Evaluates these processes and implement any changes needed to ensure that these processes achieve their intended results.
 - h) Improves the processes and the quality management system.
- 4.4.2 To the extent necessary, MKS:
- a) Maintains documented information to support the operation of its processes (See Procedure List);
 - b) Retain documented information to have confidence that the processes are being carried out as planned (See Records Table).

MKS has established and maintains documented information that includes:

- a general description of relevant interested parties (see [4.2 a](#));
- the scope of the quality management system, including boundaries and applicability (see [4.3](#));
- a description of the processes needed for the quality management system and their application throughout the organization;
- the sequence and interaction of these processes;
- assignment of the responsibilities and authorities for these processes.

5 Leadership

5.1 Leadership and Commitment

5.1.1 General

Top management demonstrates leadership and commitment with respect to the quality management system by:

- a) Taking accountability for the effectiveness of the quality management system;
- b) Ensuring that the quality policy and quality objectiveness are established for the quality management system and are compatible with the context and strategic direction of MKS;
- c) Ensuring the integration of the quality management system requirements into MKS' business process;
- d) Promoting the use of the process approach and risk-based thinking;
- e) Ensuring that the resources needed for the quality management system are available;
- f) Communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g) Ensuring that the quality management system achieves its intended results;
- h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- i) Promoting improvement; and

- j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

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

- 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 Developing the Quality Policy

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

- a) Is appropriate to the purpose and context of MKS and supports its strategic direction;
- b) Provides a framework for setting quality objectives;
- c) Includes a commitment to satisfy applicable requirements; and
- d) Includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the Quality Policy

The Quality Policy:

- a) is available and maintained as documented information;
- b) is communicated, understood and applied within the organization; and
- c) is available to relevant interested parties, as appropriate.

The stated quality policy is as follows:

It is the policy of M K Services to provide and support our valued customers with the highest quality products and services that satisfy or exceed their needs and expectations while effectively utilizing every employee to achieve this goal. MKS will comply with all applicable U.S. export control laws and regulations.”

5.3 Organizational Roles, Responsibilities, and Authorities

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

Top management assigns the responsibility and authority for:

- a) Ensuring that the quality management system conforms to the requirements of this International Standard;
- b) Ensuring that the processes are delivering their intended outputs;
- c) Reporting on the performance of the quality management system and on opportunities for improvement (see [10.1](#)), in particular to top management;
- d) Ensuring the promotion of customer focus throughout MKS; and

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

Top management has appointed a specific member of MKS' management, identified as the management representative, who has the responsibility and authority for oversight of the above requirements.

The management representative has the organizational freedom and unrestricted access to top management to resolve quality management issues.

6 Planning

6.1 Actions to Address Risks and Opportunities

6.1.1 When planning for the quality management system, MKS considered the issues referred to in [4.1](#) and the requirements referred to in [4.2](#) and determined the risks and opportunities that need to be addressed to:

- a) Give assurance that the quality management system can achieve its intended results;
- b) Enhance desirable effects;
- c) Prevent, or reduce, undesired effects; and
- d) Achieve improvement.

6.1.2 MKS 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 [4.4](#))
 2. Evaluate the effectiveness of these actions.

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

6.2 Quality Objectives and Planning to Achieve Them

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

The quality objectives are:

- a) Consistent with the quality policy;
- b) Measurable;
- c) Taken into account applicable requirements;
- d) Relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) Monitored;
- f) Communicated; and
- g) Updated as appropriate.

MKS maintains documented information on the quality objectives. (See Dashboard)

6.2.2 When planning how to achieve its quality objectives, MKS has determined:

- a) What will be done;
- b) What resources will be required;

- c) Who will be responsible;
- d) When it will be completed; and
- e) How the results will be evaluated.

6.3 Planning of Changes

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

MKS considers:

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

7 Support

7.1 Resources

7.1.1 General

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

MKS considers:

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

7.1.2 People

MKS 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

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

- a) Buildings and associated utilities;
- b) Equipment, including hardware and software;
- c) Transportation resources; and
- d) Information and communication technology.

7.1.4 Environment for the Operation of Processes

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

- 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

MKS 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.

MKS 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.

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

7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is considered by MKS to be an essential part of providing confidence in the validity of measurement results, measuring equipment are:

- 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 standard exists, 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.

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

MKS maintains a register of the monitoring and measuring equipment. The register includes the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

Calibration or verification of monitoring and measuring equipment is carried out under suitable environmental conditions (see [7.1.4](#)).

MKS determines if the validity of previous measurement results have been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action as necessary (see [P-012](#)).

7.1.6 Organizational Knowledge

MKS 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, MKS considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates. (See P-008)

7.2 Competence

MKS:

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

- b) Ensures that these persons are competent on the basis of appropriate education, training, or experience;
- c) Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; and
- d) Retain appropriate documented information as evidence of competence (see P-008).

7.3 Awareness

MKS ensures that persons doing work under the MKS' 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 implication 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 (see [P-008](#)).

7.4 Communication

MKS determined 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; and
- e) Who communicates.

7.5 Documented Information

7.5.1 General

MKS' quality management system includes:

- a) Documented information required by ISO 9001:2015/AS9100D; and
- b) Documented information determined by MKS as being necessary for the effectiveness of the quality management system.

7.5.2 Creating and Updating

When creating an updating documented information, MKS ensures appropriate:

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

(See [P-001](#))

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the quality management system and by ISO 9001:2015/AS9100D are controlled to ensure:

- a) Availability and suitable for use, where and when it is needed; and
- 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, MKS has addressed 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); and
- 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 MKS to be necessary for the planning and operation of the quality management system is identified as appropriate and controlled.

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

When documented information is managed electronically, data protection processes are defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage). (See [P-002](#))

8 Operation

8.1 Operational Planning and Control

MKS planned, implemented and controls the processes (see [4.4](#)) needed to meet the requirements for the provision of products and services, and implemented the actions determined in [Clause 6](#), by:

- a) Determining the requirements for the products and services;
- b) Establishing criteria for:
 1. The processes;
 2. The acceptance of products and services;
- c) Determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services
- d) Implementing control of the processes in accordance with the criteria; and
- e) Determining and keeping 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.

The output of this planning is in a form suitable to MKS' method of operations.

MKS ensures that outsourced processes are controlled (see [8.4](#)).

MKS will establish, implement, and maintain 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.

8.1.1 Operational Risk Management

MKS will plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization 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 (see [P-017](#))

8.1.2 Configuration Management

MKS has planned, implemented, and controls a process for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process:

- a) controls product identity and traceability to requirements, including the implementation of identified changes;
- b) ensures 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

MKS has planned, implemented, and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.

8.1.4 Prevention of Counterfeit Parts

MKS has planned, implemented, and controls processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer (see [P-021](#)).

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with Customers includes:

- a) Providing information relating to products and services;

- b) Handling inquiries, contracts or orders, including changes;
- c) Obtaining customer feedback relating to products and services, including customer complaints;
- d) Handling or controlling customer property; and
- e) Establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements Related to Products and Services

When determining the requirements for the product and services to be offered to customers, MKS ensures that:

- a) The requirements for the product and services are defined, including:
 - a) Any applicable statutory and regulatory requirements;
 - b) Those considered necessary by MKS;
- b) MKS can meet the claims for the product and services it 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) have been identified. (See [P-010](#))

8.2.3 Review of Requirements Related to Products and Services

8.2.3.1 MKS ensures that it has the ability to meet the requirements for products and services offered to customers. MKS conducts a review before committing to supply products and services to a 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 intended use, when known;
- c) Requirements specified by MKS;
- d) Statutory and regulatory requirements applicable to the products and services; and
- e) Contract or order requirements differing from those previously expressed.

This review is coordinated with applicable functions of MKS

If upon review MKS determines that some customer requirements cannot be met or can only partially be met, MKS will negotiate a mutually acceptable requirement with the customer.

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

The customer's requirements are confirmed by MKS before acceptance, when the customer does not provide a documented statement of their requirements. (See [P-010](#))

8.2.3.2 MKS retains documented information, as applicable:

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

8.2.4 Changes to Requirements for Products and Services

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

8.3 Design and Development of Products and Services

MKS does not provide design or development (See [P-022](#))

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

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

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

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

MKS 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.

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

MKS determines the control applied to externally provided processes, products, and services when:

- a) Products and services from external providers are intended for incorporation into MKS' own products and services;
- b) Products and services are provided directly to the customer(s) by external providers on behalf of MKS; and
- c) A process, or part of a process, is provided by an external provider as a result of a decision by MKS

MKS determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. MKS retains documented information of these activities and any necessary actions arising from the evaluations. (See [P-011](#))

8.4.1.1 MKS:

- 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 performance;
- 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 of Extent Control

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

MKS:

- 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 MKS' 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 [8.4.1.1 c](#));
- d) Determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

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

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

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

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

8.4.3 Information for External Providers

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

MKS 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 MKS;
- e) Control and monitoring of the external providers' performance to be applied by MKS; and
- f) Verification or validation activities that MKS, 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 the organization;
- k) the need to:
 - implement a quality management system;
 - use customer-designated or approved external providers, including process sources (e.g., special processes);
 - notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;
 - prevent the use of counterfeit parts (see [8.1.4](#));
 - notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization'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 the organization, 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

MKS implements production and service provision under controlled conditions. (See [P-019](#))

Controlled conditions include, as applicable:

- a) The availability of documented information that defines:
 1. The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 2. The results to be achieved;

- b) The availability and use of suitable monitoring and measuring resources;
- c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met;
 - a. 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;
 - b. 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;
- e) The appointment of competent persons, including any required qualification;
- f) The validation and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g) The implementation of actions to prevent human error;
- h) The implementation of release, delivery and post-delivery activities;
- i) The establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
- j) The accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
- k) The control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
- l) 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 (see [7.1.3](#));
- q) The identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

8.5.1.1 Control of Equipment, Tools, and Software Programs

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

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

8.5.1.2 Validation and Control of Special Processes

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

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

8.5.1.3 Production Process Verification

MKS has implemented production process verification activities to ensure the production process is able to produce products that meet requirements.

MKS use 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).

MKS retains documented information on the results of production process verification.

8.5.2 Identification and Traceability

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

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

MKS 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), the organization establishes controls for the media.

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

8.5.3 Property Belonging to Customers or External Providers

MKS exercises care with property belonging to customer or external providers while it is under MKS' control or being used by MKS

MKS identifies, verifies, protects and safeguards customer's 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, MKS reports this to the customer or external provider and retains documented information on what has occurred.

8.5.4 Preservation

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

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

MKS does not provide any post-delivery activities. (See [P-022](#))

8.5.6 Control of Changes

MKS reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. (See [P-019](#))

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

MKS 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 Service

MKS has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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

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

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

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

MKS 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 MKS ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. (See [P-004](#))

MKS 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.

MKS' 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 [10.2](#)).

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

- a) Correction;
- b) Segregation, containment, return or suspension of provision of products and services;
- c) Informing the customer;
- d) Obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products 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 are verified when nonconforming outputs are corrected.

8.7.2 MKS 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

MKS determines:

- a) What needs to be monitored and measured;

- b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) When the monitoring and measuring is performed;
- d) When the results form monitoring and measurement are analyzed and evaluated.

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

MKS retains appropriate documented information as evidence of the results. (See [P-009](#))

9.1.2 Customer Satisfaction

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

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. MKS 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

MKS analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of analysis are used to evaluate:

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

9.2 Internal Audit

9.2.1 MKS conducts internal audits at planned intervals to provide information on whether the quality management system: (See [P-003](#))

- a) Conforms to:
 - 1. MKS' own requirements for its quality management system;
 - 2. The requirements of ISO 9001/AS9100D
- b) Is effectively implemented and maintained.

9.2.2 MKS has:

- a) Planned, established, implemented and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which is taken into consideration the importance of the processes concerned, changes affecting MKS, and the results of previous audits;
- b) Defined the audit criteria and scope of each audit;
- c) Selected auditors and conducts audits to ensure objectively and the impartiality of the audit process;

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

9.3 Management Review

9.3.1 General

Top management reviews MKS' quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of MKS (See [P-007](#))

9.3.2 Management Review Inputs

Management review is planned and carried out taking into consideration:

- a) The status of actions from previous management reviews;
- b) Changes in external and internal issues that are relevant to the quality management system;
- c) Information on the performance and effectiveness of the quality management system, including trends in:
 - 1. Customer satisfaction and feedback from relevant interested parties;
 - 2. The extent to which quality objectives have been met;
 - 3. Process performance and conformity of products and services;
 - 4. Nonconformities and corrective actions;
 - 5. Monitoring and measurement results;
 - 6. Audit results;
 - 7. The performance of external providers;
 - 8. On-time delivery performance
- d) The adequacy of resources;
- e) The effectiveness of actions taken to address risks and opportunities (see 6.1); and
- f) Opportunities for improvement

9.3.3 Management Review Outputs

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

- a) Opportunities for improvement;
- b) Any need for changes to the quality management system; and
- c) Resource needs.
- d) Risks identified.

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

10 Improvement

10.1 General

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

These include:

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

10.2 Nonconformity and Corrective Action

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

- 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;
 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) flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
- h) take specific actions when timely and effective corrective actions are not achieved.

Corrective actions are appropriate to the effects of the nonconformities encountered (see [P-005](#)).

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

10.2.2 MKS 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

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

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

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