Micro-Technic Tool & Stamping

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QUALITY MANUAL

ISO 9001:2015

Change Record

Rev	Date	Responsible Person	Description of Change
1.0	11/01/13	Les Davie	Propose Quality Manual for review
1.1	09/30/14	Steve Miller	Amendments to 6.3, inclusion of 7.5.2
2.0	10/03/16	Steve Miller	Version change to ISO 9001:2015 standards
2.1	10/09/17	Steve Miller	Amended 9.3.1 (Recommended to read "quarterly")
2.1.1	01/22/18	Steve Miller	Amended 4.1 "External issues"
2.1.2	01/24/18	Steve Miller	Revised 8.4.1 to clarify "criteria"
2.1.3	06/06/18	Steve Miller	Revised 5.2.2 Quality Objectives
2.1.4	08/07/18	Steve Miller	Amended 4.1 "Internal issues"
2.1.5	08/10/18	Steve Miller	Transferred Int/Ext Issues to QMSD-1011
2.2	08/27/19	Steve Miller	Amended 8.5.3 Customer supplied material
2.3	11/19/20	Steve Miller	Amendments to improve clarity and understanding. Objectives changed to 88%

QUALITY MANUAL INDEX

1. Scope

The purpose of this quality manual is to describe the policies and company-wide control structure of the Quality Management System (QMS) used to achieve the corporate quality policy and objectives at Micro-Technic Tool & Stamping. It is also to ensure that the quality policy and quality objectives are established for the quality management system and are compatible with the strategic direction and the context of the organization.

The true measure of quality at Micro-Technic Tool & Stamping is customer satisfaction. Because customer satisfaction and the quality of our products are and will continue to be the keys to our competitiveness for years to come, it is increasingly vital for us at Micro-Technic Tool & Stamping to understand and use our quality management system to do the best job, the first time, every time. To ensure that our quality management system continues to provide a solid foundation for success, it is essential that we continually improve our quality management system and related processes.

Scope of the quality management system

The scope of the Quality Management System for Micro-Technic Tool & Stamping encompasses all processes and provisions, both internal and external, which are necessary for the manufacturing of high quality precision stamped and/or machined products that meet or exceed customer, statutory, and regulatory requirements.

Exclusion: *Clause 8.3 Design and Development of Products and Services.*
"All products are manufactured per customer specifications and requirements."
As such the exclusion does not affect Micro-Technic Tool & Stamping's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

Strategic direction of the company

To excel as a supplier through the use of innovation and technology, enabling us to consistently supply precision, defect free, cost effective products for the manufacturing industry worldwide.

The quality management system described in this Quality Manual addresses the requirements of the ISO Quality Standards as defined in ISO 9001:2015.

All references made to ISO 9001 in this manual refer to the 2015 version of the Standard.

2. Normative references

The following referenced documents are indispensable for the application of this document. ISO 9000:2015, Quality management systems - Fundamentals and vocabulary

3. Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply. (Refer to Appendix A)

4. Context of the organization

4.1. Understanding the organization and its context

The organization has determined the external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system: These issues are listed on *QMSD-1011 Context of the Organization*.

The organization will monitor and review the information regarding these external and internal issues. These issues will be discussed at every management review meeting, taking into consideration whether or not they remain pertinent. Should they be modified, updated or appended, are they still appropriate for the organization?

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

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.

Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge, and performance of the organization. Performance metrics, if used, should be clearly measureable.

Documented information is maintained through the use of the form *QMSF-1013 Management Review*.

4.2. Understanding the needs and expectations of interested parties

Should the company do business with a customer or other potential interested party, (for example, owners, people in an organization, suppliers, bankers, unions, partners or society that may include competitors or opposing pressure groups), that could affect or potentially affect the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization will determine:

- All of the interested parties that are relevant to the quality management system. See the form, *QMSF-1014 Contract Review*.
- The list of special requirements relevant to the quality management system. See the form, *QMSF-1014 Contract Review*.

The organization will monitor and review the information about these interested parties and their relevant requirements. This will be accomplished by using the form, *QMSF-1014 Contract Review*. The company name and list of these interested party/special/relevant requirements will be stated on the completed form and the form will be retained as documented information.

An example of an interested party/special/relevant requirement could be something such as: As part of the employment agreement, the customer wants all of their parts produced to undergo a first article inspection utilizing AS9102.

4.3. Determining the scope of the quality management system

The company has established the boundaries of the quality management system to be, any and all sets of company sanctioned activities which are relevant to product development. During the development of the scope of the quality management system, the following details were taken into consideration in order to be compliant with the standard.

- The external and internal issues relating to the context of the organization. These are listed on the document *QMSD-1011 Context of the Organization*.
- The requirements of relevant interested parties. See section 4.2 of this manual to understand where the requirements are recorded.
- The products and services of the organization.

All requirements of this International Standard, that affect the organization's ability and responsibility to ensure conformity of its products and services and the enhancement of customer satisfaction, are considered applicable by the organization within the determined scope of its

quality management system, with the exception of *Clause 8.3 Design and Development of Products and Services*, since Micro-Technic only produces products and services to customer determined specifications and requirements.

The scope of the organization's quality management system is available and is maintained as documented information within Section 1 of this Quality Manual.

4.4. Quality management system and its processes

4.4.1 Quality management system and its processes cont.

The organization has established, implemented, maintained and continually improved a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard: Continual improvement of the quality management system and its processes is accomplished through the use of corrective action reports. The interactions between the processes are represented in the process map, *QMSM-1001 Process Interaction*.

The organization has determined the processes needed for the quality management system and their application throughout the organization. Every process has been documented in a process map. Every process requires that a process failure mode and effects analysis be completed on the process. This is accomplished, and documented information will be maintained by completing and retaining the form, *QMSF-1015 PFMEA* for each process.

The organization has implemented the following:

- Determine the inputs required and the outputs expected from these processes. This is recorded on the form, *QMSF-1016 Process Data Sheet*.
- Determine the sequence and interaction of these processes. See the process map, *QMSM-1001 Process Interaction*.
- Determine and apply the criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of these processes. See the form, *QMSF-1016 Process Data Sheet*.
- Determine the resources needed for these processes and ensure their availability. See the form, *QMSF-1016 Process Data Sheet*.
- Assign the responsibilities and authorities for these processes. See the form, *QMSF-1016 Process Data Sheet.*

- Address the risks and opportunities in accordance with the requirements of 6.1 of the standard, and plan and implement the appropriate actions to address them. See the form, *QMSF-1016 Process Data Sheet* and the associated form *QMSF-1015 PFMEA*.
- Evaluate these processes and implement any changes needed to ensure that these processes achieve intended results: See *QMSF-1016 Process Data Sheet*.
- Improve the processes of the quality management system: See *QMSF-1015 PFMEA* and *QMSP-1006 Corrective Actions*.

4.4.2 Quality management system and its processes cont.

- The organization maintains documented information to support the operation of processes such as customer purchase orders, customer prints, job travelers, routers, and a parts library.
- The organization retains documented information that provides evidence that the processes are carried out as planned, such as PFMEA results (*QMSF-1015 PFMEA*), process data sheets (*QMSF-1016 Process Data Sheet*), and completed inspection reports (*QMSF-1021 First Article Inspection*, *QMSF-1012 In-Process Inspection*, *QMSF-1022 Final Inspection Report*).

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:

- Taking accountability of the effectiveness of the quality management system: This is accomplished by having a member of top management, or their designee, if unavailable, present at every management review meeting. See section 3.05 of Terms and definitions of this manual for a definition of top management.
- Ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization: This is accomplished by ensuring that a member of top management has reviewed and approved the policy and objectives. In addition, making sure that the policy and objectives are posted on the quality bulletin board and that all employees know and understand the policy and objectives. Top management defines the "Strategic direction of the company", in Section 1. Scope, of this manual.

- Ensuring the integration of the quality management system requirements into the organization's business processes: This is accomplished through discussions at the management review meeting, in particular, the discussion of external and internal issues that are relevant to the purpose of the company and its strategic direction, along with reviewing the strategic direction of the company considering those issues. These issues are considered as well in the crafting of the quality policy and objectives to ensure adequate integration with the quality management system.
- Promoting the use of the process approach and risk-based thinking: This is accomplished through the use of the quality bulletin board and *QMSF-1015 PFMEA*.
- Ensuring that the resources needed for the quality management system are available: Resource availability is discussed at every management review meeting and documented information is maintained using *QMSF-1013 Management Review*.
- Communicating the importance of effective quality management and of conforming to the quality management system requirements: This is accomplished through the use of the quality bulletin board.
- Ensuring that the quality management system achieves its intended results: This is accomplished through the monitoring of quality management system processes for intended results, utilizing the forms *QMSF-1029 Process Analysis & Evaluation*, and *QMSF-1016 Process Data Sheet*.
- Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system: This is accomplished at the management review meeting by involving individual contributors to participate in the resolutions of non-conformance reports within their respective work areas. In addition, as part of an employee's performance review, they are rated against their contributions to the effectiveness of the quality management system. See the form *QMSF-1011 Employee Performance Evaluation*.
- Promoting improvement: This is accomplished by utilizing the bulletin board for tracking quality management system metrics. Management review meetings also promote continual improvement.
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility: This is accomplished by the participation of relevant management in management review meetings. See *QMSF-1013 Management Review*.

5.1.2 Customer Focus

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

- Customer and applicable statutory and regulatory requirements are determined, understood and consistently met: This is accomplished by utilizing the procedure *QMSP-1003 Requirements Review* and the form *QMSF-1014 Contract Review*.
- The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed: This is accomplished through the use of the form *QMSF-1016 Process Data Sheet* and the form *QMSF-1015 PFMEA*.
- The focus on enhancing customer satisfaction is maintained: This is accomplished through the use of the form *QMSF-1002 Customer Survey* and the E2 Shop System / Quality / Feedback module, for recording customer feedback.

5.2. Policy

5.2.1 Establishing the quality policy

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

- Is established, reviewed and maintained: The quality policy is established at the company by providing all employees with basic ISO training and informing them that everybody in the company needs to know and understand the quality policy. The policy is implemented as evidenced by its inclusion in the company's quality bulletin board. The policy is maintained in conjunction with *QMSF-1013 Management Review*. Should the policy need to be revised, it is edited, re-posted, and maintained on the quality bulletin board.
- Is appropriate to the purpose of the organization and supports its strategic direction: The quality policy was reviewed and approved by top management to be appropriate to the purpose of the organization. See the Quality Policy in Section 5.2.2 of this manual.
- Provides a framework for setting quality objectives: See the Quality Policy and Quality Objectives in Section 5.2.2 of this manual.
- Includes a commitment to satisfy applicable requirements: See the Quality Policy in Section 5.2.2 of this manual.
- Includes a commitment to continual improvement of the quality management system: See the Quality Policy in Section 5.2.2 of this manual.

5.2.2 Communicating the quality policy

The quality policy will:

- Be available and be maintained as documented information: See the Quality Policy in Section 5.2.2 of this manual.

- Be communicated, understood and applied within the organization: The quality policy is communicated by being posted on the quality bulletin board. It is understood and applied due to employees being questioned about the quality policy at every internal audit.
- Be available to relevant interested parties, as appropriate: The quality policy as well as the quality manual is made available to all interested parties, considering doing business with the company, upon request.

Micro-Technic Tool & Stamping's Quality Policy and Objectives:

Quality Policy: *Micro-Technic Tool & Stamping strives to achieve complete customer satisfaction through the on-time delivery of quality products and services, and by meeting or exceeding all customer, statutory, and regulatory requirements; while continuously reviewing and improving the effectiveness of the Quality Management System.*

Quality Objectives:

- **88**% On-Time Delivery
- No more than **2** customer returns per month average, per annum.

5.3. Organizational roles, responsibilities and authorities

Top management has ensured that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. The responsibilities and authorities for all relevant roles in the company are defined in *QMSD-1002 Organization Chart* and *QMSD-1007 Responsibilities and Authorities*. They are communicated by the inclusion of the two documents in the organization's Quality Bulletin Board.

Top management has assigned the responsibility and authority for the following:

- Ensuring that the quality management system conforms to the requirements of this International Standard.
- Ensuring that the processes are delivering their intended outputs.
- Reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management.
- Ensuring the promotion of customer focus throughout the organization.
- Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6. Planning

6.1. Actions to address risks and opportunities

6.1.1 Actions to address risks and opportunities cont.

When planning for the quality management system, the organization considers the internal and external issues referred to in 4.1. These issues are listed in *QMSD-1011 Context of the Organization*. The organization also considers the requirements referred to in 4.2, which are recorded on the form, *QMSF-1014 Contract Review*. Considering this information and the use of the procedure, *QMSP-1008 Risk Management*, the company determines the risks and opportunities that need to be addressed to;

- Give assurance that the quality management system can achieve its intended result(s): This is accomplished by reviewing the results of completed PFMEA forms.
- Enhance desirable effects: This is accomplished by reviewing the results of completed PFMEA forms and writing Corrective Actions utilizing the E2 Shop System / Quality / Corrective Action module.
- Prevent, or reduce, undesired effects: This is accomplished by reviewing the results of completed PFMEA forms and writing Corrective Actions utilizing the E2 Shop System / Quality / Corrective Action module.
- Achieve continual improvement: This is accomplished by reviewing the opportunities that may have been discovered during the PFMEA exercises and writing Corrective Actions in the E2 Shop System / Quality / Corrective Action module.

6.1.2 Actions to address risks and opportunities cont.

The company has also planned actions to address risks and opportunities: This is accomplished by following the procedure, *QMSP-1008 Risk Management*, which states that Corrective Action reports and Feedback reports in the E2 Shop System will be used for this activity.

The company has also planned how to integrate and implement these actions into its quality management system processes: See *QMSP-1008 Risk Management* and *QMSF-1016 Process Data Sheet*.

The company evaluates the effectiveness of actions taken by completing the “Verification of Implementation” section of the associated corrective action reports and completing the “Verification of Effectiveness” section of the associated corrective action reports in the E2 Shop System.

6.2. Quality objectives and planning to achieve them

6.2.1 Quality objectives and planning to achieve them cont.

The organization has established the quality objectives at all relevant functions, all levels and all processes needed for the quality management system.
The quality objectives are:

- Consistent with the quality policy: Quality objectives at the company are based on and developed in conjunction with the quality policy and represent improvements in the quality management system. See the Quality Objectives in Section 5.2.2 of this manual.
- Measurable: Quality objectives are quantifiable. Metrics to support the quality objectives are obtained using applicable reports in the E2 Shop System.
- Taking into account applicable requirements: The quality objectives do not in any way conflict with customer requirements.
- Relevant to conformity of products and services and the enhancement of customer satisfaction: The quality objectives are related to product quality and/or on-time delivery in an effort to enhance customer satisfaction. See the Quality Objectives in Section 5.2.2 of this manual.
- Monitored: The quality objectives are measured monthly and graphed. Related graphs can be generated from Quick View, Executive Overview in the E2 Shop System.
- Communicated: The graphs mentioned in the step above are displayed on the quality bulletin board and updated monthly.
- Updated as appropriate: The quality objectives are reviewed for continuing suitability at every management review meeting. See *QMSF-1013 Management Review*.

The organization retains documented information on the quality objectives. The quality objectives are published in section 5.2.2 of this manual. They are discussed at management review. Documented information of those discussions is maintained using *QMSF-1013 Management Review*.

6.2.2 Quality objectives and planning to achieve them cont.

The company has planned how to achieve its quality objectives. The organization has determined:

- What will be done: The quality objectives are discussed at every management review meeting. The progress against the objectives, i.e., the graphs of the metrics, is analyzed. If positive progress is made against the objectives, no action is required. If there is a lack of progress, a corrective action report is written to investigate, propose, and implement a solution to achieve progress with the objective. If the solution is effective, the corrective

action is closed. If the solution is ineffective, another action is implemented. Should the situation recur, the process is used again.

- What resources will be required: Documented information is maintained in the corrective action report in the E2 System, in the fields "Investigated By", "Implemented by" and "Verification of Effectiveness By".
- Who will be responsible: The quality manager or designee is responsible.
- When it will be completed: This information is recorded in the E2 Shop System / Quality / Corrective Action module in the "Immediate Action" and "Permanent Action" fields. See *QMSP-1006 Corrective Actions* for instructions.
- How the results will be evaluated: The corrective action report in the E2 Shop System is evaluated in the management review meeting, and the "Verification of Effectiveness" field in the E2 Shop System Corrective Action is updated, thereby creating and maintaining documented information.

6.3. Planning of changes

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

All such changes are added to the agenda of the management review meeting, i.e., the form *QMSF-1013 Management Review*, under the agenda item "Changes that could affect the quality management system". This ensures that documented information is maintained for this type of activity.

The organization considers:

- The purpose of the changes and any of its potential consequences: Refer to the form, *QMSF-1013 Management Review*, under the agenda item "Changes that could affect the quality management system".
- The integrity of the quality management system: Refer to the form, *QMSF-1013 Management Review*, under the agenda item "Changes that could affect the quality management system".
- The availability of resources: Refer to the form, *QMSF-1013 Management Review*, under the agenda item "Changes that could affect the quality management system".
- The allocation or reallocation of responsibilities and authorities: Refer to the form, *QMSF-1013 Management Review*, under the agenda item "Changes that could affect the quality management system".

7. Support

7.1. Resources

7.1.1 General

The organization has determined and provided the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system: *QMSD-1007 Responsibilities and Authorities* describes who is responsible for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization has considered:

- The capabilities of, and constraints on, existing internal resources: The capabilities and constraints of personnel in the company can be found in their job descriptions.
- What needs to be obtained from external providers: External providers are companies that provide both products and services. These companies are listed in the E2 System under "Tables", "Vendors". The products and services that they provide are also indicated by "Vendor Type" in the E2 Shop System. Utilize *QMSP-1010 Control of External products and services*.

7.1.2 People

The organization determines and provides the persons necessary for the effective implementation of the quality management system and the operation and control of its processes. The persons responsible for the overall care of the quality management system are listed in *QMSD-1007 Responsibilities and Authorities*. The responsible authorities for individual processes are listed on the completed Process Data Sheets retained at the company for all of the company's processes.

7.1.3 Infrastructure

The organization determines, provides and maintains the infrastructure necessary for the operation of its processes to achieve conformity of products and services. To ensure that infrastructure is suitable to create conforming product, critical infrastructure is identified and maintained. Each Manager/Foreman/Supervisor periodically assesses the infrastructure in his/her area(s) of responsibility to ensure that conformity of product is achieved. This information is reviewed at Management Review meetings attended by the Managers/Foremen/Supervisors and Top Management.

The critical infrastructure includes:

- Buildings and associated utilities.
- Suitable equipment including hardware and software.
- Transportation resources.
- Information and communication technology.

7.1.4 Environment for the operation of processes

The organization determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services. This includes social (e.g. non-discriminatory, calm, non-confrontational), psychological (e.g. stress-reducing, burnout prevention, emotionally protective), and physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.
It is the responsibility of each Manager/Foreman/Supervisor to identify and manage both the social, psychological, and physical factors of the work environment that are necessary to achieve conforming product.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization 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,

The organization ensures that the resources provided:

- Are suitable for the specific type of monitoring and measurement activities being undertaken: Suitability of personnel is determined using *QMSF-1010 Job Description*. Suitability of monitoring and measuring equipment is determined using *QMSF-1014 Contract Review*.
- Are maintained to ensure their continued fitness for their purpose: Refer to *QMSF-1011 Employee Performance Evaluation* which ensures the continued fitness of personnel. Refer to *QMSM-1007 Calibration* which ensures that measuring instruments are maintained to ensure their continued fitness.

The organization retains appropriate documented information as evidence of fitness for the purpose of monitoring and measurement resources. These are the employees' job descriptions

(*QMSF-1010 Job Description*), along with any other pertinent documented information, that convey additional qualifications, for example, resumes, experience, training, etc.

7.1.5.2 Measurement traceability

Where measurement traceability is a requirement, or considered by the organization to be an essential part of providing confidence in the validity of measurement results; measuring instruments are:

- 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;
- Identified in order to determine their status;
- Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization will determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and take appropriate action as necessary. Calibration results are recorded, in either the E2 Shop System / Quality / Tooling Maintenance module, a calibration program, a spreadsheet, a log, or whatever method is used to record calibrations.

7.1.6 Organizational knowledge

The organization has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge is maintained, and made available to the extent necessary. When addressing changing needs and trends, the organization considers its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

This knowledge is retained, and documented information is maintained in the completed forms, *QMSF-1016 Process Data Sheet*. These completed forms contain the information necessary for the proper operation and control of the company's processes. Should the company decide to address changing needs and trends, the Process Data Sheets are updated to reflect these new conditions.

In addition, the organization maintains documented information, such as customer purchase orders, customer prints, job travelers, routers, and a parts library, to support the operation of processes. There is also documented information that provides confidence that the processes are being carried out as planned, such as PFMEA results (*QMSF-1015 PFMEA*), process data sheets

(*QMSF-1016 Process Data Sheets*), and completed inspection reports (*QMSF-1021 First Article Inspection Report*, *QMSF-1012 In-Process Inspection Report*, *QMSF-1022 Final Inspection Report*). There are also Corrective Action reports in the E2 Shop System to demonstrate continual improvement in this area of the system.

7.2. Competence

The organization:

- Determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system: This is accomplished by utilizing the form, *QMSF-1010 Job Description*. The completed form contains the required skills and competence for personnel.
- Ensures that these persons are competent on the basis of appropriate education, training, or experience: This is accomplished by utilizing the form, *QMSF-1010 Job Description*. The required education, training and experience is listed in the completed form.
- Where applicable, takes actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken: This is accomplished by providing various levels of training for personnel. Documented training information is stored in the E2 Shop System, Quality module under Employee Training. Personnel are evaluated utilizing the form, *QMSF-1011 Employee Performance Evaluation*.
- Retains appropriate documented information as evidence of competence: This is accomplished by retaining the completed forms, *QMSF-1011 Employee Performance Evaluation* as documented information.

7.3. Awareness

The organization ensures that persons doing work under the organization's control are aware of:

- The quality policy: All employees at the company receive basic training for ISO 9001:2015 where it is explained that they are required to be aware of and understand the quality policy. The quality policy is also posted on the quality bulletin board.
- Relevant quality objectives: All employees at the company receive basic training for ISO 9001:2015 where it is explained that they are required to be aware of and understand the quality objectives. The quality objectives are also posted on the quality bulletin board, along with graphs which demonstrate performance against the objectives.
- Their contribution to the effectiveness of the quality management system, including the benefits of improved performance: All employees at the company receive basic training

for ISO 9001:2015 where it is explained that their contributions have a direct effect on the quality management system, in particular the quality objectives.

- The implications of not conforming to the quality management system requirements: All employees at the company receive basic training for ISO 9001:2015 where it is explained that non-conforming product and poor performance against objectives, for example, have a direct effect on the maintenance and continued improvement of the organization's quality management system as well as customer satisfaction.

7.4. Communication

The organization has determined the internal and external communications relevant to the quality management system including:

- On what it will communicate: The company communicates with both internal and external parties regarding:
  - Issues relevant to the strategic direction of the organization, as described in section 4.1 of this manual.
  - Understanding the needs and requirements of interested parties, as described in section 4.2 of this manual.
  - Conveying the company's requirements for suppliers and outsourced services, as described in sections 8.1, 8.4.2 and 8.4.3 of this manual.
- When to communicate: The Company communicates as needed, on an ongoing basis on all of the items listed above in this section.
- With whom to communicate: The Company communicates from top management, or designee, to the other parties' top management as needed on an ongoing basis on all of the items listed above in this section.
- How to communicate: The Company's top management, or designee, communicates via email for all of the items listed above in this section. This is necessary in order to retain the pertinent documented information.
- Who communicates: The Company's top management, or designee, communicates via email for all of the items listed above in this section.

7.5. Documented Information

7.5.1 General

The organization's quality management system includes:

- Documented information required by this International Standard: The quality management system documentation set at the company complies with all of the requirements of the standard for documented information.

- Documented information determined by the organization as being necessary for the effectiveness of the quality management system: The quality management system documentation set at the company contains documented information determined by the organization as being necessary for the effectiveness of the quality management system. An example of this is the form, *QMSF-1015 PFMEA*. The form is not specifically required by the standard but is used as the method in which risk management of processes and products is realized.

7.5.2 Creating and updating

When creating and updating documented information the organization has ensured appropriate:

- Identification and description (e.g. a title, date, author, or reference number): See the procedure *QMSP-1001 Control of Documents*, section titled, General, starting on page 1, for identification and description of the document.
- Format (e.g. language, software version, graphics) and media (e.g. paper, electronic): All quality management system documented information is written in English and is in electronic format. This is also stated in the procedure, *QMSP-1001 Control of Documents*, section titled General, in the first sentence.
- Review and approval for suitability and adequacy: See the procedure *QMSP-1001 Control of Documents*, section titled Procedure for Controlled Documents – Approval Guidelines, on page 4.

7.5.3 Control of documented information

7.5.3.1 Control of documented information cont.

Documented information required by the quality management system and by this International Standard is controlled to ensure:

- It is available and suitable for use, where and when it is needed: All E2 users in the company have access to the quality management system documentation set. Some are more limited than others, read-only access versus edit access, depending on the security settings in E2 User Maintenance as specified in *QMSP-1001 Control of Documents*. The E2 Shop System is available to every employee in the company.
- It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity): Most employees in the company have read-only access to the quality management system documentation set. Only top management and representatives of top management have the ability to alter the files, mostly for reviewing and approval functions as described in *QMSP-1001 Control of Documents*.

All of the quality management system documentation set resides in the E2 Shop System, in the Quality module under the Document Control feature. The files are access protected and under revision control.

7.5.3.2 Control of documented information cont.

For the control of documented information, the organization has addressed the following activities, as applicable:

- Distribution, access, retrieval and use: See the procedure *QMSP-1001 Control of Documents*, section titled General, on page 1, for information on access, retrieval and use.
- Storage and preservation, including preservation of legibility: See the procedure *QMSP-1001 Control of Documents*, section titled General, on page 1, for information on storage, preservation and legibility (electronic files are always legible).
- Control of changes (e.g. version control): See the procedure *QMSP-1001 Control of Documents*, section titled Procedure for Controlled Documents – Editing an Existing Document, on page 4, steps d thru j.
- Retention and disposition: See the procedure *QMSP-1002 Quality Records Matrix* for information on retention and disposition (all files will be retained, obsolete files will be "retired in E2").

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system is identified as appropriate, and controlled. See the procedure *QMSP-1001 Control of Documents*, section titled Purpose, on page 1, for information on documents of external origin.

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

8. Operation

8.1. Operational planning and control

The organization has planned, implemented and controlled the processes (see 4.4) needed to meet the requirements for the provision of products and services and to implement the actions determined in Clause 6, by:

- Determining requirements for the product and services: See the procedure *QMSP-1003 Requirements Review* and *QMSF-1014 Contract Review*.
- Establishing criteria for the processes: See the form *QMSF-1016 Process Data Sheet* which establishes the criteria for the manufacturing processes.

- Establishing the criteria for the acceptance of products and services: See *QMSF-1014 Contract Review*, which indicates that the criteria for acceptance of products and services has been established.
- Determining the resources needed to achieve conformity to product and service requirements: See the form *QMSF-1016 Process Data Sheet*, for resource detail.
- Implementing control of the processes in accordance with the criteria: See the form *QMSF-1016 Process Data Sheet*, for performance, testing and risk analysis detail.
- Determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to their requirements: All of the completed forms, *QMSF-1016 Process Data Sheet*, are retained as documented information to show that the processes are carried out as planned. All of the completed inspection reports, *i.e.* *QMSF-1012 In-Process Inspection Report*, are retained as documented information to demonstrate conformity of products and service requirements.

The output of this planning is suitable for the organization's operations. The organization has controlled planned changes and reviewed the consequences of unintended changes, by taking action to mitigate any adverse effects, as necessary. This is accomplished by using the form *QMSF-1016 Process Data Sheet* for all processes at the company.

The organization has ensured that outsourced processes are controlled in accordance with 8.4: See section 8.4 of this manual and *QMSP-1010 Control of External Products and Services*.

8.2. Requirements for products and services

8.2.1 Customer communication

The organization’s communication with customers includes:

- Providing information relating to products and services: This information is communicated via email for the purpose of retaining documented information. If the information affects a current order in the E2 Shop System, the information is stored permanently in the “Job Notes” of the E2 Shop System Order.
- Handling enquiries, contracts or order handling, including changes: This information is communicated via email for the purpose of retaining documented information. If the information affects a current order in the E2 Shop System, the information is stored permanently in the “Job Notes” of the E2 Shop System order.
- Obtaining customer feedback relating to products and services, including customer complaints: Customers are surveyed annually for their views and perceptions using the form, *QMSF-1002 Customer Survey*. Customer views, perceptions, and complaints are recorded in the E2 Shop System, Quality Module, Feedback feature on feedback reports.

- Handling or treatment of customer property, if applicable: See section 8.5.3 of this manual for handling of customer property.
- Establishing specific requirements for contingency actions, when relevant: The organization makes every effort to provide for contingency events and immediately informs the customer of any such events by email. Should the customer request a contingency plan for certain events, then a plan is drafted using *QMSF-1019 Contingency Plan* and communicated via email.

8.2.2 Determining requirements for products and services

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

- Product and service requirements (including those considered necessary by the organization) and applicable statutory and regulatory requirements are defined: This is accomplished through the use of the procedure, *QMSP-1003 Requirements Review* and the form, *QMSF-1014 Contract Review*.
- The organization can meet the claims for the products and services it offers: This is accomplished through the use of the procedure, *QMSP-1003 Requirements Review*, the form, *QMSF-1014 Contract Review*, and by entering a Quotation in the E2 Shop System to substantiate and verify that the company has the capability to meet the defined requirements for the products or services.

8.2.3 Review of the requirements related to products and services

8.2.3.1 Review of the requirements cont.

The organization ensures that it has the ability to meet the requirements of products and services to be offered to customers. The organization conducts a review before committing to supply products and services to a customer, which includes:

- Requirements specified by the customer, including the requirements for delivery and post-delivery activities: See the procedure *QMSP-1003 Requirements Review* and form *QMSF-1014 Contract Review*.
- Requirements not stated by the customer, but necessary for the customers' specified or intended use, when known: See the procedure *QMSP-1003 Requirements Review* and form *QMSF-1014 Contract Review*.
- Requirements specified by the organization: See the procedure *QMSP-1003 Requirements Review* and form *QMSF-1014 Contract Review*.
- Statutory and regulatory requirements applicable to the products and services: See the procedure *QMSP-1003 Requirements Review* and form *QMSF-1014 Contract Review*.

- Contract or order requirements differing from those previously expressed: See the procedure *QMSP-1003 Requirements Review* and form *QMSF-1014 Contract Review*.

The organization ensures that order requirements differing from those previously defined are resolved. This is accomplished by questioning the customer via phone or email and then completing the form *QMSF-1014 Contract Review*.

The customer's requirements are confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements: This is accomplished by providing an E2 Order Acknowledgement to the customer in conjunction with *QMSM-1009 Order Entry*.

8.2.3.2 Review of the requirements cont.

The organization retains documented information, as applicable:

- On the results of the review: This is accomplished using *QMSF-1014 Contract Review*.
- On any new requirements of the products and services: This is accomplished using *QMSF-1014 Contract Review*.

8.2.4 Changes to requirements for products and services

The organization 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: This is accomplished using *QMSF-1014 Contract Review* and the E2 Shop System Job Notes per *QMSM-1009 Order Entry*.

8.3. Design and development of products and services (Excluded)

All products are manufactured per customer specifications and requirements.

8.4. Control of externally provided processes, products and services

8.4.1 General

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

The organization determines the controls to be applied to externally provided processes, products and services when:

- Products and services from external providers are intended for incorporation into the organization's own products and services: See the procedure, *QMSP-1010 Control of External Products and Services*.
- Products and services are provided directly to the customer(s) by external providers on behalf of the organization: See the procedure, *QMSP-1010 Control of External Products and Services*.
- A process, or part of a process, is provided by an external provider as a result of a decision by the organization: See the procedure, *QMSP-1010 Control of External Products and Services*.

The organization 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. This is accomplished by executing and reviewing the results of the procedure, *QMSP-1004 Supplier Evaluation*. Additional criteria for the selection of "new" external providers will include a 3 order probationary evaluation, and the presence of a third party certification to a quality management standard, or adherence to a documented quality management system, or at a minimum be subject to a quarterly performance review if no formal quality management system exists.

The organization retains documented information of these activities and any necessary actions arising from the evaluations in the E2 Shop System: See the procedure, *QMSP-1004 Supplier Evaluation* and *QMSP-1010 Control of External products and services*, for details of where the documented information in the E2 Shop System is recorded.

8.4.2 Type and extent of control

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

- Ensures that externally provided processes remain within the control of it quality management system: See the procedure, *QMSP-1010 Control of External products and services*.
- Defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output: See the procedure, *QMSP-1010 Control of External products and services*.
- Takes into consideration the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and

applicable statutory and regulatory requirements: See the procedure, *QMSP-1010 Control of External products and services* and *QMSP-1004 Supplier Evaluation*.

- Takes into consideration the effectiveness of the controls applied by the external provider: See the procedure, *QMSP-1010 Control of External products and services*.
- Determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements: See the procedure, *QMSP-1010 Control of External products and services*.

8.4.3 Information for external providers

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

The organization communicates to external providers its requirements for:

- The processes, products and services to be provided: This information is documented in the Purchase Order that is provided to the external provider. See the procedure, *QMSP-1010 Control of External products and services*.
- The approval of products and services, methods, processes and equipment, and the release of products and services: This information is documented in the Purchase Order that is provided to the external provider. See the procedure, *QMSP-1010 Control of External products and services*.
- Competence, including any required qualification of persons: This information is documented in the Purchase Order that is provided to the external provider. See the procedure, *QMSP-1010 Control of External products and services*.
- The external provider's interactions with the organization: See the procedure, *QMSP-1010 Control of External products and services*.
- Control and monitoring of the external provider's performance to be applied by the organization: Refer to *QMSP-1004 Supplier Evaluation* and the procedure, *QMSP-1010 Control of External products and services*.
- Verification or validation activities that the organization, or its customer, intends to perform at the external provider's premises: This information is documented in the Purchase Order that is provided to the external provider. See the procedure, *QMSP-1010 Control of External products and services*.

8.5. Production and service provision

8.5.1 Control of production and service provision

The organization has implemented production and service provision under controlled conditions.

Controlled conditions include, as applicable:

- The availability of documented information that defines the characteristics of the products to be produced, the services to be provided, or the activities to be performed: This information is contained in the E2 Job Traveler.
- The availability of documented information that defines the results to be achieved: This information is contained in the E2 Job Traveler (within the routing steps) and in the E2 Order.
- The availability and use of suitable monitoring and measuring resources: See *QMSF-1014 Contract Review* and *QMSM-1007 Calibration*.
- 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: This information can be found in the results of inspections retained at the company using *QMSF-1021First Article Inspection Report*, *QMSF-1012 In-Process Inspection Report*, and *QMSF-1022 Final Inspection Report*.
- The use of suitable infrastructure and environment for the operation of processes: The infrastructure and environment at the company is adequate for the products and services that the company provides. The Work Center Maintenance module in the E2 Shop System, or similar spreadsheet or hardcopy methods are used to document the suitability of the process environment, where applicable.
- The appointment of competent persons, including any required qualifications: Competencies and qualifications are found in job descriptions (*QMSF-1010 Job Description*), documented training information (E2 Shop System / Quality / Employee Training), and personnel files at the company.
- The validation, and periodic revalidation, of the ability to achieve planned results of the process for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement: This is only applicable if the company has any "special processes", see section 3.12, Note 4 for clarification. If the company has any special processes, they are validated using (*QMSF-1020 Vendor Process Validation*) form, or by obtaining a copy of the vendor's Quality Standard Third-Party Certification. The documented information regarding the validation and its results is retained.
- The implementation of actions to prevent human error: This is accomplished using *QMSD-1008 Error Proofing*.
- The implementation of release, delivery and post-delivery activities: Product release and delivery is implemented through inspection at the company. There are no planned post-delivery activities at the company.

8.5.2 Identification and traceability

The organization uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services: All products at the company are identified by a part number and are stored in the E2 Shop System database. Work in progress is identified by the Job Traveler throughout production. Finished goods are packaged and labeled with a part number, quantity, and job number for identification and traceability purposes.

The organization identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision: All production processes at the company include inspections. The only product that proceeds to the subsequent process is conforming product. The only product that is provided to customers is product that has been inspected throughout the manufacturing process.

The organization controls the unique identification of the outputs when traceability is a requirement and retains the documented information necessary to ensure traceability: This is accomplished through the use of the E2 Shop System which contains a parts library, and every product has a unique number assigned to it by the system. In addition, within the Inventory Items area of the E2 Shop System, the part and/or raw material is assigned a bin location and can be assigned a heat/lot number. This effectively provides batch/lot level traceability within the E2 Shop System. The documented information necessary to maintain traceability is stored in the E2 Shop System. Batch/lot level traceability documented information is retrieved using the Inventory Summary and the Inventory Usage Summary.

8.5.3 Property belonging to customers or external providers

The organization exercises care with property belonging to the customer or external providers while it is under the organization's control or being used by the organization. The organization identifies, verifies, protects and safeguards the customer’s or external provider’s property provided for use or incorporation into the products and services: This is accomplished by placing an identification tag on the property and writing “Customer Property” on the tag. All parts at the company including those belonging to external providers are verified, and documented information is retained in the E2 Shop System Inventory and/or Order Entry module(s). All parts and property belonging to external providers are properly stored, handled, and safeguarded.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization reports this to the customer or external provider and retains documented information on what has occurred: This is accomplished using email and stating

what happened to the customer or external provider property and suggesting or requesting steps to resolve the situation. The email is retained as documented information.

8.5.4 Preservation

The organization preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements: All product and property is properly identified, handled, packaged, shipped and stored with care throughout the entire production or service process.

8.5.5 Post-delivery activities

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

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

- Statutory and regulatory requirements: See the procedure, *QMSP-1003 Requirements Review* and *QMSF-1014 Contract Review*.
- The potential undesired consequences associated with its products and services: See the procedure, *QMSP-1008 Risk Management*.
- The nature, use and intended lifetime of its products and services: *All products are manufactured per "customer" specifications and requirements*.
- Customer requirements: See the procedure, *QMSP-1003 Requirements Review* and *QMSF-1014 Contract Review*.
- Customer feedback: Customer feedback is stored in the E2 System, Quality Module, under the "Feedback" feature. Feedback information is directly solicited from customers using *QMSF-1002 Customer Survey*.

8.5.6 Control of changes

The organization reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements: Changes essential to production and service provision are included in Job Travelers generated by the E2 Shop System.

The organization 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:

- If a change is instigated by a customer, *QMSF-1014 Contract Review* and E2 Job Notes are used to document the change.

- If a need for a change is identified during Management Review, the E2 Shop System / Quality / Corrective Action module is used (See *QMSP-1006 Corrective Actions*), and *QMSF-1013 Management Review* is updated to include a reference to the change.

8.6. Release of products and services

The organization implements planned arrangements at appropriate stages, to verify that the product and service requirements have been met: See *QMSF-1021 First Article Inspection Report*, *QMSF-1012 In-Process Inspection Report*, and *QMSF-1022 Final Inspection Report*.

The release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer: See *QMSF-1022 Final Inspection Report*.

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

- Evidence of conformity with the acceptance criteria: Evidence of conformity with the acceptance criteria is retained using the completed forms, *QMSF-1021 First Article Inspection Report*, *QMSF-1012 In-Process Inspection Report*.
- Traceability to the person(s) authorizing the release: The quality manager or designee is responsible for authorizing the release of products using the completed form, *QMSF-1022 Final Inspection Report*.

8.7. Control of nonconforming outputs

8.7.1 Control of nonconforming outputs cont.

The organization ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. See the procedure, *QMSP-1005 Control of Nonconforming Product*.

The organization takes appropriate corrective 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. See the procedure, *QMSP-1005 Control of Nonconforming Product*.

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

- Correction: See the procedure, *QMSP-1005 Control of Nonconforming Product*.

- Segregation, containment, return or suspension of provision of products and services: See the procedure, *QMSP-1005 Control of Nonconforming Product*.
- Informing the customer: See the procedure, *QMSP-1005 Control of Nonconforming Product*.
- Obtaining authorization for acceptance under concession: See the procedure, *QMSP-1005 Control of Nonconforming Product*.

Conformity to the requirements shall be verified when nonconforming outputs are corrected: See the procedure, *QMSP-1005 Control of Nonconforming Product*.

8.7.2 Control of nonconforming outputs cont.

The organization retains documented information that:

- Describes the nonconformity: Documented information is retained in the E2 Shop System Nonconformance Module per *QMSP-1005 Control of Nonconforming Product*.
- Describes the actions taken: Documented information is retained in the E2 Shop System Nonconformance Module per *QMSP-1005 Control of Nonconforming Product*.
- Describes any concessions obtained: Documented information is retained in the E2 Shop System Nonconformance Module per *QMSP-1005 Control of Nonconforming Product*.
- Identifies the authority deciding the action in respect of the nonconformity: Documented information is retained in the E2 Shop System Nonconformance Module per *QMSP-1005 Control of Nonconforming Product*.

9. Performance evaluation

9.1. Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization determines:

- What needs to be monitored and measured: All products and services are monitored and measured. All processes of the quality management system are monitored and measured.
- The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results: Products and services are monitored and measured through the use of *QMSF-1021 First Article Inspection Report*, *QMSF-1012 In-Process Inspection Report*, *QMSF-1022 Final Inspection Report*, the E2 Nonconformance Module, and *QMSF-1013 Management Review*. Processes of the quality management system are monitored and

measured through the use of *QMSF-1016 Process Data Sheet*, *QMSF-1015 PFMEA*, and *QMSF-1013 Management Review*.

- When the monitoring and measuring is performed: All of the process maps for production processes contain inspection steps. This indicates that all parts in production are inspected for those processes. Additional inspections may also be scheduled utilizing inspection steps on Job Travelers.
- When product is found to be nonconforming, *QMSP-1005 Control of Nonconforming Product*, and the E2 Shop System Nonconformance module are used.
- When the results from monitoring and measurement are analyzed and evaluated: Results of inspections are reviewed at the conclusion of an inspection to determine if a nonconformance report needs to be entered into the E2 Shop System. Trends in product quality, nonconformance data, and process performance are evaluated using *QMSF-1029 Process Analysis and Evaluation*. Discussions regarding process performance are documented at management review meetings using *QMSF-1013 Management Review*.

The organization evaluates the performance and the effectiveness of the quality management system: This is accomplished by conducting annual internal audits where the quality management system is evaluated for effectiveness, and it is determined that the quality management system is established, implemented, maintained, and continually improved. See the procedure, *QMSP-1007 Internal Audit*.

The organization retains appropriate documented information as evidence of the results: This is accomplished using *QMSF-1021 First Article Inspection Report*, *QMSF-1012 In-Process Inspection Report*, *QMSF-1013 Management Review*, and *QMSD-1004 Internal Audit Report*.

9.1.2 Customer satisfaction

The organization monitors customers perceptions of the degree to which their needs and expectations have been fulfilled: This is accomplished through the use of *QMSF-1002 Customer Survey* and the E2 Shop System / Quality / Feedback module.

The organization determines the methods for obtaining, monitoring and reviewing this information: The results of customer surveys (*QMSF-1002 Customer Survey*) and data entered into the E2 Shop System Feedback module are discussed at management review meetings, under the topic “Customer Feedback”. See the form *QMSF-1013 Management Review*.

9.1.3 Analysis and evaluation

The organization analyzes and evaluates appropriate data and information arising from monitoring and measurement: This activity generally takes place at the management review meeting. See the completed forms, *QMSF-1013 Management Review*.

The results of analysis are used to evaluate:

- Conformity of products and services: The analysis, verification, disposition and monitoring of nonconformance data, using the E2 Nonconformance Summary, at management review is the method for improving conformity of products and services to requirements. See the completed forms, *QMSF-1013 Management Review*.
- The degree of customer satisfaction: The analysis, verification, disposition of Feedback reports, using the E2 Feedback Summary, and results of customer surveys at management review is the method for improving customer satisfaction at the company. See the completed forms, *QMSF-1013 Management Review*.
- The performance and effectiveness of the quality management system: The analysis of results of audits at management review, *QMSD-1004 Internal Audit Report*, is the method for ensuring the conformity and effectiveness of the quality management system at the company. See the completed forms, *QMSF-1013 Management Review*.
- If planning has been implemented effectively: The analysis of data regarding the review and control of unplanned changes essential for production or service provision is the method for ensuring better planning going forward and lessons learned. See the completed forms, *QMSF-1013 Management Review*.
- The effectiveness of actions taken to address risks and opportunities: The company utilizes *QMSF-1015 PFMEA* to manage risks and opportunities and uses *QMSF-1013 Management Review* to review the effectiveness of actions taken.
- The performance of external provider(s): The company has implemented a procedure for evaluating supplier performance whereby ratings and evaluation dates are input into the E2 Shop System Vendor Table and a Hot Spot report is created to provide a list of approved suppliers. In conjunction with the procedure, supplier performance is evaluated during management review, and supplier ratings are periodically updated. See *QMSP-1004 Supplier Evaluation* and *QMSF-1013 Management Review*.
- The need for improvements to the quality management system: The company discusses the topic at every management review meeting under the topic "New actions to incorporate opportunities for improvement". See the completed forms, *QMSF-1013 Management Review*.

The results of analysis and evaluation are also used to provide inputs to management review.

9.2. Internal audit

9.2.1 Internal audit cont.

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

- Conforms to:
  - The organization's own requirements for its quality management system: See *QMSP-1007 Internal Audit* and *QMSD-1003 Internal Audit Plan*.
  - The requirements of this International Standard: See *QMSP-1007 Internal Audit* and *QMSD-1003 Internal Audit Plan*.
- Is effectively implemented and maintained. See *QMSP-1007 Internal Audit* and *QMSD-1003 Internal Audit Plan*.

9.2.2 Internal audit cont.

The organization:

- 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 the organization, and the results of previous audits: See *QMSP-1007 Internal Audit* and *QMSD-1003 Internal Audit Plan*.
- Define the audit criteria and scope for each audit: See *QMSD-1003 Internal Audit Plan*.
- Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process: See *QMSP-1007 Internal Audit* and *QMSD-1003 Internal Audit Plan*.
- Ensure that the results of the audits are reported to relevant management: See *QMSP-1007 Internal Audit*, *QMSD-1003 Internal Audit Plan*, and *QMSF-1013 Management Review*.
- Take appropriate correction and corrective actions without undue delay: See *QMSP-1007 Internal Audit*, *QMSD-1003 Internal Audit Plan*, *QMSF-1013 Management Review*, and *QMSP-1006 Corrective Action*.
- Retain documented information as evidence of the implementation of the audit program and the audit results: See the document *QMSP-1007 Internal Audit* and *QMSD-1004 Internal Audit Report*.

9.3. Management review

9.3.1 General

Top management reviews the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization: Management review meetings are held triannually at the company.

9.3.2 Management review inputs

The management review is planned and carried out taking into consideration:

- The status of actions from previous management reviews: See the form, *QMSF-1013 Management Review*.
- Changes in external and internal issues that are relevant to the quality management system: See the form, *QMSF-1013 Management Review*.
- Information on the performance and effectiveness of the quality management system, including trends in:
    - Customer satisfaction and feedback from relevant interested parties: See the form, *QMSF-1013 Management Review* and utilize *QMSF-1002 Customer Survey* and the E2 Feedback Summary.
    - The extent to which quality objectives have been met: See the form, *QMSF-1013 Management Review*
    - Process performance and conformity of products and services: See the form, *QMSF-1013 Management Review* and utilize *QMSF-1012 In-Process Inspection Form*, the E2 Nonconformance Summary, and *QMSF-1016 Process Data Sheet*.
    - Nonconformities and corrective actions: See the form, *QMSF-1013 Management Review* and utilize the E2 Nonconformance Summary and the E2 Corrective Action Summary.
    - Monitoring and measurement results: See the form, *QMSF-1013 Management Review* and utilize *QMSF-1012 In-Process Inspection Report* and the E2 Nonconformance Summary.
    - Audit results: See the form, *QMSF-1013 Management Review* and utilize *QMSD-1004 Internal Audit Report*.
    - The performance of external providers: See the form, *QMSF-1013 Management Review* and utilize *QMSP-1004 Supplier Evaluation*.
- Adequacy of resources required for maintaining an effective quality management system: See the form, *QMSF-1013 Management Review*.
- The effectiveness of actions taken to address risks and opportunities (see 6.1): See the form, *QMSF-1013 Management Review* and utilize *QMSF-1015 PFMEA*.

- Opportunities for improvement: See the form, *QMSF-1013 Management Review*.

9.3.3 Management review outputs

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

- Opportunities for improvement: The method to record these outputs is to write corrective action reports in the E2 Shop System / Quality Module / Corrective Action Module.
- Any need for changes to the quality management system: The method to record these outputs is to write corrective action reports in the E2 Shop System / Quality Module / Corrective Action Module.
- Resource needs: The method to record these outputs is to write corrective action reports in the E2 Shop System / Quality Module / Corrective Action Module.

The organization retains documented information as evidence of the results of management reviews: All completed forms, *QMSF-1013 Management Review*, from all management review meetings in the company are retained as documented information in addition to the associated corrective action reports in the E2 Shop System.

10. Improvement

10.1. General

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

This includes:

- Improving products and services to meet requirements as well as to address future needs and expectations: The sources of these types of improvements are found in the E2 Feedback module, results of customer surveys, and in E2 Nonconformance module.
- Correcting, preventing or reducing undesired effects: See the form, *QMSF-1016 Process Data Sheet*, i.e., the section labeled, “Corrective actions required”.
- Improving the performance and effectiveness of the quality management system: The source of these types of improvements is found in the results of management review meetings, i.e., *QMSF-1013 Management Review*, the section labeled, “New actions to incorporate potential opportunities for continual improvement”.

10.2. Nonconformity and corrective action

10.2.1 Nonconformity and corrective action cont.

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

- Reacts to the nonconformity, and as applicable:
  - Takes action to control and correct it: See the procedure, *QMSP-1005 Control of Nonconforming Product*.
  - Deals with the consequences: See the procedure, *QMSP-1005 Control of Nonconforming Product*.
- Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere by:
  - Reviewing and analyzing the nonconformity: See the procedure, *QMSP-1006 Corrective Actions* and utilize the E2 Corrective Action module.
  - Determining the causes of the nonconformity: See the procedure, *QMSP-1006 Corrective Actions* and utilize the E2 Corrective Action module.
  - Determining if similar nonconformities exist, or could potentially occur: See the procedure, *QMSP-1006 Corrective Actions* and utilize the E2 Corrective Action module.
- Implement any action needed: See the procedure, *QMSP-1006 Corrective Actions* and utilize the E2 Corrective Action module.
- Review the effectiveness of any corrective action taken: See the procedure, *QMSP-1006 Corrective Actions* and utilize the E2 Corrective Action module.
- Update risks and opportunities determined during planning, if necessary: See *QMSF-1015 PFMEA*.
- Make changes to the quality management system, if necessary: See the procedure, *QMSP-1006 Corrective Actions*, *QMSF-1013 Management Review*, and utilize the E2 Corrective Action module.

Corrective actions are appropriate to the effects of the nonconformities encountered: This is accomplished in conjunction with *QMSP-1006 Corrective Actions* which states that Corrective Actions Codes will be utilized in the E2 Shop System as follows: Critical (24 hours), High (3 days), Medium (14 days), and Low (30 days). All corrective actions are reviewed at management review meetings. See the form, *QMSF-1013 Management Review*.

10.2.2 Nonconformity and corrective action cont.

The organization retains documented information as evidence of:

- The nature of the nonconformities and any subsequent actions taken: See the procedure, *QMSP-1005 Control of Nonconforming Product* and utilize the E2 Shop System Nonconformance module.
- The results of any corrective action: See the procedure, *QMSP-1006 Corrective Actions* and utilize the E2 Corrective Action module.

10.3. Continual improvement

The organization continually improves the suitability, adequacy, and effectiveness of the quality management system: It is the overall responsibility of top management to continually improve the effectiveness of the quality management system as described throughout this manual. Each Foreman/Supervisor is responsible for the continual improvement of the quality management system in his or her respective area. Effectiveness of continual-improvement activity is assessed during the Management Review Process.

Continual improvement of the quality management system at Micro-Technic Tool & Stamping is facilitated through the use of:

- Quality policy
- Quality objectives
- Audit results
- Analysis and evaluation
- Corrective action
- Management review

The organization considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities to be addressed as part of continual improvement: See the form, *QMSF-1013 Management Review*, the section labeled, "New actions to incorporate potential opportunities for continual improvement".

11. Appendix A

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

3.01
organization
person or group of people that has its own *functions* (3.25) with responsibilities, authorities and relationships to achieve its *objectives* (3.08)

Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

3.02
interested party
person or *organization* (3.01) that can affect, be affected by, or perceive themselves to be affected by a decision or activity

EXAMPLE *Customers* (3.26), owners, people in an *organization* (3.01), *suppliers* (3.27), bankers, unions, partners or society that may include competitors or opposing pressure groups.

3.03
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the *organization* (3.01) and *interested parties* (3.02) that the need or expectation under consideration is implied.
Note 2 to entry: A specified requirement is one that is stated, for example in *documented information* (3.11).
Note 3 to entry: A qualifier can be used to denote a specific type of requirement e.g. *product* (3.47) requirement, *quality management* (3.30) requirement, *customer* (3.26) requirement, quality requirement.
Note 4 to entry: Requirements can be generated by different *interested parties* (3.02).
Note 5 to entry: It can be necessary for achieving high *customer satisfaction* (3.57) to fulfill an expectation of a *customer* (3.26) even if it is neither stated nor generally implied or obligatory.

3.04
management system
set of interrelated or interacting elements of an *organization* (3.01) to establish *policies* (3.07) and *objectives* (3.08) and *processes* (3.12) to achieve those *objectives*

Note 1 to entry: A management system can address a single discipline or several disciplines e.g. *quality management* (3.30), financial *management* (3.29) or environmental *management*.
Note 2 to entry: The management system elements establish the *organization's* (3.01) structure, roles and responsibilities, planning, operation, *policies* (3.07), practices, rules, beliefs, *objectives* (3.08) and *processes* (3.12) to achieve those *objectives*.
Note 3 to entry: The scope of a management system may include the whole of the *organization* (3.01), specific and identified *functions* (3.25) of the *organization*, specific and identified sections of the *organization*, or one or more *functions* across a group of *organizations*.

3.05
top management
person or group of people who directs and controls an *organization* (3.01) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the *organization* (3.01).
Note 2 to entry: If the scope of the *management system* (3.04) covers only part of an *organization* (3.01), then *top management* refers to those who direct and control that part of the *organization*.

3.06
effectiveness
extent to which planned activities are realized and planned results achieved

3.07
policy
intentions and direction of an *organization* (3.01), as formally expressed by its *top management* (3.05)

3.08
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, *product* (3.47), *service* (3.48), and *process* (3.12)).
Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a *quality* (3.37) objective, or by the use of other words with similar meaning (e.g. aim, goal, or target).
Note 4 to entry: In the context of *quality management systems* (3.33), quality objectives are set by the *organization* (3.01), consistent with the *quality policy* (3.34), to achieve specific results.

3.09
risk
effect of uncertainty on an expected result

Note 1 to entry: An effect is a deviation from the expected — positive or negative
Note 2 to entry: Uncertainty is the state, even partial, of deficiency of *information* (3.50) related to, understanding or *knowledge* (3.53) of, an event, its consequence, or likelihood.
Note 3 to entry: Risk is often characterized by reference to potential "events" (as defined in ISO Guide 73:209, 3.5.1.3) and "consequences" (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.
Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.
Note 5 to entry: The term "risk" is sometimes used when there is only the possibility of negative consequences.

3.10
competence
ability to apply *knowledge* (3.53) and skills to achieve intended results

Note 1 to entry: Demonstrated competence is sometimes referred to as qualification.
3.11
documented information
information (3.50) required to be controlled and maintained by an *organization* (3.01) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.
Note 2 to entry: Documented information can refer to:
- the *quality management system* (3.33), including related *processes* (3.12);
- *information* (3.50) created in order for the *organization* (3.01) to operate (documentation);

- evidence of results achieved (records).

3.12
process
set of interrelated or interacting activities which transforms inputs into *outputs* (3.46)

Note 1 to entry: Inputs to a process are generally outputs (3.46) of other processes.
Note 2 to entry: In some processes, some inputs become *outputs* (3.46) without any transformation e.g. a blueprint used in a manufacturing process or a catalyst in a chemical process.
Note 3 to entry: Processes in an *organization* (3.01) are generally planned and carried out under controlled conditions to add value.
Note 4 to entry: A process where the *conformity* (3.18) of the resulting *output* (3.46) cannot be readily or economically validated is frequently referred to as a "special process".

3.13
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.
Note 2 to entry: Performance can relate to the *management* (3.29) of activities, *processes* (3.12), *products* (3.47), *services* (3.48), *systems* (3.31) or *organizations* (3.01).

3.14
outsource (verb)
make an arrangement where an external *organization* (3.01) performs part of an organization's *function* (3.25) or *process* (3.12)
Note 1 to entry: An external *organization* (3.01) is outside the scope of the *management system* (3.04), although the outsourced *function* (3.25), or *process* (3.12), is within the scope.

3.15
monitoring
determining (3.67) the status of a *system* (3.31), a *process* (3.12) or an activity

Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.
Note 2 to entry: Monitoring is generally a *determination* (3.67) of the *object* (3.36) being monitored, carried out at different stages or at different times.

3.16
measurement
process (3.12) to *determine* (3.67) a value

Note 1 to entry: According to ISO 3534-2:2006 the value determined is generally the value of a quantity.

3.17
audit
systematic and independent *process* (3.12) for obtaining *objective evidence* (3.61) and evaluating it objectively to determine the extent to which the *audit criteria* (3.60) are fulfilled

Note 1 to entry: An audit can be an internal audit (first party), or an external audit (second party or third party), and it can be a combined audit or a joint audit.
Note 2 to entry: Internal audits, sometimes called first-party audits are conducted by, or on behalf of, the *organization* (3.01) itself for *management* (3.29) *review* (3.68) and other internal purposes, and may form the basis for an organization's declaration of *conformity* (3.18). In many cases, particularly in smaller *organizations*, independence can be demonstrated by the freedom from responsibility for the activity being audited.
Note 3 to entry: External audits include those generally called second and third-party audits. Second party audits are conducted by parties having an interest in the *organization* (3.01), such as *customers* (3.26), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations such as those providing certification/registration of *conformity* (3.18) to ISO 9001 or ISO 14001.

3.18
conformity
fulfillment of a *requirement* (3.03)

Note 1 to term: In English the word 'conformance' is synonymous but deprecated. In French the word 'compliance' is synonymous but deprecated.

3.19
nonconformity
non-fulfillment of a *requirement* (3.03)

3.20
corrective action
action to eliminate the cause of a *nonconformity* (3.19) and to prevent recurrence

Note 1 to definition: There can be more than one cause for a *nonconformity* (3.19).
Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

3.21
continual improvement
recurring activity to enhance *performance* (3.13)

Note 1 to entry: The *process* (3.12) of establishing *objectives* (3.08) and finding opportunities for *improvement* (3.28) is a continual *process* through the use of *audit findings* (3.62) and audit conclusions, analysis of *data* (3.49), *management* (3.29) *reviews* (3.68) or other means and generally leads to *corrective action* (3.21) or preventive action.

3.22
correction
action to eliminate a detected *nonconformity* (3.19)

Note 1 to entry: A correction can be made in conjunction with a *corrective action* (3.21).
Note 2 to entry: A correction can be, for example, rework or regrade.

3.23
involvement
engagement in, and contribution to, shared *objectives* (3.08)

3.24
context of the organization
business environment combination of internal and external factors and conditions that can have an effect on an *organization's* (3.01) approach to its *products* (3.47), *services* (3.48) and investments and *interested parties* (3.02)

Note 1 to entry: The concept of context of the organization is equally applicable to not-for-profit or public *service* (3.48) *organizations* (3.01) as it is to those seeking profits.
Note 2 to entry: In English this concept is often referred to by other phrases such as business environment, organizational environment or ecosystem of an *organization* (3.01).

3.25
function
role to be carried out by a designated unit of the *organization* (3.01)

3.26
customer
person or *organization* (3.01) that could or does not receive a *product* (3.47) or a *service* (3.48) is intended for or required by this person or *organization*

EXAMPLES Consumer, client, end-user, retailer, input to internal *process* (3.12), beneficiary and purchaser.
Note to entry: A customer can be internal or external to the *organization* (3.01). Customers outside of the *organization* are external customers. The *output* (3.46) of each internal *process* (3.12) is the input of the next *process*. The next *process* is the internal customer of the preceding *process*.

3.27
supplier
provider
person or *organization* (3.01) that provides a *product* (3.47) or a *service* (3.48)

EXAMPLE Producer, distributor, retailer or vendor of a *product* (3.47) or a *service* (3.48) or *information* (350).
Note 1 to entry: A provider can be internal or external to the *organization* (3.01).
Note 2 to entry: In a contractual situation, a supplier is sometimes called a "contractor".

3.28
improvement
activity to enhance *performance* (3.13)

Note to entry: Improvement can be achieved by a recurring or by a singular activity.

3.29
management
coordinated activities to direct and control an *organization* (3.01)

Note 1 to entry: Management can include establishing *policies* (3.07) and *objectives* (3.08) and *processes* (3.12) to achieve these *objectives*.
Note 2 to entry: The term "management" sometimes refers to people, i.e. a person or group of people with authority and responsibility for the conduct and control of an *organization* (3.01). When "management" is used in this sense, it should always be used with some form of qualifier to avoid confusion with the concept of "management" as a set of activities defined above. For

example, "management shall…" is deprecated whereas "*top management* (3.05) shall…" is acceptable. Otherwise different words should be adopted to convey the concept when related to people e.g. managerial or managers.

3.30
quality management
management (3.29) with regard to *quality* (3.37)

Note to entry: Quality management generally includes establishment of the *quality policy* (3.34) and *quality objectives* (3.45), quality planning, quality control, quality assurance and quality improvement.

3.31
system
set of interrelated or interacting elements

3.32
infrastructure
system (3.31) of facilities, equipment and *services* (3.48) needed for the operation of an *organization* (3.01)

3.33
quality management system
management system (3.04) with regard to *quality* (3.5.2)

3.34
quality policy
policy (3.07) related to *quality* (3.37)

Note 1 to entry: Generally the quality policy is consistent with the overall *policy* (3.07) of the *organization* (3.01), can be aligned with the *organization's* vision and mission and provides a framework for the setting of *quality objectives* (3.45).
Note 2 to entry: *Quality management* (3.30) principles presented in this International Standard can form a basis for the establishment of a *quality policy* (3.34)

3.35

strategy
planned activities to achieve an *objective* (3.08).

3.36
object
entity anything perceivable or conceivable

EXAMPLES *Product* (3.47), *service* (3.48), *process* (3.12), person, *organization* (3.01), *system* (3.31), resource.
Note 1 to entry: Objects may be material (e.g. an engine, a sheet of paper, a diamond), immaterial (e.g. conversion ratio, a project plan) or imagined (e.g. a unicorn).

3.37
quality
degree to which a set of inherent *characteristics* (3.65) of an *object* (3.36) fulfills *requirements* (3.03)

Note 1 to entry: The term "quality" can be used with adjectives such as poor, good or excellent.
Note 2 to entry: "Inherent", as opposed to "assigned", means existing in the *object* (3.36).

3.38
statutory requirement
obligatory *requirement* (3.03) specified by a legislative body

3.39
regulatory requirement
obligatory *requirement* (3.03) specified by an authority mandated by a legislative body

3.40
defect
nonconformity (3.19) related to an intended or specified use

Note 1 to entry: The distinction between the concepts defect and *nonconformity* (3.19) is important as it has legal connotations; particularly those associated with *product* (3.47) *and service* (3.48) liability issues.
Note 2 to entry: The intended use as intended by the *customer* (3.26) can be affected by the nature of the *information* (3.50), such as operating or maintenance instructions, provided by the *supplier* (3.27).

3.41
traceability
ability to trace the history, application or location of an *object* (3.36)

Note 1 to entry: When considering *a product (3.47) or a service* (3.48), traceability can relate to:
- the origin of materials and parts;
- the processing history; and
- the distribution and location of the *product* (3.47) *or service* (3.48) after delivery.
Note 2 to entry: In the field of metrology the definition in ISO/IEC GUIDE 99: 2007, is the accepted definition.

3.42
innovation
process (3.12) resulting in a new or substantially changed *object* (3.36)

Note 1 to entry: The *object* (3.36) for the purpose of innovation can be e.g. a *management system* (3.04), a *process* (3.12), a *product* (3.47), *a service* (3.48) or technology.

3.43
contract
binding agreement

3.44
design and development
set of processes (3.12) that transforms *requirements* (3.03) for an *object* (3.36) into more detailed *requirements*

Note 1 to entry: The *requirements* (3.03) forming input to design and development can be expressed in a broader, more general sense than the requirements forming the *output* (3.46) of design and development. In a project there can be several design and development stages.
Note 2 to entry: In English the words “design” and “development” and the term “design and development” are sometimes used synonymously and sometimes used to define different stages of the overall design and development. In French the words “conception” and “development” and the term “conception et development” are sometimes used synonymously and sometimes used to define different stages of the overall design and development.
Note 3 to entry: A qualifier can be applied to indicate the nature of what is being designed and developed, e.g. *product* (3.47) design and development, or *process* (3.12) design and development.

3.45
quality objective
objective (3.08) related to *quality* (3.37)

Note 1 to entry: Quality objectives are generally based on the *organization*'s (3.01) *quality policy* (3.34).
Note 2 to entry: Quality objectives are generally specified for relevant *functions* (3.25) and levels in the *organization* (3.01).

3.46
output
result of a *process* (312)

Note 1 to entry "output": There are four generic output categories, as follows:
- services (e.g. transport);
- software (e.g. computer program, dictionary);
- hardware (e.g. engine mechanical part);
- processed materials (e.g. lubricant).

Many outputs comprise elements belonging to different generic output categories. Whether the output is then called service, product, software, hardware or processed material depends on the dominant element. For example, a car consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).
Note 2 to entry "output": The ownership of a product can usually be transferred. This is not necessarily the case for a service.

3.47
product
output (3.46) that is a result of activities where none of them necessarily is performed at the interface between the *provider* (3.27) and the *customer* (3.26)

Note 1 to entry "product": Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods. Software consists of information and is generally intangible and can be in the form of approaches, transactions or *documented information* (3.11).

3.48
service
intangible *output* (3.46) that is the result of at least one activity necessarily performed at the interface between the provider and the customer

Note 1 to entry "service": Provision of a service can involve, for example, the following:
- an activity performed on a customer-supplied tangible product (e.g. a car to be repaired);
- an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);
- the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);
- the creation of ambience for the customer (e.g. in hotels and restaurants);

A service is usually experienced by the customer.

3.49
data
facts about an *object* (3.36)

3.50
information
meaningful *data* (3.49)

3.51
objective evidence
data (3.49) supporting the existence or verity of something

Note 1 to entry: Objective evidence may be obtained through observation, *measurement* (3.16), test, or other means.
Note 2 to entry: Objective evidence for the purpose of *audit* (3.17) generally consists of records, statements of fact or other *information* (3.50) which are relevant to the *audit criteria* (3.60) and verifiable

3.52
information system
<QMS> network of communication channels used within an *organization* (3.01)

3.53
knowledge

available collection of *information* (3.50) being a justified belief and having a high certainty to be true

3.54
verification
confirmation, through the provision of *objective evidence* (3.51), that specified *requirements* (3.03) have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of *determination* (3.67) such as performing alternative calculations or reviewing *documented information* (3.11).
Note 2 to entry: The activities carried out for verification are sometimes called a qualification *process* (3.12)
Note 3 to entry: The word "verified" is used to designate the corresponding status.

3.55
validation
confirmation, through the provision of objective evidence, that the *requirements* (3.03) for a specific intended use or application have been fulfilled

Note 1 to entry: The *objective evidence* (3.51) needed for a validation is the result of a test or other form of *determination* (3.67) such as performing alternative calculations or reviewing *documented information* (3.11).
Note 2 to entry: The word "validated" is used to designate the corresponding status.
Note 3 to entry: The use conditions for validation can be real or simulated.

3.56
feedback
opinions, comments and expressions of interest in a product, a service or a complaints-handling process

3.57
customer satisfaction
customer's (3.26) perception of the degree to which the customer's expectations have been fulfilled

Note 1 to entry: It can be that the *customer's* (3.26) expectation is not known to the *organization* (3.01) or even to himself/herself until the *product* (3.47) or *service* (3.48) is delivered. It can be necessary for achieving high customer satisfaction to fulfill an expectation of a *customer* even if it is neither stated nor generally implied or obligatory.
Note 2 to entry: *Complaints* (3.58) are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.
Note 3 to entry: Even when *customer* (3.26) *requirements* (3.03) have been agreed with the *customer* and fulfilled, this does not necessarily ensure high customer satisfaction.
Note 4 to entry: See ISO 10004, *Quality Management — Customer satisfaction — Guidelines for monitoring and measuring*.

3.58
complaint
<customer satisfaction> expression of dissatisfaction made to an *organization* (3.01), related to its *product* (3.47) or *service* (3.48), or the complaints-handling *process* (3.12) itself, where a response or resolution is explicitly or implicitly expected

3.59
audit program
set of one or more *audits* (3.17) planned for a specific time frame and directed towards a specific purpose

3.60
audit criteria
set of *policies* (3.07), *documented information* (3.11) or *requirements* (3.03) used as a reference against which *audit evidence* (3.61) is compared

3.61
objective / audit evidence
records, statements of fact or other *information* (3.50), which are relevant to the *audit criteria* (3.60) and verifiable

3.62
audit findings
results of the evaluation of the collected *audit evidence* (3.61) against *audit criteria* (3.60)

Note 1 to entry: Audit findings indicate *conformity* (3.18) or *nonconformity* (3.19).
Note 2 to entry: Audit findings can lead to the identification of opportunities for *improvement* (3.28) or recording good practices.

Note 3 to entry: In English, if the *audit criteria* (3.60) are selected from *statutory requirements* (3.38) or *regulatory requirements* (3.39), the audit finding can be called compliance or non-compliance.

3.63
concession
permission to use or *release* (3.64) a *product* (3.47) or *service* (3.48) that does not conform to specified *requirements* (3.03)

Note to entry: A concession is generally limited to the delivery of *products* (3.47) and *services* (3.48) that have *nonconforming* (3.19) *characteristics* (3.65) within specified limits and is generally given for a limited quantity of products and services, for a period of time, and for a specific use.

3.64
release
permission to proceed to the next stage of a *process* (3.12)

Note to entry: In English, in the context of software and *documented information* (3.11), the word "release" is frequently used to refer to a version of the *software* or the *documented information* itself.

3.65
characteristic
distinguishing feature

Note 1 to entry: A characteristic can be inherent or assigned.
Note 2 to entry: A characteristic can be qualitative or quantitative.
Note 3 to entry: There are various classes of characteristic, such as the following:
- physical (e.g. mechanical, electrical, chemical or biological characteristics);
- sensory (e.g. related to smell, touch, taste, sight, hearing);
- behavioral (e.g. courtesy, honesty, veracity);
- temporal (e.g. punctuality, reliability, availability).
- ergonomic (e.g. physiological characteristic, or related to human safety);
- functional (e.g. maximum speed of an aircraft).

3.66
performance indicator
performance metric

characteristic (3.65) having significant impact on realization of the *output* (3.46) and *customer satisfaction* (3.57)

EXAMPLES *Nonconformities* (3.19) per million opportunities, first time capability, *nonconformities* per unit.
Note to entry: The *characteristic* (3.65) can be quantitative or qualitative

3.67
determination
activity to find out one or more *characteristics* (3.65) and their *characteristic* values

3.68
review
determination (3.67) of the suitability, adequacy or e*ffectiveness* (3.06) of an *object* (3.36) to achieve established *objectives* (3.08)

EXAMPLES *Management* (3.29) review, design and development review, review of *customer* (3.26) *requirements* (3.03), *nonconformity* (3.19) review and peer review.
Note to entry: Review can also include the *determination* (3.67) of efficiency.

3.69
measuring equipment
measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a *measurement* (3.16) *process* (3.12)