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1.0 Introduction

Tooling Dynamics LLC. developed and implemented a Quality Management System to demonstrate its ability to provide consistent product that meets customer and applicable regulatory requirements, and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformity. The quality system complies with the international standard ISO 9001 and IATF 16949.

The manual is divided into five sections modeled on the sectional organization of the ISO 9001 and IATF 16949 standards. Sections are further subdivided into several subsections representing main quality system elements or activities. Each subsection starts with a general policy statement expressing the commitment to implement the basic principles of the pertinent quality system element or activity. The general policy statement is followed by more specific procedural policies outlining how the general policy is implemented, and referencing applicable operational procedures.

The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide general procedures for all activities comprising the quality system.

Another purpose of this manual is to present the quality system to our customers and other external interested parties, and to inform them what specific controls are implemented to assure quality.

2.0 Quality Manual Organization

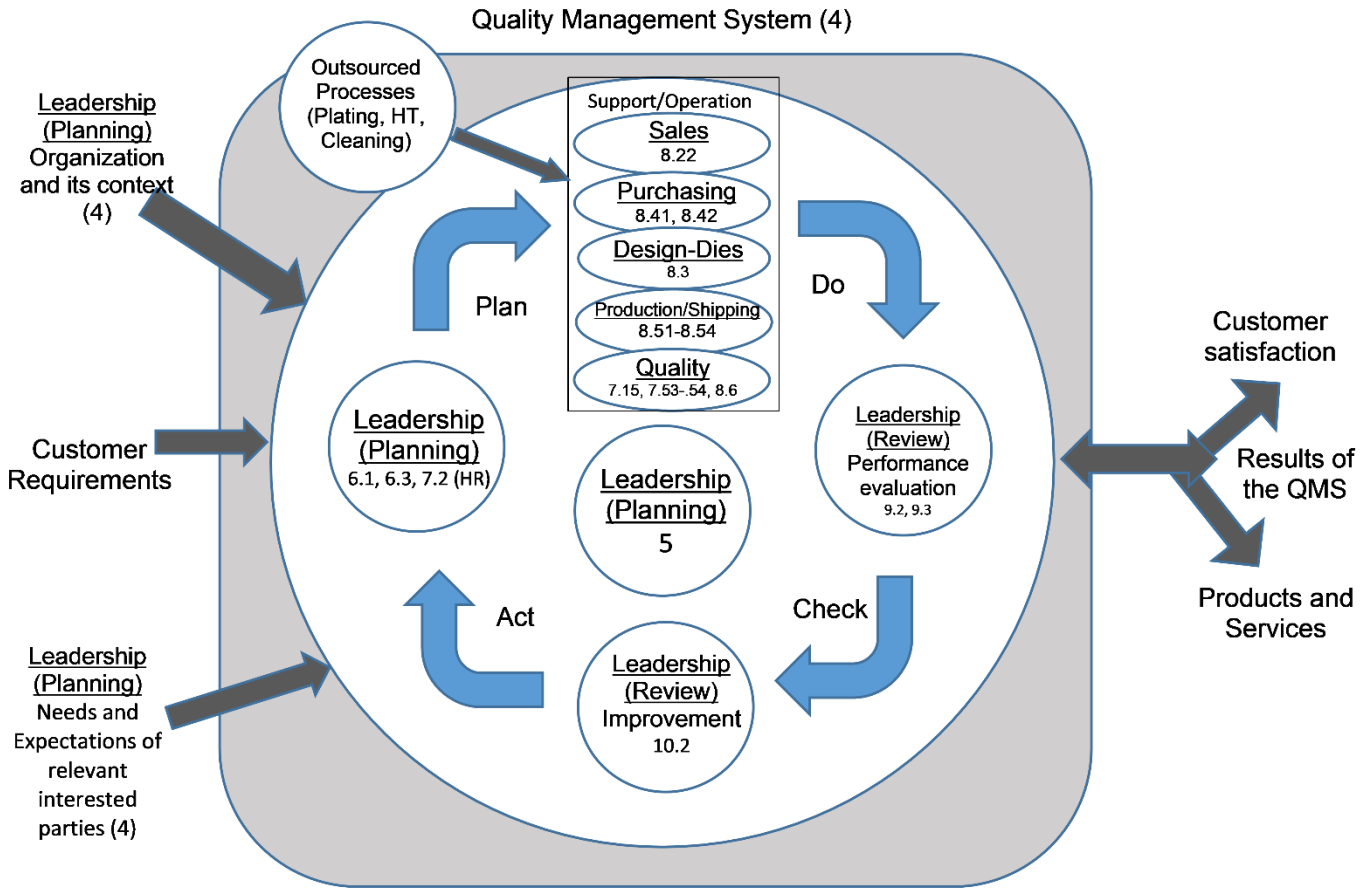
2.1 Scope of the Quality Manual

This manual is prepared for the purpose of defining the company's interpretations of the ISO 9001:2015 international standard, as well as to demonstrate how the company complies with that standard.

This manual follows the numbering structure of ISO 9001 and presents "Notes" which are used to define how Tooling Dynamics LLC. has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in ISO 9001 and IATF 16949. *Notes appear in italics, with gray background.*

2.2 Plan-Do-Check-Act

This QMS is designed around the Plan-Do-Check-Act Cycle as defined below:



3.0 Terms and Definitions

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

4.0 Organizational Context

4.1 Determining Our Strategic Direction

Tooling Dynamics LLC. has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This involves:

Understanding our core products and services, and scope of management system (see 4.2. below).

Identifying “interested parties” (stakeholders) who receive our products or services, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are defined in the **Business Context Document**.

Understanding internal and external issues that are of concern are also identified in the **Business Context Document**. Many such issues are identified through an analysis of risks faced internally or the interested parties. Such issues are monitored and updated as appropriate, and discussed as part of management reviews.

This information is then used by senior management to determine the company’s strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.2 Scope of the Management System

4.2.1 Scope Statement

Scope of Registration:

- **ISO 9001 – Build and Stamp High Speed Connectors, Including Die Build**
- **IATF16949 – Manufacture of Stamped Products**

Quality Management System Scope: **The quality system applies to all processes, supporting functions, (on-site or remote), customer-specific requirements, and both activities and employees internally and externally as defined in the Business Context Document.**

The facility is located at:

905 Vogelsong Road
York, PA 17404
Phone: 717-764-8873

4.3 Applicability

4.3.1 Permissible Non-Applicability Exceptions

The QMS shall be relevant to the nature of our organization and products, and to customer and regulatory requirements. For this purpose, those requirements of ISO 9001 and IATF 16949 that do not apply are deemed not applicable from the scope of our quality system.

PROCEDURE

1. An ISO 9001/IATF 16949 requirement may be deemed not applicable only when it may not affect our

ability, nor absolves us from the responsibility, to provide product that meets customer and applicable regulatory requirements. Per IATF 16949 the only permitted exclusion relates to product design and development.

2. Management is responsible for identifying those requirements of ISO 9001/IATF 16949 that do not apply to our organization or products, and to propose exclusions of such requirements from the scope of the quality system.

3. Senior Management has the responsibility and authority for evaluating whether the proposed items are appropriately identified, and for approving them. Evaluation and approvals are conducted within the framework of management reviews of the quality system (refer to Operational Procedure SOP-9.3, Management Review).

4. Any item deemed not applicable is documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

NOT APPLICABLE

1. ISO 9001 Section 8.3.3.1, Product Design Input

Justification: Tooling Dynamics LLC. does not provide product design input.

4.4 Management System and its processes

4.4.1 Key Process Identification

Tooling Dynamics LLC. has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming instances discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

Note: not all activities are considered "key processes" – the term "process" in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the top-level processes identified.

The top-level processes have been identified for in the Business Context Document and includes:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources
- criteria and methods employed to ensure the effectiveness of the process
- quality objectives related to that process (Defined in Section 6.2)

The sequence of interaction of these processes is illustrated in the Business Context Document.

Note: The sequence of interaction represents the typical sequence of processes, and may be altered depending on customer or regulatory requirements at the job or contract level, as required.

4.4.2 Conformance of products and processes

Tooling Dynamics LLC. ensures conformance of all products and processes, including both service parts and outsourced, to all applicable customer, statutory, and regulatory requirements. Quality management system processes are regularly reviewed by top management to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and management improvement projects. Sections 9 and 10 of this quality manual and the corresponding operational procedures define how management reviews and corrective/preventive actions are used to ensure conformance and improvement.

When processes that affect product conformity are outsourced, special controls are implemented to ensure that these processes meet specified requirements. Such controls may include, as appropriate: evaluation and pre-qualification of suppliers; assessment of supplier realization processes and quality system; monitoring of supplier quality performance; requirements for inspection, testing or other records demonstrating product conformity; or containment and verification of the supplied product. Ensuring control over outsourced processes shall not remove the responsibility of conformity to all customer requirements. Section 8 of this quality manual and the corresponding operational procedures define the purchasing control system.

4.4.2.1 "Counterfeit Part is an unauthorized copy, imitation, or substitute part or material that has been misrepresented, identified, or marked as a genuine part of an original or authorized manufacturer. Sigma Engineered Solutions / Tooling Dynamics shall not obtain or provide any part to customers or vendors that is not the Original Equipment Manufacturer or other authorized source.

4.4.3 Product Safety

Tooling Dynamics LLC. maintains documented processes for management of manufacturing process and product safety. SOP 6.1 Risk Management Addresses Product Safety Reviews. Reviews include, but are not limited to:

- identification by the organization of statutory and regulatory product-safety requirements;
- customer notification of requirements in item a);
- special approvals for design FMEA;
- identification of product safety-related characteristics;
- e) identification and controls of safety-related characteristics of product and at the point of manufacture;
- special approval of control plans and process FMEAs;
- reaction plans;
- defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;
- training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes;
- changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes
- transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources
- product traceability by manufactured lot (at a minimum) throughout the supply chain;
- lessons learned for new product introduction.

Tooling Dynamics LLC. has adopted a process approach for its management system. By identifying the top-

level processes within the company, and then

5.0 Management & Leadership

5.1.1 Management Leadership and Commitment

Senior Management provides evidence of its leadership and commitment to the development and implementation of the management system and continually improving its effectiveness by:

a) taking accountability of the effectiveness of the management system;

b) ensuring that the ***Quality Policy*** and ***Quality Objectives*** are established for the management system and are compatible with the strategic direction and the context of the organization;

c) ensuring that the quality policy is communicated, understood and applied within the organization;

d) ensuring the integration of the management system requirements into the organization's other business processes, as deemed appropriate (see note);

e) promoting awareness of the process approach;

f) ensuring that the resources needed for the management system are available;

g) communicating the importance of effective quality management and of conforming to the management system requirements;

h) ensuring that the management system achieves its intended results;

i) engaging, directing and supporting persons to contribute to the effectiveness of the management system;

j) promoting continual improvement;

k) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

l) define corporate responsibility policies outlining at a minimum anti-bribery policies, employee code of conduct and ethics escalation policy (whistle-bolwoing policy).

m) Review product realization processes and support processes to evaluate and improve their effectiveness and efficiency. The results of the reviews are included in management review.

n) Identify process owners that are aware, competent to perform and responsible for managing the organization's process and related outputs, which are defined in the Business Context Document.

Note: "business processes" such as accounting, employee benefits management and legal activities are out of scope of the QMS.

5.1.2 Customer Focus

Senior Management adopts a customer focus approach which ensures that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction.

This is accomplished by assuring:

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

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

c) the focus on enhancing customer satisfaction is maintained.

5.2.1 Quality Policy

Senior Management has developed the ***Quality Policy***, defined in Section 5.2.2, that governs day-to-day operations to ensure quality and is communicated and implemented throughout the organization and to relevant interested parties as appropriate.

5.2.2 Quality Policy

It is the policy of Tooling Dynamics to provide product and Customer service that meets or exceeds Customer expectations. We are committed to continual improvement by adhering to a Quality Management System that defines requirements for meeting our business needs and defines the tools to establish, measure, and review quality objectives.

Social and Environmental Statement

Tooling Dynamics, LLC recognizes the obligations to well-being of employees, community, and customers in all areas of social and environmental responsibility and strive to meet these ethically and with integrity.

5.3.1 Organizational Roles Responsibilities & Authorities

Senior Management has assigned responsibilities and authorities for all relevant roles in the company. These are communicated through the Organization Chart defined in the Business Context Document. Senior Management accepts responsibility and authority for:

a) ensuring that the management system conforms to applicable standards;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of the management system;

d) providing opportunities for improvement for the management system;

e) ensuring the promotion of customer focus throughout the organization;

f) ensuring that the integrity of the management system is maintained when changes are planned and implemented;

g) ensure personnel responsible for conformity to product requirements have the authority to stop shipment and stop production to correct quality problems or contain a batch/shipment as necessary;

h) ensure personnel with authority and responsibility for corrective action are promptly informed of products or process that do not conform to requirements to ensure that nonconforming product is not shipped to the customer and that all potential nonconforming product is identified and contained;

i) ensure that production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.

An ISO Representative has also been assigned in the Business Context Document which acts as the point of contact to reach senior management and duplicates the defined responsibilities. This ISO Representative is also responsible and has the authority to ensure that customer requirements are met and include selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards and customer portals. The ISO Representative may delegate some of these items but maintains overall responsibility. Shift responsibility is defined in the business context document.

6.0 Planning

6.1 Risks and Opportunities

Tooling Dynamics LLC. considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services.

6.1.1 Risk Evaluations

Risks and opportunities are managed in accordance with the document SOP 6.1 Risk Management. When planning for the QMS, issues referred to in the Business Context Document are addressed to:

a) give assurance that the QMS can achieve its intended results;
b) enhance desired effects;
c) prevent, or reduce, undesired effects;
d) achieve improvement.

6.1.2 Actions to Address Risks

Tooling Dynamics LLC. plans for actions to address defined risks and how to integrate and implement the actions into the defined process, including evaluating the effectiveness of these actions. Actions taken to address risk are proportionate to the potential impact on the conformity of products and services and include lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework. Preventive actions are utilized to address and eliminate the causes of potential nonconformities to prevent their occurrence as defined in section 10.2.2 and 10.2.3.

Note: Formal risk management may not be utilized in all instances; instead, the level of risk assessment, analysis, treatment and record keeping will be performed to the level deemed appropriate for each circumstance or application.

6.1.2 Contingency plans

Tooling Dynamics LLC. has developed contingency plans to satisfy customer requirements in the event of an emergency. The plans include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed. Plans are developed by:

1. identifying and evaluating internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met;
2. defining contingency plans according to risk and impact to the customer;
3. prepare contingency plans for continuity of supply in the event of any of the following:
    a. key equipment failures;
    b. interruptions from externally provided products, processes and services;
    c. recurring natural disasters;
    d. fire;
    e. utility interruptions;
    f. labor shortages;
    g. or infrastructure disruptions;
4. including, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations;
5. periodically testing the contingency plans for effectiveness as appropriate;
6. conducting contingency plan reviews annually at Management Review and update as required;
7. document the contingency plans and retain documented information describing any revisions(s), including the person(s) who authorized the change.

6.2 Process Controls & Objectives

Quality Objectives are established at relevant functions, levels and process and are designed to:

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

Note: processes may have multiple objectives as determined by the nature of the process, it's impact on outputs and associated risks.

Note: Whereas ISO 9001 discusses process measurements and "quality objectives" as separate concepts, Tooling Dynamics LLC. combines them; i.e., quality objectives are used to control the processes. Additional objectives may be assigned, but these will also be used to measure process effectiveness.

6.2.2 Objective Planning

Each process has at least one objective established; this is a statement of the intent of the process. Each objective is then supported by at least one "metric" or key performance indicator (KPI) which is then measured to determine the process' ability to meet the quality objective.

a) Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, in order to present the data to Senior Management. The data is then analyzed in order that Senior Management may set goals and make adjustments for the purposes of long-term continual improvement.
b) The specific quality objectives for each process are defined in the Business Context Document.
c) Metrics, along with current standings and goals for each objective, are recorded in records of management review.
d) When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

Top Management ensures that the quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organizations. The results of the organizations review regarding interested parties and their relevant requirements are considered when the organization establishes its quality objectives and related performance targets as noted in the Business Context Document and reviewed during Management Review.

6.3 Change Management

When Tooling Dynamics LLC. determines the need for changes to the QMS or its processes, these changes are planned, implemented, and then verified for effectiveness; the process is defined SOP 6.3, Change Management with consideration made to:

a) the purpose of the changes and their potential consequences;
b) the integrity of the Quality Management System;
c) the availability of resources;
d) the allocation or reallocation of responsibilities and authorities.

Documents are changed in accordance with section 7.5.

7.0 Support

7.1 Provision of Resources

Tooling Dynamics LLC. determines and provides the resources needed:

a) to implement and maintain the management system and continually improve its effectiveness
b) to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations.

Resources and resource allocation are assessed during management reviews.

7.1.2 People

Senior management ensures that it provides sufficient staffing for the effective operation and control of the management system, as well its identified processes, see Section 7.2 Competence and SOP 7.2 Training.

7.1.3 Infrastructure

Tooling Dynamics LLC. determines, provides and maintains the infrastructure needed to achieve conformity

to product requirements. Infrastructure includes, as applicable:

a) buildings, workspace and associated facilities;

b) process equipment, hardware and software;

c) supporting services such as transport;

d) information and communication technology.

Infrastructure is maintained per appropriate schedules.

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification as defined in Section 7.1.5.2

Note: Calibration and measurement traceability is not employed for all measurement devices. Instead, Senior Management determines which devices will be subject to calibration based on its processes, products and services, or in order to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.

7.1.3.1 Plant, facility and equipment planning

A multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans. In designing plant layouts Tooling Dynamics LLC. optimizes material flow, handling and value-added use of the floor space including control of nonconforming product, and facilities synchronous material flow, as applicable.

New products or operations undergo manufacturing feasibility reviews during the quoting and planning phase of the project and include capacity planning. These reviews are also applicable for evaluating proposed changes to existing operations, where relevant, the application of lean manufacturing principles and on-site supplier activities as applicable.

Process effectiveness is maintained, including periodic re-evaluation relative to risk, to incorporate any changes made during process approval, control plan maintenance and verification of job set ups.

Manufacturing feasibility and evaluation of capacity planning are inputs to the management review meetings.

7.1.4 Environment for the operation of processes

Tooling Dynamics LLC. provides and maintains the environments necessary for the operation of its processes. Senior Management manages the work environment needed to achieve conformity to product requirements. Specific environmental requirements for products are determined during quality planning and are documented in subordinate procedures, work instructions, or job documentation.

Human factors are considered to the extent that they directly impact on the quality of process outputs. The premises is maintained in a state of order, cleanliness and repair that is consistent with the product and manufacturing process needs.

Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the management system. Only work environment aspects which can directly affect process efficiency or product and service quality are managed through the management system.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General and Measurement Systems Analysis

Monitoring and measuring resources are provided to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

All monitoring and measurement resources:

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

Statistical studies are conducted to analyses the variation present in the results of each type of inpsection, measurement, and test equipment system identified in the control plan. The analytical methods and acceptance criteria conform to those in reference manuals on measurement systems analysis or are otherwise approved by the customer with associated records and focus on critical or special product or process characteristics. Appropriate records are maintained to demonstrate fitness for use as is described in SOP 7.15, Measuring and Monitoring Resources.

7.1.5.2 Measurement Identification and Calibration

When measurement traceability is required, or is considered to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:

- 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 for calibration or verification records shall be retained;
- identified in order to determine their status;
- safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

SOP 7.15, Measuring and Monitoring Resources, describes the calibration process and the process for managing calibration/verification records. Records of the calibration/verification activity for all gages and measuring and test equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or on-site supplier-owned equipment) needed to provide evidence of conformity to internal requirements, legislative and regulatory requirements, and customer-defined requirements are retained.
When measuring equipment is found to be unfit for its intended purpose, the validity of previous measurements will be evaluated and appropriate actions will be taken as necessary.
Both Internal and External laboratory requirements are defined in SOP 7.15 Measuring and Monitoring Resources.

7.1.5.3 Validation of Software

In-house developed inspection, test, and monitoring software is validated before it is used for product assurance or verification. Commercial software is purchased with validation certificates where available. Software is revalidated or recertified when conditions for which it was initially validated are materially changed.

7.1.6 Organizational Knowledge

Tooling Dynamics LLC. also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;
b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained, and made available to the extent necessary.

When addressing changing needs and trends, consideration is made to current knowledge and determinations on how to acquire or access the necessary additional knowledge.

7.2 Competence

Senior Management focuses training and evaluation efforts on competence by:

a) determining the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS;
b) ensuring that these persons are competent on the basis of appropriate education, training, or experience;
c) where applicable, taking actions to acquire the necessary competence, and evaluating the effectiveness of the actions taken;
d) establishing the process for identifying training needs (including awareness) and achieving competence of all personnel performing activities affecting conformity to product and process requirements
e) providing on the job training for new or modified responsibilities affecting requirements
f) recording appropriate documented information as evidence of competence as defined in SOP 7.2, Training along with the associated processes.
g) Defining a process for verification that internal auditors and second-party auditors are competent as defined in SOP 9.2 Internal Audits.

7.3 Awareness

Training and subsequent communication is defined in SOP 7.2 Training and ensure that staff are aware of:

a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the management system, including the benefits of improved performance;
d) the documented employee motivation processes to achieve the quality objective, make continual improvements and to create an environment that promotes innovation;
e) the implications of not conforming with the management system requirements.

Documented information is retained that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with non-conforming product.

Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.

7.4 Internal Communication

Senior Management ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods may include:

a) use of corrective and preventive action processes to report nonconformities or suggestions for improvement
b) use of the results of analysis of data

c) meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS

d) use of the results of the internal audit process

e) regular company meetings with all employees

f) internal emails

g) memos to employees

7.5 Documentation & Records

7.5.1 General

The management system documentation includes both documents and records.

Note: the ISO 9001:2015 standard uses the term "documented information"; Instead, the terms "document" and "record" are utilized to avoid confusion. In this context the terms are defined as:

- *Document – written information used to describe how an activity is done.*
- *Record – captured evidence of an activity having been done.*

The quality system documentation comprises the following types of documents:

a) Quality manual (including a documented quality policy);
b) The scope of the quality management system, including details of and justification for any exclusions;
c) Documented statements of quality objectives
d) Documented processes established for the quality management system or reference to them (Quality procedures);
e) The organization processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes;
f) A document indicating where within the organization's quality management system their customer-specific requirements are addressed.
g) Work instructions;
h) Standards and other technical reference materials;
i) Engineering documents, including drawings, specifications, procedures, and other documents defining products;
j) Customer engineering documents;
k) Product realization and inspection plans;
l) QMS related forms.

Purpose, scope, and responsibility for controlling various types of documents are defined in SOP-7.53, Control of Documents.

7.5.2 General

The top-level document defining the overall quality management system is the Quality Manual. It includes:

a) The scope of the quality system, including details of and justification for any sections not applicable;
b) Description of quality system processes, their sequence, and interrelation; and
c) References to documented procedures;

7.5.3 Document Control

New documents and document changes may be initiated by anyone in the organization, but may only be issued by an authorized function. The authorized functions and the rules governing the issue of documents are defined in procedures SOP 7.53 Control of Documents. All documents are reviewed and approved prior

to issue.

7.5.4 Control of Quality Records

7.5.4.1 Documented Information/records are established and maintained to provide evidence that:

a) Product designs satisfy design input requirements;
b) Materials, components, and production processes meet specified requirements;
c) Finished products conform to specifications: and
d) The quality system is operated in accordance with documented procedures and that it is effective.
e) Where required, quality records also include traceability information.
f) Records shall be legible, readily identifiable, retrievable and protected from unintended alterations.
g) Retention periods for quality records are determined on the basis of the lifetime of the product or the event to which the record pertains, and on regulatory and contractual requirements.

7.5.4.2 All categories of quality records maintained by the company are listed in SOP 7.54, Control of Records. The list identifies their storage location and retention period and includes production part approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders, contracts/amendments.

7.5.5 Engineering Specifications

Customer engineering standards / specifications and changes shall be reviewed, distributed and implemented based on a customer-required schedule. The timely review, within 10 working days of receipt, should be completed as soon as possible and shall not exceed two working weeks. Records shall be maintained of the implementation of such changes, including the date. Production part approval documents may be revisited as necessary or required.

8.0 Operation

8.1 Operational Planning and Control

8.1.1 Products and services are defined in drawings and specifications, contract documents, internal and external standards, product samples and workmanship standards, and applicable legal and regulatory requirements.

8.1.2 Quality Assurance is responsible for identifying product quality objectives and requirements. This may be integrated with the process of determining customer and product requirements (refer to SOP 8.22, Customer Communication), and/or with defining design input (refer to SOP 8.3, Design Control).

8.1.3 Product realization planning includes, as applicable:
a) Definition and evaluation of manufacturing operations and processes, including outsourced processes,
b) Development of adequate and capable processes,
c) Identification of special processes and consideration of associated risks and consequences,
d) Establishment and implementation of appropriate process control measures,
e) Determining the resources needed to achieve conformity to the product and service requirements;
f) Development of instructions and training for process operators, and

g) Requirements for records necessary to demonstrate process conformity.

8.1.4 Product realization plans are established in collaboration between Production, Engineering, and Quality Assurance. The plans are defined in various types of production documents, production work orders, inspection plans, operator instructions, process product validation reports, etc. Topics included in product realization planning include customer product requirements and technical specifications, logistics requirements; manufacturing feasibility; project planning and acceptance criteria.

8.1.5 Product verification plans determine the inspection and testing program for a product, and for materials and components incorporated into the product. This includes:

a) Identification of inspection and testing points,
b) Inspection and testing scope, frequency, and method,
c) Acceptance criteria, and
d) Requirements for records necessary to demonstrate product conformity.

8.1.6 Procedures SOP 8.42, Receiving Inspection, and SOP 8.6, Release of Products and Services, explain how outputs of product verification planning are used.

8.1.7 Confidentiality of customer-contracted products and projects under development is maintained, including related product information.

8.2 Requirements for products and services

8.2.1 Customer Communication

Tooling Dynamics LLC. has implemented effective communication with customers detailed in SOP 8.22 Customer Communication with relation to:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant.

Written or verbal communication shall be in the language agreed with the customer and Tooling Dynamics LLC. maintains the ability to communicate necessary information, including data in a customer-specified computer language and format.

8.2.2 Determining the requirements for products and services

During the intake of new business Tooling Dynamics LLC. captures:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities including all applicable government, safety and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material;

b) requirements not stated by the customer but necessary for specified or intended use, where known

c) statutory and regulatory requirements related to the product;

d) recycling, environmental impact and characteristics identified as a result of the organizations' knowledge of the product and manufacturing process;

e) any additional requirements determined by Tooling Dynamics LLC.

These activities are defined in greater detail in the procedure SOP 8.22 Customer Communication.

8.2.3 Review of the requirements for products and services

Once requirements are captured, Tooling Dynamics LLC. reviews the requirements prior to its commitment. This review ensures that:

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved,

c) documented evidence of customer-authorized waivers for the requirements is retained;

d) the organization has the ability to meet the defined requirements, and/or the claims for the products and services it offers with reference to relation to manufacturing feasibility and

e) risks have been identified and considered.

These activities are defined in greater detail in the procedure ***SOP 8.22 Customer Communication.***

8.2.4 Changes to requirements for products and services

Changes to requirements are communicated appropriately and documented information is amended as defined and required by the **SOP 8.22 Customer Communication**.

8.3 Design and development of products and services

8.3.1 General

Tooling Dynamics LLC. designs its own standard catalog products as well as customer-specified products and modifications. Engineering is responsible for design and the design and development process is documented. The quality control system for design is defined in Procedure SOP 8.3, Design Control and applies to manufacturing process design and development with a focus on error prevention rather than detection.

8.3.2 Design and development planning

The Engineering Manager, along with a multidisciplinary team, are responsible for the planning of design projects, including the identification of design, review, verification, and validation activities; scheduling the project; assignment of qualified personnel; and control of organizational and technical interfaces that include all affected stakeholders within the organization and as appropriate its supply chain.

Personnel with product design responsibility are competent to achieve design requirements and are skill in applicable product design tools and techniques as identified by the organization.

If embedded software is internally developed an assessment methodology will be used to asses the development process using prioritization based on risk and potential impact to the customer, the organization will retain documented information of software development capability self-assessment and will be included in the internal audit program is applicable.

8.3.3 Design and development inputs

Design inputs (production and manufacturing) may be defined and documented in two ways. Design input for the company's standard products comes in the form of a product brief. Design input for customer products and is documented in a design order. Design inputs are reviewed and approved before their release to the design team and input requirements are identified, documented and reviewed as a result of contract review and include a review of special characteristics. See SOP 8.3 Design for details.

8.3.4 Design and development controls

Controls are designed and developed to ensure that results to be achieved are defined, reviews are conducted, verification and validation activities are conducted appropriately, necessary actions are taken and documented information is retained. At a minimum, every design is verified by holding and recording design reviews and undertaking qualification tests and demonstrations. For new products, and when there is no experience with similar products, prototypes may be built and tested.

Monitoring is completed with measurements at specified stages during the design and development of products and processes which is designed, analyzed and reported as an input to management review. If required by the customer, measurements of the product and process development activities reported to the customer at the appropriate stages.

Design and development validation is performed in accordance with the customer requirements including any applicable industry and governmental agency issue regulatory standards. Timing of design and development validation is planned in alignment with the customer-specified timing as applicable. Contractual agreements related to the interaction of products including embedded software within the system of the final customer's product are include.

If required a prototype program and control plan is utilized to use as possible the same suppliers, tooling and manufacturing processes that will be used in production. Performance testing activities will be monitored for timely completion and conformity to requirements. Outsourced service types and extent of control are noted in the scope of the QMS to ensure they require to requirements.

A product/manufacturing process approval process is established, implemented and maintained that conforms to customer requirements and externally provided products/services are approved per Section 8.4.3 prior to submissions for part approval to the customer. Approval will be obtained prior to shipment if required by the customer and a record of the approval is retained.

8.3.5 Design and development outputs

Design outputs are documented on two levels: Primary output consists of documents defining the designed product, while secondary output supports the design with calculations, analysis, etc. Design output documents are checked and approved before they are released for production and are expressed in terms that can be verified and validated against product design input requirements. All design output documents are maintained and controlled. See SOP 8.3 Design for details.

8.3.6 Design changes

Design changes are initiated using Engineering Change Requests. Requests for engineering changes are evaluated, and are recommended or rejected, by Engineering or Production as applicable. The ECN provides design input for designing the change.

8.4 Control of externally provided processes, products and services

8.4.1 Outsourced Processes

Any process performed by a third party is considered an "outsourced process" and must be controlled, as well. The company's outsourced processes, and the control methods implemented for each, are defined in ***SOP 8.41, Purchasing Processes***.

The type and extent of control to be applied to the outsourced process, including all products and services that affect customer requirements, take into consideration:

e) the potential impact of the outsourced process on the company's capability to provide product that conforms to requirements,

f) the degree to which the control for the process is shared,

g) the capability of achieving the necessary control through the purchasing contract requirements.

8.4.2 Purchasing

Tooling Dynamics LLC. ensures that purchased products or services conform to specified purchase requirements as defined by the customer or other requirement. The type and extent of control applied to the supplier and the purchased product is dependent on the effect on subsequent product realization or the final product.

Tooling Dynamics LLC. evaluates and selects suppliers based on their ability to supply product and service in accordance with the organization's requirements or as directed by the customer. Criteria for selection of all suppliers, evaluation and re-evaluation are established and documented and supplier QMS systems are required to develop, implement and improve with the ultimate objective of becoming certified to IATF 16949.

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who provide non-conforming products or services may be requested to conduct formal corrective action.

These activities are further defined in the documents SOP 8.41 Purchasing and 8.42 Receiving Inspection.

8.5 Production and service provision

8.5.1 Control of Provision of Products or Services

To control its products or services, Tooling Dynamics LLC. considers, as applicable, the following:

a) the availability of documents or records that define specific characteristics as well as the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources to ensure effective control of manufacturing processes;

c) the implementation of monitoring and measurement activities;

d) the use of suitable infrastructure, including appropriate manufacturing equipment required to ensure product compliance, and environment;

e) the appointment of competent persons, including any required qualifications;

f) the implementation of actions to prevent human error;

g) the implementation of release, delivery and post-delivery activities.

"Special processes" where the result of the process cannot be verified by subsequent monitoring or measuring may be utilized. When an internal "Special Process" is utilized the methods for validation are defined in the Business Context Document. See SOP 8.51 Control of Provision of Products or Services.

8.5.1.1 Control Plans

Control plans are developed and list the controls used for the manufacturing process control, including customer required information and control of special characteristics and initiation of specified reaction plans. Control plans shall be reviewed and updated when any change occurs, affecting product, processing, measurement, logistics, supply source or FMEA as defined in SOP 8.51 Control of Provision of Products and

services.

8.5.1.2 Standardised work

Work instructions and workmanship standards may be in the form of manuals, procedures, sheets, posted signs, or samples. They instruct on how to carry out a process or perform an operation or task. The need for work instructions is evaluated on the basis of criticality, importance and complexity of the process; the ability to verify results of the process; operator qualifications; and history of quality problems associated with the process. Workmanship standards are provided when acceptability of the process output can only be determined by comparison with a standard sample.

8.5.1.2 Verification of job set-ups and after shut down

Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover or job change. Planned or unplanned production shutdowns also include verification. Work instructions shall be available for set-up personnel when needed.

8.5.1.2 Total productive maintenance and Tooling Management

Key process equipment, machines, hardware, and software are regularly maintained in accordance with maintenance plans specified by equipment manufacturers or departmental managers responsible for the equipment. The system shall include the availability of replacement parts for key equipment and documenting, evaluating and improving maintenance objectives. Predictive maintenance is used to improve effectiveness and efficiency of equipment.

Resources are provided for tool and gage design, fabrication and verification activities. If these services are outsourced they are still monitored.

SOP 8.51 Control of Products, Provisions and Services details the maintenance program.

8.5.1.2 Production Scheduling

Production shall be scheduled in order to meet customer requirements utilizing an information system that permits access to production information at key stages. Relevant planning information is included during production scheduling.

8.5.2 Identification and Traceability

Where appropriate, Tooling Dynamics LLC. identifies products or other critical process outputs by suitable means. Such identification includes the status with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection or disposition, or some other similar identifier, all products shall be considered conforming and suitable for use.

If unique traceability is required by contract, regulatory, or other established requirement, Tooling Dynamics LLC. controls and records the unique identification.

The purpose of traceability is to support identification of clear start and stop points for product received by the customer or in the field that may contain quality and/or safety related nonconformities.

The documented procedure ***SOP 8.52 Identification and Traceability*** defines these methods in detail.

8.5.3 Property Belonging to Third Parties

Tooling Dynamics LLC. exercises care with customer property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use.

This activity is defined in greater detail in the documents **SOP 8.53 Customer Supplied Product**.

8.5.4 Preservation

Tooling Dynamics LLC. preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

The documented procedure ***8.54 Preservation of Product*** defines the methods for preservation of product.

8.5.5 Post-Delivery Activities

As applicable, Tooling Dynamics LLC. conducts activities which are considered "post-delivery activities" which are considered in conjunction with:

a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products and services;
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback.

Post-delivery activities are conducted in compliance with the management system defined herein. Communication of information on service concerns through the use of SOP 8.7 Control of Non-Conforming Product records or customer complaints.

If a service agreement with the customer is in place, verification is completed that relevant service centers comply with applicable requirements, special purpose tools/measuring equipment will be verified and all service personnel are trained in applicable requirements.

8.5.6 Control of changes

Tooling Dynamics LLC. reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements and retain appropriate documentation.

Change management is defined in the document ***SOP 6.3 Change Management and SOP 7.53 Control of Documents.***

8.6 Release of products and services

Acceptance criteria for products and services are defined in appropriate subordinate documentation and control plans. Reviews, inspections and tests are conducted at appropriate stages to verify that the product and service requirements have been met prior to release and per the planned arrangements for initial release and when changes occur. Traceability is maintained as required.

Each process utilizes different methods for measuring and releasing products or services. SOP 8.6, Release of Products and Services defines the release of products and services.

8.7 Control of Nonconforming Products

Tooling Dynamics LLC. ensures that products, services or other process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

8.7.1 Identification and documentation

All product nonconformities are identified and documented, regardless of how insignificant they seem to be or how easily they can be repaired or reworked. Product nonconformity records are invaluable for tracking performance and trends, and for identifying areas where corrective or preventive actions should be implemented.

Nonconforming products are documented using a nonconformity report. It describes the nonconformity, documents the disposition decision, and records close-out of follow-up activities (re-inspection, concessions, corrective actions, etc.). To prevent nonconforming products from being used or shipped, the products are identified and segregated. The use of nonconformity report and its processing are explained in Procedure **SOP 8.7, Control of Nonconforming Product**.

8.7.2 Nonconformity review and disposition

The disposition decision may be: Rework, Return to Vendor, Accept As-Is, Regrade, or Scrap.

Detailed rules for nonconformity review, for making the disposition decision, and for recording these activities are provided in Procedure **SOP 8.7, Control of Nonconforming Product**.

8.7.3 Re-verification of repaired or reworked product

Repaired or reworked products are reinspected in accordance with applicable procedures and instructions.

8.7.4 Product returns and recalls

When product nonconformity is detected by the customer after delivery or use has started, the customer is instructed to return the product, or a part, on a return authorization.

When product nonconformity is detected internally after delivery or use has started, customers are informed and instructed what to do with the product. In situations when the nonconformity may create a safety or other hazard, the product may be recalled. Only the Senior Management of the company is authorized to make recall decisions.

9.0 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

Tooling Dynamics LLC. uses the Quality Management System to improve its processes, products and services by determining appropriate measurements based on the following criteria:

a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

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

Quality Objectives, defined in the Business Context Document, define the measurements which evaluate the performance and effectiveness of the quality management system. Appropriate documentation is maintained as evidence of the results in conjunction with SOP 7.54 Control of Records.

9.1.1.1 Monitoring and measurement of manufacturing processes

Tooling Dynamics LLC. performs process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, including those for special characteristics when applicable. Where it is not possible to demonstrate product compliance through process capability, alternative methods may be used. Records of the capability or performance results are maintained as required by the customer and the process flow diagram, PFMEA and control plan are implemented, including adherence to the following:

a) measurement techniques;
b) sampling plans;
c) acceptance criteria;
d) records of actual measurement values and/or test results for variable data;
e) reaction plans and escalation process when acceptance criteria are not met.

Significant process events are recorded and retained as documented information as well as records of effective dates of process changes.

A reaction plan is indicated on the control plan and evaluated for impact on compliance to specifications for characteristics that are either not statistically capable or are unstable. These reactions plans include containment of product and 100 percent inspection as appropriate. A corrective plan is required to be developed and implemented by the organization indicating specific actions, timing and assigned responsibilities to ensure that the process becomes stable and statistically capable which is reviewed and approved by the customer when required.

9.1.1.2 Identification and application of statistical tools and concepts

Tooling Dynamics LLC. determines the appropriate use of statistical tools and verifies that appropriate tools are included as part of the APQP or equivalent process and included in the design risk analysis, the process risk analysis and control plan.

Statistical concepts, such as variation, control (stability), process capability, and the consequence of over-adjustment, are understood and used by employees involved in the collection, analysis, and management of statistical data.

9.1.2 Customer satisfaction

As one of the measurements of the performance of the management system, Tooling Dynamics LLC. monitors information relating to customer perception as to whether the organization has met customer requirements. Satisfactions is monitored through the continual evaluation of internal and external performance indicators to ensure compliance to the product and process specifications and other customer requirements. The methods for obtaining and using this information must at a minimum include:

a) Delivered part quality performance
b) Customer disruptions
c) Field returns, recalls and warranty as applicable
d) Delivery schedule performance (including incidents of premium freight
e) Customer notifications related to quality or delivery issues, including special status

It may also include:

f) recording customer complaints
g) product rejections or returns
h) repeat orders for product
i) changing volume of orders for product
j) trends in on-time delivery
k) obtain customer scorecards from certain customers
l) submittal of customer satisfaction surveys

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

9.1.3 Analysis and evaluation

Tooling Dynamics LLC. uses the management system to improve its processes, products and services. Trends in quality and operational performance are compared with progress toward objectives and lead to action to support prioritization of actions for improving customer service. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible at the Management Review Meeting, see Section 9.3.

The results of analysis shall be used to evaluate:

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the management system;
d) the effectiveness of planning;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) other improvements to the management system.

9.2 Internal Audit

Tooling Dynamics LLC. conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of IATF 16949, and to management system requirements. It includes QMS audits, manufacturing process audits and product audits and is prioritized based upon risk, internal and external performance trends and criticality of processes. If software development is applicable it is included in the audit program. Frequency of audits is reviewed and adjusted based on occurrence of process changes, internal and external nonconformities and or customer complaints and the effectiveness of the program is reviewed at management review. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

These activities are defined in the document ***SOP 9.2 Internal Audits.***

9.3 Management Review

9.3.1 General

The purpose of management reviews is to:

a) Evaluate the suitability, adequacy and effectiveness of the quality system;
b) Consider changes to the quality management system and to the quality policy and quality objectives; and
c) Identify opportunities for improvement of the quality system, processes and products.

Management reviews are chaired by the Senior Management Team and are attended by managers representing the key processes. Management reviews are conducted at least once a year. More frequent reviews are scheduled in periods when organizational or product changes, or other circumstances require increased attention and input from the top management. The details of the Management Review, including agenda/inputs and records/outputs are covered in SOP 9.3 Management Review.

10.0 Improvement

10.1 General

10.1.1 Opportunities for improvement

Opportunities and priorities for improvement are identified by comparing present quality performance to objectives defined in the quality policy and quality objectives.

Quality performance is determined by analyzing information about customer satisfaction, records of product and process nonconformity, results of internal audits, and other data and information relevant to quality performance. Section 9.1.3, Analysis and evaluation, defines the scope and system for collecting and analyzing such information.

Quality performance is evaluated by management reviews of the quality system. Where quality performance falls short of a defined objective, the management review identifies specific improvement actions to reach the objective. When a quality objective is reached, the management review may set a new, higher objective in this area and specify new improvement actions for reaching it.

In addition to management reviews, departmental managers identify improvement opportunities continually, based on daily feedback from their operations and other activities. Employees are also encouraged to come forward with ideas for improving products, processes, systems, productivity, and working environment. These improvement opportunities are evaluated and prioritized by Management and are implemented though a system of corrective, preventive actions.

10.1.2 Implementation of improvement projects

Improvement projects are usually implemented through management review actions and through corrective and preventive actions. Where appropriate, improvement projects may also be initiated by management directives, such as policy statements, announcements, memoranda, and so forth.

10.2 Nonconformity and corrective action

10.2.1 Nonconformity Response

When a nonconformity occurs Tooling Dynamics LLC. plans to react to the extent required to take action to control and correct the issue and deal with the potential consequences. Appropriate action is taken to prevent recurrence as defined by Section 8.7.

10.2.2 Preventive versus corrective action

Preventive actions are requested and implemented when there are trends of decreasing quality capability and/or effectiveness of the quality system that create a risk for a potential nonconformity. Corrective actions are used when an actual nonconformity is identified.

The need for corrective action is determined on the basis of identified actual nonconformities. Corrective action requests are typically triggered by such events as a failed inspection, customer complaint and/or product return, nonconforming delivery from a supplier, or a quality system audit finding.

The need for preventive action is determined on the basis of information and data regarding capability and performance of processes, product nonconformity rates, post-production experience feedback, service records, customer complaints, in responses to risk analysis and quality system audit findings. Such information and data are collected and analyzed to detect unfavorable trends that, if not checked, will increase the risk of nonconformities.

10.2.3 Processing of corrective and preventive actions

Preventive and corrective actions are initiated, processed and followed up Per SOP 10.2 Corrective and Preventive Action. Actions are taken to correct and lessen the impact of negative effects of risks including the following:

- Determining potential nonconformities and their causes;
- Evaluating the need for action to prevent occurrence of nonconformities;
- Determining and implementing action needed;
- Documented information of action taken;
- Reviewing the effectiveness of the preventive/corrective action taken;
- Utilizing lessons learned to prevent recurrence in similar processes;
- Defining approaches for various types and scale of problems;
- Containments, interim actions and related activities necessary for control of nonconforming outputs
- Root cause analysis, methodology uses, analysis and results;
- Implementation of systemic corrective actions, including consideration of the impact on similar processes and products;
- Verification of the effectiveness of implemented corrective actions;
- Reviewing and where necessary updating appropriate documented information such as the control plan.

10.3 Continual improvement

Continual improvement actions are often defined as corrective and preventive actions. This is especially true for preventive actions. The process is documented in SOP 10.2 Corrective and Preventive Action.

Revision History and Approval

Rev.	Nature of changes	Approval	Date
A	Original release.	Bob Updike	12/22/17
B	Updated Plan-DO-Check-Act diagram	Bob Updike	2/19/18
C	Added section 4.4.2.1 Counterfeit Parts, changed company logo in title block and changed Approval status to Justin Cutshall.	Justin Cutshall	2/18/22
D	Changed Company Logo in Title Box	Justin Cutshall	3/4/22