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GENERAL Rev. 2

0.1 Index and Revision Status

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3. Warehouse Office
4. Quality Engineering Office

**0.3 Introduction**

Tooling Dynamics LLC developed and implemented a quality management system to demonstrate its ability to consistently provide 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 9001:2008 and ISO/TS 16949:2009.

The manual is divided into five sections modeled on the sectional organization of the ISO/TS 16949:2009 standard. 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 function 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 at Tooling Dynamics, LLC to assure quality.

President \_Robert W. Updike\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**0.4 Exclusions**

The quality management system shall be relevant to the nature of our organization and products, and to customer and regulatory requirements. For this purpose, those requirements of ISO 9001:2008 and ISO/TS 16949:2009 that do not apply are excluded from the scope of our quality system.

**PROCEDURE**

1. An ISO 9001:2008 and ISO/TS 16949:2009 requirement may be excluded only when both of the following conditions are met:

1. The requirement must be within ISO 9001 and ISO/TS 16949 Clause 7, Product Realization; and
2. The exclusion may not affect our ability, nor absolves us from the responsibility, to provide product that meets customer and applicable regulatory requirements.

2. The Quality Manager is responsible for identifying those requirements that do not apply to our organization or products, and to propose exclusions of such requirements from the scope of the quality system.

3. Top executive management has the responsibility and authority for evaluating whether the proposed exclusions are appropriate, and for approving them. Evaluation and approval of exclusions are conducted within the framework of management reviews of the quality system (refer to Operational Procedure OP-56-01, Management Review).

4. Any exclusion taken 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.

**EXCLUSIONS**

1. **Exclusion:** ISO 9001 Section 7.3, Product Design and/or Development, including all subsections
2. **Exclusion:** ISO/TS 16949 Section 7.3, Product Design and/or Development

**Justification:** Tooling Dynamics, LLC does not design or develop products. All principal product characteristics are specified by the customers. Our engineering activities are limited to developing methods and means of production.

0.5 Scope

Scope of Registration:

ISO 9001Manufacture of stamped products and Swiss Turned Products.

ISO/TS 19649 – Manufacture of stamped, heat-treated products.

0.6

**Quality Management System Flowchart**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Management  Human Resources  Sales  Engineering  Planning  Production  Purchasing  Inspection & Test  Customer Requirements  Customer Feedback  Product  Continual Improvement  Nonconforming Product  Maintaining Inspection Equipment  Output  Supplier   |  | | --- | |  | |  |  |  |  |  |  |  |  |  |
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**Revision Record**

|  |  |  |
| --- | --- | --- |
| **Date** | **Revision Level** | **Description** |
| 9/1/14 | 0 | New Change from ISO 9001 to ISO/TS 16949 |
| 10/31/14 | 1 | Updated Revision levels for Section 5 and 7. |
| 1/21/15 | 2 | Added ISO/TS 16949 Scope of registration, changed process flow, added ISO/TS 16949 Exclusions. Revised Section 5 Rev to 2 |

**4.1 GENERAL REQUIREMENTS**

***GENERAL POLICY***

*Tooling Dynamics LLC is committed to establish, document, implement and maintain a quality management system, and continually improve its effectiveness, in conformance with requirements of ISO 9001 and ISO/TS 16949 International Standard.*

**PROCEDURAL POLICIES**

**1. Quality system processes**

1.1 Processes needed for the quality management system are determined in this quality manual and in associated operational procedures and work instructions. The documentation defines these quality system processes, their sequence, and interaction, and instructs on how to implement and apply them throughout the organization.

1.2 Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This usually includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

1.3 Standard Operation Procedure [OP-42-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-42-01.doc), Quality System Documentation, explains in more detail how quality system processes are defined and documented.

**2. Resources and information**

2.1 Quality Manager is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to the top management. The top executive management is responsible for ensuring the availability of necessary resources and information.

**3. Monitoring and measurement**

3.1 The performance of quality system processes is systematically monitored and/or measured. This is to ensure their effectiveness and identify opportunities for improvement.

3.2 The performance of product realization processes is usually monitored by measuring process parameters and/or product characteristics resulting from the process; and through the program of inspections and tests applied to the product. The performance of processes required for quality management is usually monitored through internal quality audits. The overall performance of the quality system is monitored by measuring customer satisfaction.

3.3 Monitoring and measuring activities are defined in Section 8 of this quality manual, and in the corresponding operational procedures.

**4. Conformance and continual improvement**

4.1 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 5 and 8 of this quality manual and the corresponding operational procedures define how management reviews and corrective/preventive actions are used to ensure conformance and improvement.

1. **Outsourced processes**

5.1 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 7 of this quality manual and the corresponding operational procedures define the purchasing control system.

**4.2 DOCUMENTATION REQUIREMENTS**

***GENERAL POLICY***

*Scope of the quality system documentation is defined. Establishment, revision of documents, and their distribution, is controlled. New documents and revisions are reviewed and approved prior to issue; and are identified with respect to their revision level. Appropriate documents are available at locations where they are used. Obsolete documents are removed from points of use. Documents of external origin are identified and their distribution is controlled.*

*Quality records are legible, indexed to facilitate their retrieval, and are stored in a suitable environment to minimize deterioration.*

**PROCEDURAL POLICIES**

**1. Scope**

1.1 Tooling Dynamics LLC quality system documentation comprises the following types of documents:

1. Quality manual (including a documented quality policy);
2. Documented statements of quality objectives
3. Operational procedures;
4. Work instructions;
5. Standards and other technical reference materials;
6. Engineering documents, including drawings, specifications, procedures, and other documents defining products;
7. Customer engineering documents;
8. Product realization and inspection plans.

Purpose, scope, and responsibility for controlling various types of documents are defined in OP-42-01, Quality System Documentation.

**2. Quality Manual**

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

1. The scope of the quality system, including details of and justification for any exclusions;
2. Description of quality system processes, their sequence, and interrelation; and
3. References to documented procedures;

**3. Document control**

3.1 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 OP-42-01, Quality System Documentation, and [OP-42-02](../Standard%20Operating%20Procedures%20(SOPs)/OP-42-02.doc), Control of Documents. All documents are reviewed and approved prior to issue.

3.2 A paper document is officially issued for use when it is approved by an authorized function. An electronic document is issued by being placed in a public directory accessible from the network.

3.3 Documents are distributed to personnel and locations where they are used. Electronic documents are available on the network and are accessible at relevant terminals and computers.

3.4 Obsolete documents are removed from points of use. Obsolete electronic documents are removed from the network and, if retained, are stored in directories that are only accessible to authorized personnel.

3.5 Document changes are reviewed and authorized by the same function that issued the original document. All personnel affected are notified of revised documents. Each department issuing paper documents maintains a master list specifying the latest issues and revisions of its documents. For electronic documents such list is not necessary, as only the latest issue and revision of a document is available on the network. Exclude paper form folder in QA Room

3.6 Customer engineering standards / specifications and changes shall be reviewed, distributed and implemented based on a customer-required schedule. The timely review should be completed as soon as possible and shall not exceed two working weeks. Records shall be maintained of the implementation of such changes.

**4. Control of quality records**

4.1 Quality records are established, documented in [OP-42-03](../Standard%20Operating%20Procedures%20(SOPs)/OP-42-03.doc) Quality Records, and maintained to provide evidence that:

1. Materials, components, and production processes meet specified requirements;
2. Finished products conform to specifications: and
3. The quality system is operated in accordance with documented procedures and that it is effective.

Where required, the quality records shall also include traceability information.

* 1. Records shall be legible, readily identifiable and retrievable. Following the retention period the disposition of the records shall be determined.
  2. 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.

Revision Record

|  |  |  |
| --- | --- | --- |
| Date | Revision Level | Description |
| 9/1/14 | 0 | New |

**5.1 MANAGEMENT COMMITMENT**

***GENERAL POLICY***

*The top executive management is ultimately responsible for establishing, implementing, maintaining, and improving the quality system. Management commitment is demonstrated by communicating to the organization the importance of meeting requirements, establishing the quality policy and quality objectives, conducting management reviews of the quality system, and ensuring the availability of necessary resources. Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency.*

**PROCEDURAL POLICIES**

**1. Top management**

1.1 For the purpose of administrating the quality management system, top management is defined to include the President, Operations Manager, Sales Manager, Engineering Manager, IT Manager, Controller, Swiss Manager, Sr. Quality Technical Engineer and the Quality Manager.

**2. Customer requirements**

2.1 Top management is committed to communicate the importance of meeting customer as well as regulatory and legal requirements. The management representative is responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization. This responsibility of the management representative is stipulated in Section 5.5, Responsibility, authority and communication.

**3. Quality policy and quality objectives**

3.1 Top management defines the purpose and objectives for the quality management system. They are documented and communicated in the form of quality policy and quality objectives. Processes for establishing the quality policy and quality objectives are defined in this manual in Section 5.3, Quality Policy, and Section 5.4, Quality System Planning.

**4. Management reviews**

4.1 Top management periodically reviews the quality management system, product realization and support processes to ensure its continuing suitability, adequacy, effectiveness and efficiency. The review evaluates current status and performance of the quality system and product realization processes and initiates actions for further improvement of the system. The process for conducting management reviews is defined in Section 5.6 of this manual and in [OP-56-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-56-01.doc), Management Review.

**5. Resources**

5.1 Top management is committed to providing resources necessary for establishing, implementing, and improving the quality management system. Section 6 of this manual defines processes for identifying resource requirements and allocation of resources for specific activities and projects.

**5.2 CUSTOMER FOCUS**

***GENERAL POLICY***

*The principal objective of the quality management system is to focus our organization on the customer, and in particular, on customer satisfaction. The key to achieving high customer satisfaction is a good understanding of customer requirements and a capability to consistently fulfill these requirements.*

**PROCEDURAL POLICIES**

**1. Determining customer requirements**

1.1 Customer requirements are understood broadly to include all aspects of products and associated services that can influence customer satisfaction. When relevant, this may also include customer needs and expectations.

1.2 Customer requirements are determined and verified through the process of order review. This process is defined in [OP-72-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-72-01.doc) Contract Review.

**2. Customer needs and expectations**

2.1 When appropriate, customer needs and expectations are determined and are incorporated into product requirements. Management is responsible for collecting and analyzing information on customer needs and expectations. The purpose is to gain an understanding of:

1. How customers use (and misuse) the product;
2. How the product interfaces with customer’s other products and/or operations;
3. Which product features and characteristics are most important to customers, and which are perceived to be the strengths and weaknesses of the product or service?

2.2 Information about customer needs and expectations is also extracted from customer feedback and complaints, and customer satisfaction data. Procedure [OP-72-02](../Standard%20Operating%20Procedures%20(SOPs)/OP-72-02.doc), Customer Concerns, defines how some of this data is collected and used.

**3. Fulfillment of customer requirements**

3.1 The whole quality system is designed and implemented to ensure that customer requirements can be consistently fulfilled. Quality system processes that most directly contribute to achieving this objective are those related to the control of product realization processes and to monitoring and measuring of product. Sections 7 and 8 of this manual define these processes.

**5.3 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 ENVIRONMETAL STATEMENT**

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

**PROCEDURAL POLICIES**

**1. Authority**

1.1 The Quality policy is established by the top management and is approved by the President or Designee. Any changes to the policy must be likewise approved by the President or Designee.

**2. Role of the policy**

2.1 The primary role of the quality policy is to communicate the company’s commitments and aspirations with regard to quality, and to define principal objectives for the quality management system.

2.2 The quality policy provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort. The use of quality policy in setting quality objectives is addressed in this manual in Section 5.4, Quality Planning. The use of the policy to facilitate continual improvement is explained in Section 8, Continual Improvement.

**3. Communication**

3.1 The quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all employees.

3.2 The quality policy is also communicated to customers, consumers and other interested parties.

**4. Review**

4.1 The quality policy is periodically reviewed within the framework of management reviews of the quality system. This is to ensure its continual relevance and suitability. The process for reviewing the quality policy is defined in OP-56-01, Management Review.

**5.4 QUALITY PLANNING**

***GENERAL POLICY***

*Quality objectives are established to support and implement the quality policy and continual improvement. Quality planning includes identification and determination of quality system processes (including any exclusions of ISO 9001 and ISO/TS 16949 requirements); priorities for continual improvement; and resources needed to achieve quality objectives and to maintain and improve the quality system. Quality plans are periodically reviewed and updated to maintain the integrity of the quality system during organizational and other changes.*

**PROCEDURAL POLICIES**

**1. Quality objectives**

1.1 Top management shall define quality objectives and measurements that shall be included in the business plan and used to implement the quality policy, to meet requirements for products and processes, and to improve quality system and quality performance. The quality objectives shall be measurable and consistent with the quality policy. Quality objectives define the direction and priorities for continual improvement.

**2. Quality system planning**

2.1 Quality system elements and processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The output of quality system planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all elements and processes of the quality system.

**3. Product realization and verification planning**

3.1 Planning of product realization, verification, and validation processes is addressed in Section 7 of this manual.

**4. Continual improvement planning**

4.1 Improvements of the quality system are planned within the framework of management reviews. The output of this planning is expressed in the form of quality system objectives, as defined above in Clause 1.1 of this section, and in OP-56-01, Management Review.

**5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION**

***GENERAL POLICY***

*Functions and their interrelation within the company are defined and communicated.*

*Top management appoints a management representative responsible for establishment and maintenance of the quality system, and for reporting to the top management on the performance of the system.*

*Issues regarding the quality system are communicated internally through distribution of pertinent documents, meetings, training and awareness programs, and management reviews.*

**PROCEDURAL POLICIES**

**1. Responsibility and authority**

1.1 Departments, groups and functions within the company, and their interrelations, are defined in the company organizational chart. Production operations across all shifts shall be staffed with personnel in charge of, or delegated responsibility for, ensuring product quality.

All personnel responsible for conformity of product; shall have the authority to stop production to correct quality issues.

1.2 All departments and functions in the company are responsible for implementing, maintaining, and improving the quality system. Managers with responsibility and authority for corrective action shall be promptly informed of product or processes which do not conform to requirements. Personnel responsible for product quality shall have the authority to stop production to correct quality problems.

The following specific responsibilities and authorities are assigned:

**Top Management**

1. Formulates the quality policy
2. Provides resources necessary to maintain and improve the quality system
3. Conducts management reviews of the quality system Semi-Annually

**Manufacturing and Engineering**

1. Plans production facilities, equipment, and processes
2. Develops production processes
3. Develops process operator and set-up instructions
4. Controls and monitors processes
5. Conducts in-process checks
6. Applies and maintains in-process product identification
7. Maintains production equipment
8. Provides training for its personnel
9. Packages products
10. Ships products to customers
11. Operates the finished product inventories

**Purchasing**

1. Selects qualified supplier and subcontractors
2. Prepares and approves purchasing documents
3. Monitors and evaluates supplier performance

**Receiving**

1. Receives purchased products
2. Performs first-stage receiving inspection
3. Applies or verifies product identification for purchased products

**Sales**

1. Conducts market research to anticipate customer expectations
2. Determines customer satisfaction
3. Advertises and promotes company's products
4. Monitors the quality performance of competitors

**Customer Service**

1. Provides customer liaison and service
2. Carries out contract and order reviews
3. Provides product information
4. Handles customer feedback and complaints

**Human Resources**

1. Defines personnel qualification requirements
2. Implements measures to motivate personnel
3. Conducts company-wide training

**Quality**

1. Establishes and maintains the quality management system
2. Handles customer feedback and complaints
3. Audits implementation and effectiveness of the quality system
4. Identifies opportunities for improvement of the quality system
5. Develops quality plans and control plans
6. Initiates corrective and preventive actions
7. Maintains and calibrates measuring and test equipment
8. Verifies subcontractor ISO standings and maintains certs
9. Performs inspections and testing
10. Identifies the need for the use of statistical techniques
11. Handles nonconforming products
12. Coordinates document control activities
13. Maintains, or coordinates the maintenance of quality records
14. Coordinates collection of quality performance data
15. Provides required training for its personnel.

**2. Management representative**

2.1 Tooling Dynamics LLC appoints as the management representatives the Quality Manager and the Sr. Quality Technical Engineer. The management representatives have the authority and responsibility to:

1. Ensure that the quality management system is implemented, maintained and continually improved;
2. Promote awareness of customer requirements throughout the organization;
3. Report to the top management on the performance of the quality system, including needs for improvement; and
4. Coordinate communication with external parties on matters relating to the quality system and ISO 9001/TS 16949 registrations.

**3. Customer representative**

3.1 Top management shall designate personnel with responsibility and authority to ensure that customer requirements are addressed. This includes selection of special characteristics (Quality Manager), setting quality objectives (President) and related training (Human Resources Manager), corrective and preventive actions (Quality Manager) and design and development (Die Manufacturing Manager).

**4. Internal communication**

4.1 Internal communication regarding the quality system flows two ways:

The management communicates to the organization the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions on how to implement and use the quality system.

The organization communicates to the management information and data regarding customer needs and expectations, customer satisfaction, quality performance, the effectiveness of the quality system, and opportunities for improvement.

4.2 The information is communicated through manuals, procedures, instructions, drawings, specifications, quality records, reports, etc.; and through training, on-the-job instruction, and meetings.

4.3 Management review meetings have a special role in ensuring proper communication between the top management and the organization. The meeting provides the framework for the organization to report on the status of quality-related issues and activities, and for the management to formulate policies and directives to change and or improve the quality system. This process is defined in OP-56-01, Management Review.

4.4 The Quality Manager has the overall responsibility for ensuring that all pertinent documents, reports and records are distributed to appropriate departments and functions, and that information and data about quality performance and the effectiveness of the quality system are reported to the top management.

**5.6 MANAGEMENT REVIEW**

***GENERAL POLICY***

*Top management conducts periodic reviews of the quality system. The review evaluates the suitability and effectiveness of the system, identifies opportunities for improvement, and considers the need for changes to the quality policy and quality objectives. Results of the review are documented.*

**PROCEDURAL POLICIES**

**1. General**

1.1 The purpose of management reviews is to:

1. Evaluate the suitability, adequacy and effectiveness of the quality system;
2. Consider changes to the quality management system and to the quality policy and quality objectives; and
3. Identify opportunities for improvement of the quality system, processes and products.

1.2 Management reviews are chaired by the President and are attended by managers representing Quality, Manufacturing, Purchasing, Sales, IT, HR, Finance, and Engineering.

1.3 Management reviews are conducted semi- annually. More frequent reviews are scheduled in periods when organizational or product changes, or other circumstances require increased attention and input from the top management.

**2. Review input**

2.1 Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

1. Results of audits,
2. Customer feedback and concerns,
3. Process performance and product conformance data,
4. Status of preventive and corrective actions,
5. Changes that could affect the quality system,
6. Follow-up actions from earlier management reviews,
7. Recommendations for improvement,
8. Quality objectives,
9. Cost of poor quality,
10. Actual and potential field failures, and

Section 8 of this manual, Analysis of Data, and OP-56-01, Management Review, define the scope, and method of presentation, of the input information and data.

**3. Review output**

3.1 Management reviews are concluded with actions related to improvement of the quality management system, and improvement of processes and products to better meet customer requirements. The review also identifies resource needs to implement these actions.

**Revision Record**

|  |  |  |
| --- | --- | --- |
| **Date** | **Revision Level** | **Description** |
| 9/1/14 | 0 | New |
| 11/6/14 | 1 | Changed Quality Policy section 5.3 |
| 2/2/15 | 2 | Added Social & Environmental statement in section 5.3. |

**6.1 PROVISION OF RESOURCES**

***GENERAL POLICY***

*Top executive management is committed to provide adequate resources for the implementation and improvement of the quality system, and for addressing customer satisfaction.*

**PROCEDURAL POLICIES**

**1. General**

1.1 Resources required for implementation and improvement of the quality system, and for addressing customer satisfaction, may include people, suppliers, information, infrastructure, work environment, and financial resources.

**2. Determination of resource requirements**

2.1 The Quality Manager and other management personnel involved in the quality system are responsible for determining resource requirements for the implementation and improvement of the system.

2.2 The principal forum for determining and communicating resource requirements are management reviews of the quality system. [OP-56-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-56-01.doc), Management Review, explains this process.

**3. Provision of resources**

3.1 Top executive management has the responsibility and authority for provision of resources. Allocation of resources for particular activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.

3.2 Management review of the quality system is the principal forum for allocation of resources for the operation and improvement of the system. All actions initiated by the review are supported by allocation of specific resources necessary for their implementation. OP-56-01, Management Review, defines this process.

**6.2 HUMAN RESOURCES**

***GENERAL POLICY***

*Tooling Dynamics LLC identifies personnel training needs, provides required training, and evaluates the effectiveness of the training provided. Personnel assigned to perform specific tasks, operations, and processes are qualified on the basis of appropriate education, experience, or training. Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives. Records of personnel qualifications and training are maintained.*

**PROCEDURAL POLICIES**

**1. Identification of training needs and awareness programs**

1.1 Management is responsible for identifying training needs and awareness programs for company-wide participation, such as: general orientation, rules and regulations, quality system, safety, customer quality requirements and other company-wide systems and issues.

1.2 Management shall ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable tools and techniques.

1.3 Departmental managers are responsible for identifying competency requirements and training needs in their departments, and for establishing departmental training programs. Departmental training is primarily focused on increasing the level of skills in operating equipment and processes, operator qualification as required, conducting inspections and checks, using analytical and statistical techniques, and so forth.

1.4 In addition, training needs are often identified in response to corrective or preventive action requests (CARs), as nonconformities may be caused by inadequate training.

1.5 Employees are empowered to innovate and participate in continual improvement activities especially focused on quality objectives.

**2. Awareness and training programs**

2.1 Tooling Dynamics LLC provides, or supports, various forms of company-wide and departmental training and awareness programs. On the job training is provided in any new or modified job affecting product quality. Personnel whose work can affect quality shall be informed about the consequences to the customer of nonconformities to quality requirements.

2.2 Procedure [OP-62-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-62-01.doc), Training, describes in detail the training and awareness programs provided by Tooling Dynamics, LLC.

Management utilizes the annual performance review system to assess and manage the training requirements and competency of employees.

Management cascades goals throughout the organization annually using the Management Review process which then cascades objectives down to individuals.

Each department develops procedures regarding identification of training needs, implementation of training and assessment of competency. Training includes assuring that individuals are aware of how they contribute to quality and policies, objectives and targets.

**3. Effectiveness of training**

3.1 Effectiveness of training and employee participation in continual improvement is evaluated using the following approaches:

1. Follow-up performance evaluation of trained employees;
2. Review of the overall performance in areas relevant to particular training and improvement programs;
3. Consideration of competency and training when investigating causes of quality system failures and product or process nonconformities; and
4. A global review of all training, awareness and continual improvement programs, conducted within the framework of management reviews of the quality system.

Procedures [OP-62-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-62-01.doc), Training, and [OP-56-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-56-01.doc), Management Review, prescribe more specific methods for evaluating particular categories of training and awareness programs.

**4. Training records**

4.1 Training records are established for all types of training. Records are normally established by the department that provides the training.

**6.3 INFRASTRUCTURE**

***GENERAL POLICY***

*Suitable infrastructure, facilities and work environment are provided as required to achieve product conformity. This includes planning, provision, and maintenance of employee facilities, workspaces, equipment, software, and associated services.*

**PROCEDURAL POLICIES**

**1. Infrastructure and Facilities**

1.1 Utilizing a multidisciplinary approach, the planning of new, and/or modification of existing infrastructure and facilities is usually conducted in conjunction with product or process changes; capacity and/or work force expansions; and other such events. Facilities may also be expanded or modified to improve productivity and/or quality, or to improve the work environment. Emphasis shall be given to optimizing material travel, handling and value-added use of floor space.

1.2 Departmental managers are responsible for identifying the need and requirements for new, and/or modification of existing infrastructure and facilities in their departments. Requests for significant changes and/or expansions of facilities are submitted to the top management for review and approval.

1.3 Contingency plans shall be developed to satisfy customer requirements in the event of an emergency.

**2. Supporting services and maintenance of facilities**

2.1 Maintenance of buildings and facilities is performed as needed. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, landscaping, and cleaning.

2.2 Production equipment maintenance is conducted in accordance with schedules and records are maintained.

**3. Work environment**

3.1 Management and departmental managers are responsible for ensuring suitable working environment for personnel, including both human and physical factors.

3.2 Management is responsible for identifying those operations where extreme environmental conditions could impact quality performance of personnel and result in product nonconformities. Where appropriate, limits of exposure and/or mitigating measures shall be defined and implemented for these operations.

**Revision Record**

|  |  |  |
| --- | --- | --- |
| **Date** | **Revision Level** | **Description** |
| 9/1/14 | 0 | New |

**7.1 PLANNING OF PRODUCT REALIZATION**

***GENERAL POLICY***

*Planning of product realization processes includes determination of quality objectives for products; development of required processes and process documentation; and establishment of product verification and validation programs. The plan also defines requirements for records necessary to demonstrate process and product conformity.*

**PROCEDURAL POLICIES**

**1. Product quality objectives**

1.1 Quality objectives for product are defined in drawings and specifications, contract documents, internal and external standards, product samples and workmanship standards, and applicable legal and regulatory requirements.

1.2 Engineering is responsible for identifying product quality objectives and requirements. This may be integrated with the process of determining customer and product requirements (refer to [OP-72-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-72-01.doc), Contract Review).

**2. Product realization planning**

2.1 Product realization planning includes, as applicable:

1. Definition and evaluation of manufacturing operations and processes,
2. Development of adequate and capable processes,
3. Identification of special processes and consideration of associated risks and consequences,
4. Customer requirements and references to its technical specifications,
5. Establishment and implementation of appropriate process control measures,
6. Development of instructions and training for process operators, and
7. Requirements for records necessary to demonstrate process conformity.

2.2 Product realization plans are established in collaboration between Manufacturing, Engineering, and Quality. The plans are defined in various types of production documents, manufacturing orders, control plans, operator instructions, process product validation reports, etc.

2.3 Operational procedures related to Section 7.5, Production Provision, explain how outputs of product realization planning are used.

**3. Die Design Input**

3.1 Tooling Dynamics, LLC identifies, documents, and reviews product design input requirements per customer requirements, [OP-72-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-72-01.doc) Contract Review; internally communicated information gained throughout the manufacturing and testing process; and product requirements.

**4. Die Design Output**

4.1 The Die-Design output is expressed for verification and validation against Die-Design inputs. Specifically, this output shall include:

* Specifications and drawings;
* Manufacturing process flow chart/layout;
* Manufacturing process FMEAs;
* Control Plan;
* Work instructions;
* Process approval acceptance criteria;
* Data for quality, reliability, maintainability and measurability;
* Results of error-proofing activities, as appropriate and;
* Methods of detection and feedback of product/manufacturing nonconformities.

**5. Product verification and validation planning**

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

1. Identification of inspection and testing points,
2. Inspection and testing scope, frequency, and method,
3. Acceptance criteria defined and, where required, approved by the customer,
4. When attribute sampling is used, the acceptance level shall be zero defects, and
5. Requirements for records necessary to demonstrate product conformity.

5.2 Engineering is responsible for development of product verification plans. The plans are defined in various types of documents, such as product drawings and specifications, manufacturing orders, purchasing documents, inspection and testing procedures, and so forth. Documents defining the inspection and testing program for a product are collectively referred to as control plans and inspection plans.

5.3 Procedures [OP-74-03](../Standard%20Operating%20Procedures%20(SOPs)/OP-74-03.doc), Receiving Inspection, and [OP-82-02](../Standard%20Operating%20Procedures%20(SOPs)/OP-82-02.doc), Monitoring and Measuring of Product, explain how outputs of product verification planning are used.

5.4 Tooling Dynamics LLC maintains a change control system to control and react to changes that impact product realization. The effects of any change, including those changes caused by any supplier, shall be assessed, and verification and validation activities shall be defined, to ensure compliance to customer requirements. Changes shall be validated before implementation. For proprietary designs, impact on form, fit and function (including performance and/or durability) shall be reviewed with the customer so that all effects can be properly evaluated. When required by the customer, additional verification/validation requirements, such as those required for new product introduction, shall be met.

**7.2 CUSTOMER-RELATED PROCESSES**

***GENERAL POLICY***

*Product requirements are determined to include customer requirements and legal, regulatory, and necessary requirements that may not be specified by customers. Orders are reviewed to ensure that product and order requirements are defined and can be met, and to resolve any incomplete or conflicting requirements. Order amendments and changes are likewise reviewed and are communicated to all relevant functions. Order reviews are recorded.*

*Arrangements for communication with customers relating to product information, order handling, and customer feedback, are defined and implemented. Where appropriate, operational procedures and instructions for these activities are established and implemented.*

**PROCEDURAL POLICIES**

**1. Quote and Order Review**

**1.1 Responsibility**

1.1.1 The Engineering Department and Operations Manager are responsible for receiving and processing all quotes and customer orders. Manufacturing, Purchasing and Quality may be called to assist with the review of quotes and orders when required.

**1.2 Contract Review**

1.2.1 The quote and order (contract) reviews comprise verification that the customer’s requirements are adequately defined and documented, and have been well understood; and that the company has the capacity to meet the requirements. Engineering is involved to investigate, confirm and document the manufacturing feasibility of the proposed products including risk analysis. Quote and contract reviews are governed by operating procedure: Procedure [OP-72-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-72-01.doc), Contract Review.

**1.3 Amendment to Contract**

1.3.1 Change orders are received and reviewed by the same functions that are responsible for the review of initial orders. Change orders are communicated to all functions within the organization that may be affected by the change of customer requirements. Operational procedure [OP-42-02](../Standard%20Operating%20Procedures%20(SOPs)/OP-42-02.doc) provides detailed instructions about how to process change orders.

**1.4 Record**

1.4.1 Quote and order (contract) reviews are recorded. More details regarding establishment and maintenance of contract review records are provided in procedure [OP-72-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-72-01.doc).

**2. CUSTOMER COMMUNICATION**

**2.1 Product Information**

2.1.1 Master copies and/or files of documents containing product information are controlled. They are reviewed and approved before release, and are identified by a unique code-number and a revision level. Superseded and obsolete materials are withdrawn to prevent them from being passed or communicated to customers.

2.1.2 The company has the ability to communicate necessary information, including data, in a customer specified language and format.

**2.2 Inquiries and order handling**

2.2.1 The Sales/Customer Service department is responsible for receiving customer inquiries and orders.

2.2.2 Handling of order amendments is controlled to the same extent as the handling of initial orders. Amendments are reviewed to verify that the new or modified requirements can be met, and a confirmation of acceptance is sent back to the customer.

2.2.3 Procedure [OP-72-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-72-01.doc) instructs how to handle inquiries, orders, and amendments.

* 1. **Customer feedback and complaints**
     1. The Quality department is responsible for receiving and processing customer feedback and complaints. All received customer communication is recorded in the customer concerns log. This includes information on service concerns.
     2. All feedback and complaints are communicated to relevant functions within and outside the organization. Quality decides how to respond to the customer and, when appropriate, what corrective or preventive actions should be implemented internally.
     3. Procedure [OP-72-02](../Standard%20Operating%20Procedures%20(SOPs)/OP-72-02.doc), Customer Concerns, provides detailed instructions how to receive, process, and respond to customer feedback and complaints.

**7.3 PROCESS DESIGN AND DEVELOPMENT**

**GENERAL POLICY**

*A multidisciplinary approach is used for the design and development planning process for product realization. This process includes product realization planning, determining die design input and output, product verification and validation planning and change control. This process is documented in section 7.1 Planning of Product Realization.*

*The multidisciplinary group reviews customer specifications for feasibility, materials, inspection requirements including special characteristics, plating requirements, packaging, and if any secondary process is required. An execution plan is documented with due dates and responsibilities to achieve delivery timelines. There is a review meeting to discuss the overall effectiveness of the job including lessons learned with improvement action plans established with responsibilities and timelines for completion.*

**7.4 PURCHASING**

***GENERAL POLICY***

*Tooling Dynamics LLC evaluates its suppliers and purchases only from those that can satisfy quality requirements. Quality performance of suppliers is monitored and evaluated. Purchasing documents clearly and completely describe ordered products, including quality requirements. Purchasing documents are reviewed and approved prior to release. Purchased products are verified before they are used or shipped.*

**PROCEDURAL POLICIES**

**1. Supplier evaluation**

1.1 Purchasing and Quality establish the criteria for selection of suppliers, and conduct supplier evaluation. The approved suppliers are entered on the approved supplier list. Existing suppliers with a satisfactory quality performance history may be exempted from the initial evaluation. Records of the initial supplier evaluation are maintained. Supplier evaluation process is governed by Procedure [OP-74-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-74-01.doc), Supplier and Subcontractor Assessment.

**2. Supplier quality performance monitoring**

2.1 Quality performance of suppliers is monitored including delivered product quality, customer disruptions, delivery schedule performance and special status customer notifications. Suppliers showing inadequate performance may be asked to implement corrective actions. If the requested corrective actions are not implemented and there is no improvement, the supplier may be removed from the approved supplier list. Records of suppler monitoring and reevaluations are maintained. The system for monitoring suppliers is defined in Procedure [OP-74-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-74-01.doc).

2.2 Suppliers supplying product for automotive customers shall be registered to ISO 9001 by an accredited third party certification body. Tooling Dynamics will work with these suppliers with the goal of conformity with the TS 16949 specification.

**3. Approved supplier list**

3.1 Purchasing maintains an approved supplier list. Orders may only be placed with vendors that are on the list. All purchased products or materials used in products shall conform to applicable regulatory requirements. Where specified by the contract (customer drawing, specification), products, materials or services shall be purchased from approved sources. The use of customer-designated sources does not relieve the organization of the responsibility for ensuring the quality of purchase products.

**4. Purchasing information**

4.1 Purchasing documents are prepared by the Purchasing department. The documents clearly and completely describe ordered products, including precise product identification and quality requirements. The Engineering Manager or Operations Manager reviews and approves all purchasing documents prior to release.

4.2 The preparation, review, and approval of purchasing documents are explained in Procedure [OP-74-02](../Standard%20Operating%20Procedures%20(SOPs)/OP-74-02.doc), Purchasing.

**5. Verification of purchased product**

5.1 Purchased products are inspected at receiving. This includes verification of product identity and quantity, visual inspection and, where applicable, verification that all requested certificates and quality records are available. Designated products are further inspected or tested by QC.

5.2 QC inspection or testing may not be necessary when products are supplied with records or certificates demonstrating conformity; or when the supplier is qualified based on their quality system certification or supplier audits, and a satisfactory quality performance history.

5.3 Procedure [OP-74-03](../Standard%20Operating%20Procedures%20(SOPs)/OP-74-03.doc), Receiving Inspection, sets forward detailed rules for selecting product verification methods and for performing receiving and QC inspections.

5.4 When verification of purchased product is to be performed at supplier’s premises, purchasing documents specify the intended verification arrangements and method of product release.

**7.5 PRODUCTION PROVISION**

***GENERAL POLICY***

*Product and process information and appropriate work instructions are established and are communicated to relevant personnel. Operations and production processes are monitored and controlled, and are validated where appropriate. Machines and equipment used in production and for monitoring and measurement activities are maintained. Methods for product release and delivery are defined.*

*Materials, components, parts, subassemblies, and finished products are identified. When required, traceability of materials and processes is recorded and maintained. Inspection and test status of product is identified to ensure that only product that has passed the required inspections is used, installed, or dispatched.*

*Customer-supplied products are normally controlled in the same manner as are purchased products. Customer-owned tools, equipment, software, or other property are marked to indicate ownership. Loss, damage, or unsuitability of a customer's product is recorded and reported to the customer.*

*Appropriate handling, storage and preservation methods are implemented to prevent product damage or deterioration. Receipt and dispatch to and from storage areas are controlled. The condition of products in stock is regularly assessed. Product packaging materials and methods are specified and controlled.*

**PROCEDURAL POLICIES**

**1. OPERATIONS CONTROL**

**1.1 Product and process specifications**

1.1.1 Information specifying product characteristics is communicated to production in the form of drawings, specifications, samples, instructions, work orders, and product-specific templates and other tooling. This information is controlled in accordance with Procedure OP-42-02, Document Control. Engineering determines the scope, form, and distribution of product specifications.

1.1.2 Engineering shall develop control plans for the automotive product supplied. The control plan shall be prepared for pre-launch and production that takes into account the FMEA outputs.

1.1.3 Control plans shall 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.

1.1.4 Product and process information required by process operators is communicated through the manufacturing order or is included in work instructions. Where required for custom products, engineering drawings and specifications may be enclosed with the manufacturing order. Procedure [OP-75-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-75-01.doc), Process Control, explains how to establish and use these documents.

**1.2 Work instructions**

1.2.1 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.

1.2.2 Procedure [OP-75-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-75-01.doc), Process Control, specifies criteria for determining when work instructions are needed, and provides guidelines for issuing, authorizing and controlling work instructions.

**1.3 Verification of Job Set-ups**

1.3.1 Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover or job change. Work instructions shall be available for set-up personnel when needed.

**1.4 Equipment maintenance**

1.4.1 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.

**1.5 Production Tooling**

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

1.5.2 Production tooling management includes:

* maintenance and repair facilities and personnel,
* set-up, storage and recovery,
* tool-change programs for perishable tools,
* tool design modification documentation,
* tool modification and revision, and
* tool identification, defining status.

**1.6 Production Scheduling**

1.6.1 Production shall be scheduled in order to meet customer requirements utilizing an information system that permits access to production information at key stages.

**1.7 Measuring and monitoring equipment**

1.7.1 Requirements for measuring and monitoring equipment are determined by Manufacturing and Quality. This is in accordance with process control and product verification programs defined in product realization planning.

1.7.2 The control system for measuring and monitoring equipment is defined in Procedure [OP-76-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-76-01.doc), Control of Monitoring and Measuring Devices.

**1.8 Process monitoring and control**

1.8.1 Processes are monitored and controlled through a variety of approaches, activities and techniques. Process monitoring activities are further defined in Section 8 of this manual.

**1.9 Product release and delivery**

1.9.1 Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Procedure OP-82-02, Monitoring and Measuring of Product, define the system for final product verification and release.

**2. IDENTIFICATION AND TRACEABILITY**

**2.1 Product identification**

2.1.1 Purchased products are identified with unique numbers, codes, or names. The identification is the same as, or is cross-referenced with, the designations used in drawings, specifications, bills of materials, parts lists, purchase orders, etc. Purchased products are identified by marking, labeling, or tagging the products or their packaging, or by identification of the area where the products are held. During all stages of production, products are identified.

2.1.2 Final products are identified by their name or part number, which are labeled or marked on the products and/or printed on the primary product packaging.

2.1.3 Rules and activities related to identification of products are governed by Procedure OP-75-02, Product Identification and Traceability.

**2.2 Traceability**

2.2.1 When required by contracts, laws and regulations, or voluntary standards, traceability is implemented to the extent specified. Traceability may also be implemented for internal reasons, to facilitate corrective action.

2.2.2 As required, traceability may apply to materials, components, parts, production processes, environmental conditions, inspection and testing, and personnel responsible for processing and verification of products.

2.2.3 Activities related to establishment and maintenance of traceability is regulated by Procedure OP-75-02, Product Identification and Traceability.

**2.3 Inspection status identification**

2.3.1 Following every inspection or test, products or records are noted to indicate whether they have passed or failed the inspection. This is to prevent nonconforming product from being used or dispatched.

2.3.2 QC inspectors, receiving clerks, and production personnel authorized to carry out inspections and testing are responsible for noting product inspection status. All personnel handling products are responsible for maintaining the identification.

2.3.3 Detailed instructions on how to identify conforming and nonconforming products are provided in Procedure [OP-75-02](../Standard%20Operating%20Procedures%20(SOPs)/OP-75-02.doc), Product Identification and Traceability, and Procedure [OP-83-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-83-01.doc), Control of Nonconforming Product.

**3. CUSTOMER PROPERTY**

**3.1 Receiving**

3.1.1 Customer-supplied products are received and inspected following the same procedure that applies to purchase products, i.e., Procedure [OP-74-03](../Standard%20Operating%20Procedures%20(SOPs)/OP-74-03.doc), Receiving Inspection. In the event the supplied products fail receiving inspection, or are not suitable for any other reason, the customer is contacted.

**3.2 Marking, storage, and handling**

* + 1. Marking, storage, handling, and preservation of customer supplied products follow the same procedures that apply to purchase products. Customer owned tooling is permanently marked so that ownership is visible and can be determined.

**3.3 Special requirements**

3.3.1 When specified in a contract, special handling instructions from customers will take precedent over the company's standard procedures.

**3.4 Loss or damage**

3.4.1 Customers are contacted in the event of loss, damage, deterioration, or unsuitability of their products.

**4. PRESERVATION OF PRODUCT**

**4.1 Product handling and preservation**

4.1.1 Production is responsible for product handling and preservation; and in particular for ensuring that containers holding products are suitable and are in good condition, that equipment used for internal transportation of products is well maintained and is properly operated, and that products are adequately protected during production and storage. Procedure [OP-75-04](../Standard%20Operating%20Procedures%20(SOPs)/OP-75-04.doc), Preservation of Product, describes in detail how these policies are implemented.

**4.2 Inventory Areas**

* + 1. Inventory Areas, staging and holding areas are controlled by the department that brings in new stock or uses the area. Only products that are properly identified and that have passed required inspections are authorized to enter and leave the inventory areas. At designated intervals the stockrooms are inspected to assess the condition of stock.
    2. Products with limited shelf life are identified. These perishable products are also rotated in the inventory area to ensure that the oldest product is used first.
    3. An inventory management system is utilized to optimize inventory turns and assure stock rotation. Procedure [OP-75-04](../Standard%20Operating%20Procedures%20(SOPs)/OP-75-04.doc), Preservation of Product, governs the operation of inventory areas.
  1. **Packaging and labeling**
     1. Primary packaging and labeling operations are controlled following the same policies and procedures that apply to production operations and processes. Product packaging and labeling are controlled.
     2. Packaging and labeling activities are governed by Procedure [OP-75-04](../Standard%20Operating%20Procedures%20(SOPs)/OP-75-04.doc), Preservation of Product.

**4.4 Shipping and delivery**

4.4.1 Shipping of finished products is initiated by a shipping order. Activities related to shipping and delivery operations are regulated by Procedure [OP-75-04](../Standard%20Operating%20Procedures%20(SOPs)/OP-75-04.doc), Preservation of Product.

**5. VALIDATION OF PROCESSES**

5.1 Processes where the resulting output cannot be verified by subsequent measurement or monitoring are designated as special processes.

5.2 Production and Quality Assurance are responsible for identifying, validating, and documenting special processes.

5.3 Special processes are validated and controlled by applicable methods, such as destructive testing of product samples, equipment and personnel qualification, and work instructions and process procedures.

* 1. Production and Quality Assurance are responsible for selecting and implementing appropriate process validation and control measures for each special process. At a minimum, all special processes are documented in work instructions.
  2. Special process records are established and maintained as appropriate. Depending on the control measures implemented, these records may include process qualification and validation reports, equipment qualification and maintenance records, SPC charts, first article inspections and tests, operator qualification and training records, and so forth.

**7.6 CONTROL OF MONITORING AND MEASURING DEVICES**

***GENERAL POLICY***

*Appropriate measuring and monitoring instruments are maintained and selected to ensure that measurement capability is consistent with the measurement requirements. Equipment used for assuring product conformity is calibrated using calibration standards traceable to the national standard. Calibration status of measuring equipment is identified with calibration stickers. Measuring equipment is properly maintained and its placement and use are controlled.*

**PROCEDURAL POLICIES**

**1. Controlled and uncontrolled equipment**

1.1 The scope of the calibration control system extends to the measuring and test equipment, comparative reference hardware (such as gages and templates), and test software used for:

1. Setup and monitoring of production processes;
2. Monitoring of environmental conditions;
3. Verification of product conformity; and
4. Operations where defined accuracy of a measurement is required to assure product conformity.

1.2 Equipment used for other purposes may be exempted from calibration. Such equipment is labeled with stickers warning that it is not calibrated.

**2. Measurement identification and selection of equipment**

2.1 Identification of measurements to be made and the tolerance of the measured characteristics are documented in control plans and/or in product drawings and specifications.

2.2 Gages, instruments, and other measuring and monitoring equipment are selected on the basis of their capability to provide the necessary accuracy of the measurement. Quality is responsible for selecting appropriate measuring and monitoring equipment.

2.3 Statistical studies shall be conducted to analyze the variation present in the results of each type measuring and test equipment reference in the control plans.

**3. Equipment calibration and maintenance**

3.1 Quality is responsible for calibrating and maintaining measuring and monitoring equipment. All active equipment is inventoried in a controlled list, indicating equipment calibration status and location.

3.2 Measuring equipment is calibrated using written instructions, unless calibration is simple and obvious. Only calibration instruments and standards having known relationship to a nationally recognized standard are used for calibrating measuring and test equipment.

3.3 Calibration is recorded in a calibration record and the calibrated equipment is labeled with a calibration sticker. The record shall include; equipment identification, any out of specification readings including assessment, statements of conformity to specification after calibration and customer notification if suspect product has been shipped.

3.4 Calibration-related activities are regulated by Procedure [OP-76-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-76-01.doc), Control of Monitoring and Measuring Devices.

**4. Validation of software**

4.1 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.

**5. Laboratory requirements**

5.1 The quality laboratory shall have a documented scope that includes it capability to perform the designated inspections, tests and calibrations.

5.2 The Quality Manager, thru the internal audit program, shall ensure the; adequacy of the laboratory procedures (including traceable to standards such as ASTM as applicable), competency of laboratory personnel, adequacy of testing of product and review of related records.

5.3 External laboratories used for inspection, testing or calibration have a defined laboratory scope that matches the services provided. These laboratories are either acceptable by the customer or accredited to ISO 17025 or national equivalent.

**Revision Record**

|  |  |  |
| --- | --- | --- |
| **Date** | **Revision Level** | **Description** |
| 9/1/14 | 0 | New |
| 10/31/14 | 1 | Added and Operations Manager to section 7.2.1.1.1. |

**8.1 GENERAL**

***GENERAL POLICY***

*Measurement and monitoring activities required to assure product conformity, and to achieve improvement, are planned and defined. When applicable, statistical techniques are used for analyzing measurement data.*

**PROCEDURAL POLICIES**

**1. Planning**

1.1 Measurement and monitoring activities to assure and verify product conformity are defined in engineering specifications and drawings, manufacturing orders, inspection and testing procedures, and process control procedures. These activities are further defined in this manual in Section 8.2, Measurement and Monitoring, and in several operational procedures referenced in this section.

1.2 The effectiveness of the quality system is monitored by internal audits and by measuring quality, performance and customer satisfaction. Results of these activities are reported to the top management and are used to identify opportunities for improvement. Activities related to internal audits and to measuring customer satisfaction and quality performance are further defined in this manual in Sections 8.2.

**2. Statistical techniques**

2.1 The application of appropriate statistical tools for each process shall be determined during advanced quality planning and included in the control plan.

2.2 Basic statistical concepts such as variation, control, process capability and over-adjustment are understood and utilized throughout the organization where appropriate.

**8.2 MONITORING AND MEASUREMENT**

***GENERAL POLICY***

*Customer satisfaction is the principal objective of the quality system, and the level of customer satisfaction is the most important measure of the effectiveness of the system. Customer satisfaction is measured by collecting and analyzing direct customer feedback, and by measuring secondary indicators of customer satisfaction. Customer satisfaction data is used by the top management to identify opportunities and priorities for improvement.*

*All activities and areas relevant to the quality system are audited at least once a year. Audits are scheduled on the basis of the status and importance of the activity. Internal auditors are independent of those having direct responsibility for the audited activity. Identified nonconforming conditions are brought to the attention of the responsible managers and corrective actions are implemented in response to audit findings.*

*Quality system processes are monitored to ensure that they achieve planned results. Relevant product characteristics are measured through inspections, tests, and other product verification activities, as specified in control plans. Evidence of product conformity is recorded. Products are released for delivery only after all specified activities have been satisfactorily completed and verified.*

**PROCEDURAL POLICIES**

**1. CUSTOMER SATISFACTION**

**1.1 General**

1.1.1 Management is responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analyzing the pertinent information.

1.1.2 Information and data pertaining to customer satisfaction is collected from several sources. Specifically, these may include:

1. Customer feedback and surveys,
2. Awards and recognitions,
3. Product returns and warranty claims,
4. Delivered part quality performance,
5. Customer disruptions including field returns,
6. Delivery schedule performance (including incidents of premium freight), and
7. Customer notifications related to quality and delivery issues.

**2. INTERNAL AUDIT**

**2.1 Planning and scheduling**

2.1.1 The Quality Assurance manager establishes an internal audit schedule in accordance with Procedure [OP-82-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-82-01.doc), Internal Audits. All quality systems (on all shifts) and manufacturing processes are audited for compliance and effectiveness at least once a year. Selected activities may be audited more frequently, depending on their importance and quality performance history including internal / external nonconformities or customer complaints.

2.1.2 At a defined frequency, products at appropriate stages of production will be audited to verify conformance to dimensions, packaging and labeling.

**2.2 Audit team and preparation for audit**

* + 1. Only personnel independent of the audited activities are assigned to conduct internal audits. Auditors receive training in auditing techniques and to the requirements of TS 16949 along with core tools.
    2. Auditors prepare for audits by reviewing applicable standards and procedures and analyzing quality records. Selection of auditors and preparation for the audit are explained in Procedure [OP-82-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-82-01.doc), Internal Audits.

**2.3 Conducting the audit**

2.3.1 Conducting the audit, auditors seek objective evidence indicating whether the audited activities comply with the requirements of the documented quality system and ISO 9001 / TS 16949, and whether the quality system is effective. The evidence is collected by observing activities, interviewing personnel, and examining records.

2.3.2 Nonconforming conditions are documented and recorded in an audit report.

**2.4 Corrective action and follow up**

2.4.1 When nonconforming conditions are identified, the manager responsible for the affected area or activity is requested to propose and implement corrective action. Implementation and effectiveness of the action are verified by a follow-up audit.

**2.5 Reporting**

2.5.1 At regularly scheduled management review meetings the status of the internal audit schedule is reviewed. When the auditing cycle is completed, all nonconformity reports established during the cycle are compiled and analyzed, and are presented at the management review meeting.

**3. MONITORING OF QUALITY SYSTEM PROCESSES**

**3.1 Process monitoring**

3.1.1 Quality system processes are monitored by a variety of approaches and techniques, as appropriate for a particular process and its importance. These include:

1. Conducting internal audits of the quality system;
2. Monitoring trends in corrective and preventive action requests;
3. Analyzing product conformity and other quality performance data and trends;
4. Measuring and monitoring customer satisfaction.

3.1.2 Process studies shall be performed on all new manufacturing processes to verify process capability and to provide input for process control. This information shall be used for establishing specifications and other forms of manufacturing documentation.

3.1.3 Tooling Dynamics, LLC shall ensure that the customer part approval process requirements including such documents as the control plan are implemented and up to date. Significant process changes shall be recorded included effective dates. Reaction plans shall be initiated for characteristics that become unstable or not statistically capable including containment and 100% inspection as appropriate.

**3.2 Response Actions**

3.2.1 When a quality system process does not conform with requirements, Quality may request the manager responsible for the process to implement a corrective action, in accordance with Procedure [OP-85-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-85-01.doc), Corrective and Preventive Action.

**4. MONITORING AND MEASUREMENT OF PRODUCT**

**4.1 Product verification**

4.1.1 Inspection and testing programs for products is defined in various types of documents, such as product drawings and specifications, manufacturing orders, purchasing documents, inspection and testing procedures, inspection flowcharts and so forth. Documents defining the inspection and testing program for a product are collectively referred to as control plans. Section 7 of this manual defines the process for establishing control plans.

4.1.2 **Verification of purchased product:** All purchased products are subjected to a visual inspection by the receiving personnel, and then some designated products are subjected to a more detailed and technical QC inspection. Operational Procedure [OP-74-03](../Standard%20Operating%20Procedures%20(SOPs)/OP-74-03.doc), Receiving Inspection, sets forward detailed rules for performing receiving and QC inspections.

* + 1. **In-process inspections:** In-process inspections may be in the form of first article inspections, operator or QC inspections, continuous product verification by automated inspection equipment, or statistical process control (SPC). The focus is on defect prevention rather than detection. In-process inspection activities are regulated by Procedures [OP-82-02](../Standard%20Operating%20Procedures%20(SOPs)/OP-82-02.doc), Monitoring and Measuring of Product.
    2. **Final inspection**: Finished products are subjected to final inspection. Only products that pass the final inspection can be shipped. Procedure OP-82-02, Monitoring and Measuring or Product, regulates these activities.
    3. **Layout inspections and functional testing**: A layout inspection and functional verification shall be performed for each product as specified in the control plan. Results are available for customer review.
    4. **Appearance items**: For characteristics designated as “appearance items”, appropriate controls will be in-place to cover such items as resources, masters and maintenance thereof and personnel qualifications.

**4.2 Inspection, test and monitoring records**

4.2.1 Results of inspections and tests are recorded. Rules for establishing records for specific types of inspections are defined in Procedure [OP-82-02](../Standard%20Operating%20Procedures%20(SOPs)/OP-82-02.doc).

**4.3 Product release**

* + 1. Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Only personnel performing final product inspections and tests have the authority to release products. The identity of the person authorizing product release is recorded. Procedure OP-82-02, defines specific methods for product release.

**8.3 CONTROL OF NONCONFORMING PRODUCT**

***GENERAL POLICY***

*Nonconforming product is identified, documented, evaluated, and prevented from being used or shipped. Repaired or reworked products are reinspected. Appropriate actions are taken when product nonconformity is identified after delivery. When appropriate, corrective and preventive actions are implemented to prevent recurrence of identified nonconformities.*

**PROCEDURAL POLICIES**

**1. Identification and documentation**

1.1 Tooling Dynamics, LLC identifies and documents product nonconformities. Product nonconformity records are invaluable for tracking performance and trends, and for identifying areas where corrective or preventive actions should be implemented.

1.2 Nonconforming products are documented using a nonconformity report. It describes the nonconformity, documents the disposition decision, and records close-out of follow-up activities (reinspection, concessions, corrective actions, etc.). The use of nonconformity report and its processing are explained in Procedure [OP-83-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-83-01.doc), Control of Nonconforming Product.

1.3 To prevent nonconforming products from being used or shipped, the products are identified and segregated.

**2. Nonconformity review and disposition**

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

2.2 When required by customers, waivers shall be obtained when the product is different from currently approved. Records shall include expiration date and quantity. When deviated material is shipped, it is properly identified.

2.3 Detailed rules for nonconformity review, for making the disposition decision, and for recording these activities are provided in Procedure [OP-83-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-83-01.doc), Control of Nonconforming Product.

**3. Re-verification of repaired or reworked product**

3.1 Repaired or reworked products are reinspected in accordance with applicable procedures and instructions accessible to personnel performing rework.

**4. Product returns and recalls**

4.1 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 President of the company is authorized to make recall decisions.

**8.4 ANALYSIS OF DATA**

***GENERAL POLICY***

*Tooling Dynamics, LLC collects, compiles and analyzes information and data required for evaluating the suitability and effectiveness of the quality system and for identifying opportunities for continual improvement.*

**PROCEDURAL POLICIES**

**1. General**

1.1 Data and information recorded in quality records are compiled and analyzed periodically to determine trends in the performance and effectiveness of the quality system and to identify opportunities for improvement.

1.2 Quality Assurance is responsible for coordinating these activities, and for reporting conclusions and trends to the top management. This is usually done within the framework of management reviews of the quality system, in accordance with Procedure [OP-56-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-56-01.doc), Management Review.

**2. Scope**

The following categories of information and data may be compiled and analyzed:

2.1 Characteristics of processes and products:

1. Process performance variation
2. Unscheduled machine downtime (including cost)

2.2 Conformance to customer requirements:

1. Scrap, rework
2. On-time delivery performance

2.3 Suppliers

1. Supplier quality and delivery performance

2.4 Customer satisfaction and dissatisfaction:

1. Customer satisfaction levels
2. Customer complaints

2.5 Quality System:

1. Effectiveness of training
2. Effectiveness of quality system

2.6 Trends in quality and operational performance are compared to objectives and lead to action to support the development of priorities to customer concerns, determination of key customer trends and the timely reporting of such.

**8.5 IMPROVEMENT**

***GENERAL POLICY***

*Tooling Dynamics LLC deploys continual improvement philosophy throughout the entire organization. The improvement effort is driven by goals defined in the quality policy and quality objectives. Improvement opportunities are identified by analyzing quality performance data and information. Improvement projects are defined and implemented through the system of corrective and preventive actions and management review actions.*

Causes of identified nonconformities are investigated and, where appropriate, corrective actions are implemented to ensure that nonconformities do not recur. Preventive actions are implemented to eliminate the causes of potential nonconformities. Corrective and preventive actions taken are recorded and are followed up to ensure that they have been properly implemented and that they are effective.

**PROCEDURAL POLICIES**

**1. CONTINUAL IMPROVEMENT**

**1.1 Opportunities for improvement**

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

1.1.2 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 8.4, Analysis of Data, defines the scope and system for collecting and analyzing such information.

1.1.3 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.

1.1.4 In addition to management reviews, departmental managers identify improvement opportunities continually, based on daily feedback from their operations and other activities. Special emphasis is given to reduction of variation. 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 Quality and are implemented though a system of corrective, preventive actions.

**1.2 Implementation of improvement projects**

1.2.1 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.

**2. CORRECTIVE AND PREVENTIVE ACTION**

**2.1 Preventive versus corrective action**

2.1.1 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.

**2.2 Corrective actions**

2.2.1 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.

**2.3 Preventive actions**

* + 1. 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, 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. The system for collecting and analyzing quality performance information and data is defined in Section 8.4 of this manual.
    2. Preventative actions are listed on the Continual Improvement and Preventative Action list and Management Review Follow Up Action List. Closed preventative actions are placed in the closes action list file.

**2.4 Processing of corrective actions**

2.4.1 Corrective actions are initiated, processed and followed up using a CAR (Corrective Action Request) form or prescribed format dictated by the customer. Error proofing techniques are utilized as appropriate. The form documents the unsatisfactory condition, cause of the condition and the corrective or preventive action to be taken, and is used to record the verification and closure of the action. Open CARs are reviewed regularly to ensure that the actions are implemented and followed up in a timely manner. Procedure [OP-85-01](../Standard%20Operating%20Procedures%20(SOPs)/OP-85-01.doc), Corrective and Preventive Actions, explains how to use the CAR system.

**2.5 Continual improvement**

2.5.1 Continual improvement actions are often defined as corrective and preventive actions. This is especially true for preventive actions.

**Revision Record**

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