

# Starn Tool and Manufacturing Quality Manual

## ISO9001:2015

## **1.0 Introduction**

At Starn Tool & Manufacturing Company, diversity and flexibility enable us to meet and exceed customer expectations. Our manufacturing diversity is evident in the range of industries we serve. (See 4.3) We supply consumer products as well as tooling for manufacturing. Starn Tool has the experience to manufacture the precision tooling that you need.

## **2.0 Purpose**

This manual is prepared for the purpose of defining Starn Tool's interpretations of the ISO 9001:2015 international standard, as well as to outline policies and requirements of the quality management system. This outline includes reference to the procedure and/or flowchart that supports the policies and requirements, as applicable.

## **3.0 Quality policy**

### **Market Leadership, Continuous Improvement & Customer Satisfaction**

We at Starn Tool & Manufacturing Company will sustain or exceed market leadership through high quality, delivery and service. Our company will maintain this high standard of growth, continuous improvement and efficient streamlining of our methods and facility. Working as a team, we will answer our customers' needs in the most expedient manner at the least possible price.

## **4.0 Context**

### **4.1 Context-Strategic direction**

Starn Tool senior management evaluates issues (external or internal) that are relevant to the strategic direction of the company, including issues that affect our ability to achieve the intended result of our quality management system.

These evaluations may include reviewing information such as:

- a. Positive and/or negative factors that need given consideration (externally or internally)
- b. Information pertaining to technology, market, competitive, social and economic environments (external)
- c. Performance, knowledge, and culture of the company (internal)

### **4.2 Interested parties**

Senior management also considers the needs and expectations of interested parties during strategic planning as many of the issues discussed per 4.1 are risk facing Starn Tool and/or our interested parties.

Senior management has identified “interested parties” and their needs as:

- a. Customers—Ensuring we are meeting their expectations of- quality, price and delivery.
- b. Suppliers-providing accurate information, keeping current with invoices
- c. Regulatory/Government- i.e. ITAR, OSHA etc. and maintaining compliance with applicable requirements.
- d. Employees- providing good work environment, job security, and training.
- e. Management team-authority, support, resources
- f. Owners/shareholders (senior management)-profitability, return on investments, sales, efficiency and effectiveness of operations
- g. Community (schools: CCCTC and PMI)-considering graduates for school to work programs, hiring graduates, providing intern opportunities

### 4.3 Scope

Starn Tool is a manufacturer for the aerospace, defense, automotive, consumer electronics, and medical industries. Starn Tool complies with the ISO 9001:2015 standard as well as with all customer requirements flowed down on purchase orders or other such customer documents.

#### **Facilities within the scope**

The quality management system applies to processes, activities, and employees at the following locations within the company:

20524 Blooming Valley Rd., Meadville, PA 16335 – sales, purchasing, manufacturing (saw, mill, lathe, grind, EDM, assembly), receiving, packaging and shipping

1057 French Street, Meadville, PA 16335- Wire EDM /Wire Cell

#### **Exclusion of Requirements from the ISO 9001:2015 Standard**

8.3 Design and development of products and services is excluded because Starn Tool does not do design and development. Starn Tool is a build to print manufacturer.

***Note: Business processes such as accounting, benefits management and legal activities are not included in the scope of the quality management system.***

### 4.4 Quality Management System and its processes

Starn tool has adopted a process approach for its quality management system. We have established processes which are management, core and supportive in nature throughout the organization.

Our organizational/process interrelationship diagram (appendage 1) defines and/or demonstrates:

- a. Interaction of processes
- b. Authority for core processes
- c. Inputs (customer requirements)
- d. Outputs (customer satisfaction)

Management Review Meetings provide documented information which includes but is not limited to other process related topics such as:

- a. Performance indicators (objectives/results of audits)
- b. Resources; needed or available
- c. Changes needed to achieve intended results
- d. Risk and opportunity as appropriate
- e. Continuous improvement activities

## **5.0 Leadership**

### **5.1 Leadership and Commitment**

Starn Tool senior management is committed to leading the management, effectiveness and continuous improvement of the quality management system, they provide evidence of this by:

- a. Being accountable for the quality management system
- b. Supporting other management roles in their areas of responsibility
- c. Ensuring that the quality policy and objectives are managed and compatible with the strategic direction and context of the organization
- d. Communicating the quality policy and making sure it is understood and applied
- e. Guiding and supporting employees to contribute to the effectiveness of the quality management system
- f. Promoting the process approach and risk based thinking
- g. Ensuring resources that are needed are made available
- h. Communicating the importance of the quality management system
- i. Ensuring intended results are achieved
- j. Promoting continuous improvement

With respect to customer focus, senior management places a strong emphasis on customer satisfaction, ensuring that customer expectations and requirements are met with the aim of enhancing customer satisfaction. They accomplish this by:

- a. Ensuring customer requirements are understood and consistently met
- b. Ensuring applicable statutory and regulatory requirements are understood and met
- c. Evaluating risk and opportunities that can affect conformity of products and customer satisfaction
- d. Maintaining focus on enhancing customer satisfaction

## **5.2 Policy**

Senior management has developed, communicated and implemented a quality policy (see section 3.0 for our quality policy statement). The quality policy provides framework for setting objectives, governing day to day operations to ensure both quality and a commitment to continual improvement of our quality management system.

## **5.3 Organizational roles, responsibilities and authorities**

Senior management has assigned authority for the management roles with in the company. This is communicated through our organizational/process interrelationship diagram. The management team is responsible for reporting to senior management the performance of their processes and any opportunities for improvement.

## **6.0 Planning**

### **6.1 Risk and opportunity**

Starn Tool considers risks and opportunities when taking actions with in the management system and improvements to our processes, services, and products that we manufacture.

Risk are managed in order to minimize their likelihood and impact, and opportunities are managed to improve their likelihood and benefit.

Formal risk and opportunity management may not be utilized in all instances; instead the level of risk assessment, analysis, actions and recordkeeping will be performed to the level deemed appropriate for each circumstance proportionate to the potential impact on the conformity of products and services.

As a whole our QMS assures that we as an organization achieve the intended results, reduce negative effect of risk, enhance positive effects of opportunities and continually improve our processes to achieve Customer Satisfaction.

### **6.2 Objectives and planning to achieve them**

Senior management along with input from the management team has established objectives needed to monitor and ensure the success of our quality management system.

Our objectives are:

- a. Consistent with our policy statement
- b. Measured and monitored
- c. Relevant to requirements and conformity of products

- d. Communicated via department, supervision, and management meetings
- e. Updated as appropriate

Review and communication of our objectives occurs monthly and is documented via our objectives matrix and meeting minutes.

Senior management leads management in achieving the objectives set for all levels of Starn Tool. Consideration has been given to:

- a. How we will accomplish the objective
- b. The resources needed to accomplish them
- c. Who is responsible for reporting data
- d. The evaluation of the data
- e. Actions needed when not achieving

### **6.3 Planning changes**

When we find it necessary to make changes to our QMS consideration is given to

- a. Potential consequences of the change
- b. Integrity of aspects relative to changes made
- c. Available resources
- d. Allocation or reallocation of responsibilities/authorities if appropriate

## **7.0 Support**

### **7.1 Resources**

Starn Tool senior management 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 to the capability and constraints on existing internal resources as well as the needs related to the expectations for suppliers. Resources and allocation of resources are assessed during management reviews.

**Human resources**-Senior management ensures that it provides sufficient staffing for the effective operation of the management system and it's identified processes. Employees performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience. Training and communication ensures that employees are aware of the quality policy, relevant quality objectives, their contribution to the

effectiveness of our management system (including the benefits of improved performance), as well as the consequence of not conforming to the requirements of our QMS.

**Infrastructure**-Senior management provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes buildings, workspace, process appropriate equipment, hardware, software, and information.

Machine equipment is maintained through preventive maintenance activities.

Inspection equipment is maintained through calibration activities.

**Note: Calibration is not implemented for employee owned inspection equipment. (The exception is employees who perform final inspection) Instead, Starn Tool teaches employees the importance of tool verification and provides work instructions on how to verify their own tools. Final inspection is performed with calibrated tools.**

**Work Environment**-Senior management provides a clean, safe and well lit working environment for their employees.

**Organizational Knowledge**-Senior management has determined the knowledge necessary for the operation of our processes and to achieve conformity of products manufactured. Our organizational knowledge is based on both internal (lessons learned on past projects, experience of employees, results of improvements) and external (standards, classes, input from customers) sources. When addressing changing needs, we will consider the current knowledge and determine how to acquire or access any necessary additional knowledge.

## **7.2 Competence**

Starn Tool senior management has also determined the necessary competence of persons doing work that affects the performance and effectiveness of the quality management system.

We ensure the competency of our employees through education, training, and/or utilizing their past experience.

Competency evaluations are periodically performed and documented. Where necessary, action is taken to improve one's competency. The effectiveness of actions taken is evaluated.

## **7.3 Awareness**

Senior management ensures that employees know and understand our quality policy, relevant quality objectives, their contribution to the QMS, and implications for not conforming.



## **7.4 Communication**

In addition to promoting awareness, senior management ensures internal communications take place regarding the QMS. Monthly meetings at all levels of the organization (departmental, supervisory, and management review) include but are not limited to the following topics:

- a. Performance
- b. Customer feedback
- c. Resource needs
- d. Other relevant information as appropriate

These meetings also provide the employees opportunity to provide their input for opportunities for improvement, corrective actions, and discussion of department specific issues/needs.

When senior management deems external communications are appropriate it will be handled through our company website, brochures and/or email.

## **7.5 Documented information**

Starn Tool's quality management system includes documentation as required by the ISO standard, as well as documented information deemed necessary to maintain the effectiveness of our QMS.

The level of control depends on the type of document/record. The latest procedures and work instructions are accessible electronically, therefore if printed they are not considered controlled. Having these as electronic documents ensures employees always have access to the most current information applicable.

Forms are used to collect information to demonstrate conformity. When this type of documented information is retained it is protected from unintended alterations.

Any externally documented information that is necessary for the operation of processes or evidence of conformity to requirements will be treated in the same manner as internal documentation.

## **8.0 Operation**

### **8.1 Operational planning and control**

Starn Tool plans the processes needed for product realization. This planning considers the information related to the context of the organization, current resources and capabilities, as well as product and customer requirements.

Documentation is maintained which demonstrates the plans, as well as the conformity of the products. The level of documentation is dependent of customer requirements. The planning process also takes into consideration any out sourced operations.

Changes to these plans are controlled and reviewed.

## **8.2 Requirements for products**

Starn Tool has implemented effective communication with our customers which include:

- a. providing information relative to their products
- b. handling enquiries, contracts, orders, including changes
- c. obtaining customer feedback relating to their products, including complaints
- d. handling or controlling customer supplied property
- e. establishing specific requirements for contingency actions, when relevant

When determining the requirements for product realization during our quoting process we ensure that:

- a. Customer requirements are understood
- b. Product requirements are defined
- c. Requirements not stated by customer but necessary for product realization are obtained/understood
- d. Applicable statutory and/or regulatory requirements are known
- e. Our capabilities meet the defined requirements

Where quotes turn into orders, the contract review process (prior to acceptance) ensures:

- a. Review of requirements including delivery
- b. Order requirements differing from those previously expressed are resolved
- c. Risk have been identified and considered
- d. Documentation of the review

Where requirements for the product change post contract review we reevaluate our capability to meet the new requirements and relevant persons are made aware. This may include request for changes on our behalf concerning price and delivery.

## **8.3 Design and Development**

Design and development of products and services is excluded because Starn Tool does not do design and development. Starn Tool is a build to print manufacturer.

#### **8.4 Control of externally provided processes, products and services (purchasing)**

Starn Tool ensures that purchased products, processes, and services conform to the specified requirements. The type and extent of control applied to the supplier and the purchase is dependent of the effect on subsequent product realization or final product.

Suppliers are evaluated and selected based on their ability to supply processes, products, and services in accordance to our requirements and/or our customers' requirements. Criteria for selection, evaluation and reevaluation are established.

Purchases are made via the release of a formal purchase order and/or contracts (including emails) which clearly describe what are being purchased. Received products/services are verified that requirements have been met satisfactorily. Suppliers who fail to meet the specified requirements may be requested to do a formal corrective action.

#### **8.5 Production Provision**

To control production provision, Starn Tool considers, as applicable, the following:

- a. The availability of documents or records that define the products as well as the results to be achieved
- b. The availability and use of suitable monitoring and measuring devices
- c. The implementation of monitoring and measuring resources
- d. The use of suitable infrastructure and environment
- e. The appointment of competent persons, including any required qualification
- f. The implementation of actions to prevent human error
- g. The implementation of release, delivery and post-delivery activities

***Note: at this time Starn Tool does not utilize any in-house "special processes" where the result of the process cannot be verified by monitoring or measurement. Special process (i.e. heat treat, coating operations, nondestructive testing, etc.) are subcontracted/outsourced and controlled as described in 8.4 Control of externally provided processes, products and services.***

Whether traceability/identification is a requirement or not, Starn Tool controls the unique identification of the product being manufactured and maintains records of status throughout product realization.

If unique traceability (serialization) is required by contract, regulatory or other established requirements the customer instructions will be followed. Records of serialization are kept.

Property belonging to third parties (customers or external providers) will be handled with care while it is under Starn Tools 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 will be reported to the customer or supplier and records maintained.

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

Preservation of product conformity is controlled during internal processing and delivery. Preservation includes identification, handling, packaging, storage, and protection. Preservation is implemented though out all stages of manufacturing, traveling to outsourced operations and delivery transit to our customer.

Post-delivery activities are typically limited to obtaining customer feedback related to the products we provide them and the service they experience.

Both planned and unplanned changes are reviewed and controlled to the extent necessary to ensure continuing conformity with requirements. Reviews of changes, persons authorizing the change, and any necessary actions arising from the review will be documented as applicable.

## **8.6 Release of products**

Starn Tool utilizes in-process inspections and final inspections to verify that the product requirements have been met. These inspections are conducted at appropriate stages to verify product conformity as well as product preservation.

The release of products to our customer does not occur until all requirements have been completed satisfactorily, unless otherwise approved by appropriate authority and/or customer where possible.

Documented information is retained as evidence of conformity traceable to the person whom authorized the release of product. The level of documentation is established by the customer requirements in conjunction with our process requirements.

## **8.7 Control of nonconforming outputs**

Starn Tool ensures that products that do not conform to the requirements are identified and controlled to prevent unintended use or delivery. The action taken is based on the nature of the nonconformance and its effect on the product. Actions could be one of the following as applicable:

- a. Correction
- b. Segregation, containment, rejection

- c. Informing the customer
- d. Obtaining authorization for acceptance under concession

Where correction is the action taken, the conformance to requirements will be re-verified.

Documentation of nonconformance's and actions taken are maintained. The documentation includes a description of the nonconformance, actions taken; concessions obtained, and identifies the authority deciding the action taken.

Where process output nonconformities are identified the executive management team along with any other personnel relative to the process will determine actions necessary to correct the nonconformance. This would typically be documented via the corrective action process and/or in meeting minutes/actions.

## **9.0 Performance evaluation**

### **9.1 Monitoring, measurement, analysis, and evaluation**

The management system is used to improve processes, enhance customer satisfaction, minimize risk and optimize opportunity. Such improvements aim to address the needs and expectations of the customers as well as other interested parties to the extent possible.

We have defined process measurables, and employ various methods of gathering data for evaluation. Documentation of process measurables, evaluations, and any actions taken where necessary to correct a process are maintained.

Customer Satisfaction is one of the measurements demonstrating performance of the overall management system. The methods for obtaining this information include but are not limited to:

- a. Customer satisfaction surveys
- b. Recording customer feedback (positive or negative)
- c. Evaluation of customer returns (DMR system)
- d. Customer provided scorecards (where received)
- e. Possible other data might be percentage of repeat orders, trends in on-time delivery, changing volume of orders, and any other information that demonstrates customer satisfaction or dissatisfaction.

Improvement is driven by these analyses. The results of the analysis are used to evaluate:

- a. Conformity of product
- b. The degree of customer satisfaction
- c. Performance and effectiveness of the management system

- d. Effectiveness of planning
- e. Effectiveness of actions taken to address risks and opportunities
- f. Performance of external providers
- g. Other improvements as identified

## **9.2 Internal Audit**

Starn Tool conducts internal audits at planned intervals to determine whether the management system conforms to our own requirements, the requirements of ISO 9001, and the contractual and regulatory requirements. Audits seek to ensure that the management system has been effectively implemented and is maintained. Results of audits are reported as part of the inputs to management review process.

## **9.3 Management Review**

Senior management reviews the management system at planned intervals to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the company.

Management review inputs include information pertaining to:

- a. The status of actions from previous management reviews
- b. Changes in issues that are relevant to the management system (internal and/or external)
- c. Information on the performance and effectiveness of the management system, including:
  - 1. Customer satisfaction and feedback from interested parties
  - 2. Quality objectives
  - 3. Process performance and conformity of products
  - 4. Nonconformities and corrective action
  - 5. Monitoring and measurement results
  - 6. Audit results
  - 7. Performance of external providers
- d. Adequacy of resources
- e. Actions taken to address risks and opportunities
- f. Opportunities for improvement

Management review outputs include decisions and actions related to:

- a. Opportunities for improvement
- b. Any need for changes the management system

c. Resource needs

Records of management review meetings and actions resulting from those meetings are maintained.

## **10.0 Improvement**

### **10.1 General**

We determine/select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

This includes:

- a. Improving product and services to meet requirements
- b. Correcting, preventing and/or reducing undesired effects
- c. Improving the performance and effectiveness of the management system.

### **10.2 Nonconformity and corrective action**

When nonconformity occurs, including those arising from complaints, Starn Tool reacts to the nonconformity as appropriate to eliminate the cause and prevent recurrence.

Additionally, reviews of nonconformities and actions taken are evaluated to ensure similar nonconformities don't exist elsewhere, actions taken were effective, make changes to the management system if necessary, and implement any additional actions as required.

Records of nonconformance's and actions taken are maintained.

### **10.3 Continuous Improvement**

Starn Tool uses the management system to continually improve processes, methods, and customer satisfaction. We consider the results of evaluations/analysis of data and the outputs of management review to determine if there are needs or opportunities that shall be addressed as part of our continuous improvement efforts.

<b>Revision History:</b>			
<b>Rev:</b>	<b>Changes:</b>	<b>Changed by/date:</b>	<b>Approved by/date:</b>
2	Rewrote to match the 2015 standard.	Joetta Flinn 2-16-18	TJM 2/22/18