

HASTEN APPLIED CNC

AS9100. D: 2016. OPERATIONS



Document # QP-08

OPERATIONS	
Procedure Title	OPERATIONS
Document Number	QP-08
Standard	AS 9100 D: 2016
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Process Owner	Hasten Applied CNC OPERATION
Related Forms/Records	F-620-002 Quality Objectives F-620-003,004 Internal and External risk F720-002,003,004 Signup Sheet, Induction, and Training Summary F-750-002,003 Rev Change and Eng. Change F-816-002, Config. Chg. Order F-820-003 Customer Contractual Quality Requirements F-840-005 Sup. System Eval. F-840-006 Quality Clauses F-850-001 Traveler F-850-002 Packing List F-850-004 NCR/CAR's F-851-001 External Property Control, F-912-004, Customer Survey Accepted Providers List" (elect) (records retention min. 7 years)
Related Work Instructions	
Related Procedures	QP-10 Improvements

APPROVAL AND REVISION HISTORY			
DATE	REVISION	DESCRIPTION	APPROVED BY
01/26/22	A	Support procedure	R.H.



8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

- a) Determining the requirements for the products and services;
 - Production planning meetings initiate the planning from customer input through delivery and service that leads to the creation of the final product or service this includes:
 - o A review of the requirements of the product/services.
 - o Quality objectives or product requirements for the product, process, or project.
- b) Establishing criteria for:
 - 1) The processes;
 - 2) The acceptance of products and services;Quality planning task list includes:
 - Quality objectives(F-620-002) or product requirements for the product, process or project
 - Hasten Applied CNC makes use of in process and system tests to validate acceptance criteria specific to their product.
- c) Determining the resources needed to achieve conformity to the product and service requirements & QTD-Quality;
 - Resource needs are determined during planning and reviewed at Management Review Meetings, or when needed per customer requirements or demands and to meet on-time delivery of products and services.
- d) Implementing control of the processes in accordance with the criteria
 - Hasten Applied CNC uses planned instructions such as Travelers (F-850-001 Electronic), job folders, Work Instructions, Drawings, Routing Instructions, and bills of material to ensure product requirements / characteristics are identified, verified, and documented. (See above listing).
- e) Determining, maintaining and retaining documented information to the extent necessary:
 - a) To have confidence that the processes have been carried out as planned;
 - b) To demonstrate the conformity of products and services to their requirements
 - Shop Travelers, customer drawings, BOM's and Picklists show that all processes have been carried out as planned.
 - Inspection Reports and final inspections demonstrate conformity of product.

- f) Determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;
 - **Critical Items and key characteristics are communicated via the Travelers and accompanying documentation.**
- g) Engaging representatives of affected organization functions for operational planning and control;
 - **During planning the President collaborates with process owners on all functions affected.**
- h) Determining the process and resources to support the use and maintenance of the products and services;
 - **Processes and resources are taken into consideration during planning.**
- i) Determining the products and services to be obtained from external providers;
 - **When required, products and services from external providers are a part of project planning.**
- j) Establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.
 - **Hasten Applied CNC makes use of in- process and final inspections to ensure non-conforming product is not delivered to customers.**

The organization shall control planned changes and review the consequences of unintended changes, acting to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4).

- **Outsourced processes (such as: Over molding and sheet metal fabrication.) are controlled by the purchasing process and the inclusion of specific Customer Mandated requirements and Specifications on the body of the purchase order. These specifics will be in addition to the general terms and conditions given to a supplier and if repetitive, will be used to emphasize the need for these requirements with attendant documentation to include (but not limited to) key characteristics and critical items. (See Sec 8.4 for control of outsourced processes)**

The organization shall establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process shall ensure that work transfer impacts and risks are managed.

NOTE: For the control of work transfer from the organization to an external provider, or from an external provider to another external provider, see 8.4. For the control of work transfer from one organization facility to another, or from an external provider to the organization, see 8.5.

Standard Control of Work Transfers: (If Required)

For standard offloading of work, Hasten Applied CNC applies each of the following bullets:

- **Uses a subcontractor with a certified Quality Management System or audits the subcontractor to evaluate their conformance with requirements.**
- **Requires Certificates of Conformance for all product; and**
- **Inspects the product with the same inspection methods and requirements as used on products manufactured in-house, or requires a First Article Inspection be sent for each product line.**

8.1.1 Operational Risk Management

The organization shall plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization and the products and services:

- a) Assignment of responsibilities for operational risk management;
- b) Definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance
- c) Identification, assessment, and communication of risks throughout operations
- d) Identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria
- e) Acceptance of risks remaining after implementation of mitigating actions.
 - **The President in collaboration with the Management Team assesses all operational risk.**
 - **When the President receives a request for a New or Unusual product, they use the customer RFQ to determine if there is any Risk needs to be mitigated.**
 - **Upon receipt of a customer order sales uses a contract review form to assess risk and evaluate mitigation.**
 - **Product risk is communicated via the Internal and External Risk documentation. (F-620 003, 004 Ext/Int Risk)**

8.1.2 Configuration Management

The organization shall plan, implement, and control a process for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:

- a) Control product identity and traceability to requirements, including the implementation of identified changes;
- b) Ensures that the documented information (e.g., requirements, design, verification, validation, and acceptance documentation) is consistent with the actual attributes of the products and services.
 - **If the customer or a representative of the organization responsible for maintaining customer designs identifies an issue a request to change the revision of a part or assembly shall be initiated to insure configuration is met.**

- The change request is reviewed and documented using the Configuration Change Order Form. (F-816-002)
- Risk to meeting requirements from implementing the change is assessed on the form.
- Disposition of work in progress is identified on the form.
- The form becomes part of the master file and the WO package is updated and all applicable personnel are informed of the changes and the impact of those changes on their work/processes.

8.1.3 Product Safety

The organization shall plan, implement, and control the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.

- **Hasten Applied CNC will assess product safety issues during the RFQ/PO risk assessment process and flow down as required.**

8.1.4 Prevention of Counterfeit Parts

The organization shall plan, implement, and control processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

- **See WI-814-001 Counterfeit Product Control.**

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

- a) Providing information relating to products and services;
 - When a Sales receives a request for product or services from a client or a potential client, top management identifies and documents customer requirements.
 - For orders received electronically, the order is reviewed using F-820-003 Customer Contractual Quality Requirements to make sure all required information has been provided.
 - Contractual requirements are reviewed to identify any special product requirements.
 - Contracts may be negotiated between the customer and top management. These contracts are reviewed and approved by management. When the President receives an order that is part of a negotiated contract, the information in the order is reviewed against the information in the Mon Engineering proposal.

Required information includes:

- Specifications.
- Delivery date,
- Special requirements,
- Delivery requirements,



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- Requirements unstated by the customer,
 - Statutory and regulatory requirements,
 - Additional requirements that Hasten Applied CNC identifies.
- b) Handling enquiries, contracts or orders, including changes;
- Sales/Project management is responsible for communication with the client after order acceptance.
 - Sales/Project Management keep the client informed and get customer approval on Hasten Applied CNC initiated contract amendments.
- c) Obtaining customer feedback relating to products and services, including customer complaints;
Customer feedback and complaints:
- Sales/Quality may receive customer feedback or complaints; All customer feedback and complaints are recorded in the Customer Survey and Analysis F-912-004, NCR/CAR F-850-004);
 - The representative who receives the inquiry takes immediate action as necessary to satisfy the customer.
 - Quality determines if the inquiry is a complaint and if corrective action is necessary.
 - If the complaint is in regards to a requirement that wasn't met, a corrective action is initiated in accordance with the Corrective Action process.
 - If the complaint is not due to an unfulfilled requirement but is regarding product or process performance, Quality may determine to open a Risk Analysis in accordance with the Corrective Action details of (QP-10, Improvement) and related Risk Analysis (F-620-004, External Risk Analysis, F-620-003, Internal Risk Analysis) to improve the product or processes involved
- d) Handling or controlling customer property;
- All property provided by customers is identified, protected and preserved from damage Intellectual property is protected according to customer confidentiality agreements.
 - All property damaged, lost or unsuitable for use is reported to the customer.
 - A record of Customer property is logged into form F-851-001 Ext. Pop. Control Log.
- e) Establishing specific requirements for contingency actions, when relevant.
- If Hasten Applied CNC fails to meet contractual goals or deadlines Sales communicates with the customer and contingency actions are agreed upon and approved in collaboration with the customer.

8.2.2 Determining the requirements for products and services

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

- a) The requirements for the products and services are defined, including:



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1. Any applicable statutory and regulatory requirements;
2. Those considered necessary by the organization;
- b) The organization can meet the claims for the products and services it offers;
- c) Special requirements of the products and services are determined;
- d) Operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.

Responsibilities:

- Sales is responsible for taking orders from clients.
- The President & Office Manager determines and record customer requirements. (Customer Contract Review and planning Req. (F-820-003)
- President & Office Manager are responsible for communicating with the client, keeping them informed as the project progresses, and getting feedback from the client.
- When the President receives a request for product or services from a client or a potential client, he identifies and documents customer requirements.
- The President or Office Manager is responsible for taking orders from clients, determines customer requirements, and then a cross check by one or the other for final acceptance.
- Required information includes:
- Specification, Delivery date, Special requirements, Delivery requirements, Requirements unstated by the customer, Statutory and regulatory requirements,
- Additional requirements that Hasten Applied CNC or customer identifies

Required information also includes:

- o Requirements unstated by the customer and additional requirements that Hasten Applied CNC or customer identifies.
- o **Special requirements of the products and services are determined.**
- o **Operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.**

- e) The organization can meet the claims for the products and services it offers.
 - The project team reviews the orders for acceptance, risks are identified and where necessary mitigated. The project team reviews the requirements to make sure: Hasten Applied CNC has the capability and capacity to meet the client requirements.
- f) Special requirements of the products and services are determined;
 - The President and or the project team identifies and documents any special requirements.
- g) Operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.
 - See section 8.1.1 of this procedure.



8.2.3 Review of the requirements for products and services

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

- a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;

Top Management reviews the requirements to make sure:

- The client requirements are adequately defined.
- For orders received electronically, the order is reviewed using ERP System to make sure all required information has been provided.
- Contractual requirements are reviewed to identify any special product requirements.

- b) Requirements not stated by the customer, but necessary for the specified or intended use, when known;

- Hasten Applied CNC anticipates the intended use of the customer requirement and from this considers and communicates any unstated requirements if and whenever they are known.

- c) Requirements specified by the organization

- Requirements specified by Hasten Applied CNC are communicated for approval with the customer.

- d) Statutory and regulatory requirements applicable to the products and services;

- The contract review form includes identifying statutory and regulatory requirements and XXX. ensures these requirements are met.

- e) Contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

- Differing order requirements are resolved via email communication with the customer, emails are retained.
- Top management and the client discuss the contract/PO amendment. If both parties agree to the changes, they are documented and confirmed to the customer.
- Undocumented customer requirements are confirmed at the issuance of the customer PO and or via email both means can be used to confirm these requirements.
- **This review shall be coordinated with applicable functions of Hasten Applied CNC.**

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

8.2.3.2 The organization shall retain documented information, as applicable:

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

Hasten Applied CNC retains documented information regarding:

- Review results including new requirements are recorded and retained in the ERP System.
- On any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

- Any Changes to products or services are communicated by Management to all employees that need to know about the changes and relevant documents are amended.

8.3 Design and development of products and services

Justifiable Exclusion.

8.4 Control of externally provided processes, products and services

8.4.1 General

Hasten Applied CNC shall ensure that externally provided processes, products and services conform to requirements.

The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

Hasten Applied CNC shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.

Hasten Applied CNC shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.

Hasten Applied CNC shall require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

Hasten Applied CNC shall determine the controls to be applied to externally provided processes, products, and services when:

- a) Products and services from external providers are intended for incorporation into the organization's own products and services;

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- b) Products and services are provided directly to the customer(s) by external providers on behalf of the organization;
- c) A process, or part of a process, is provided by an external provider as a result of a decision by the organization.

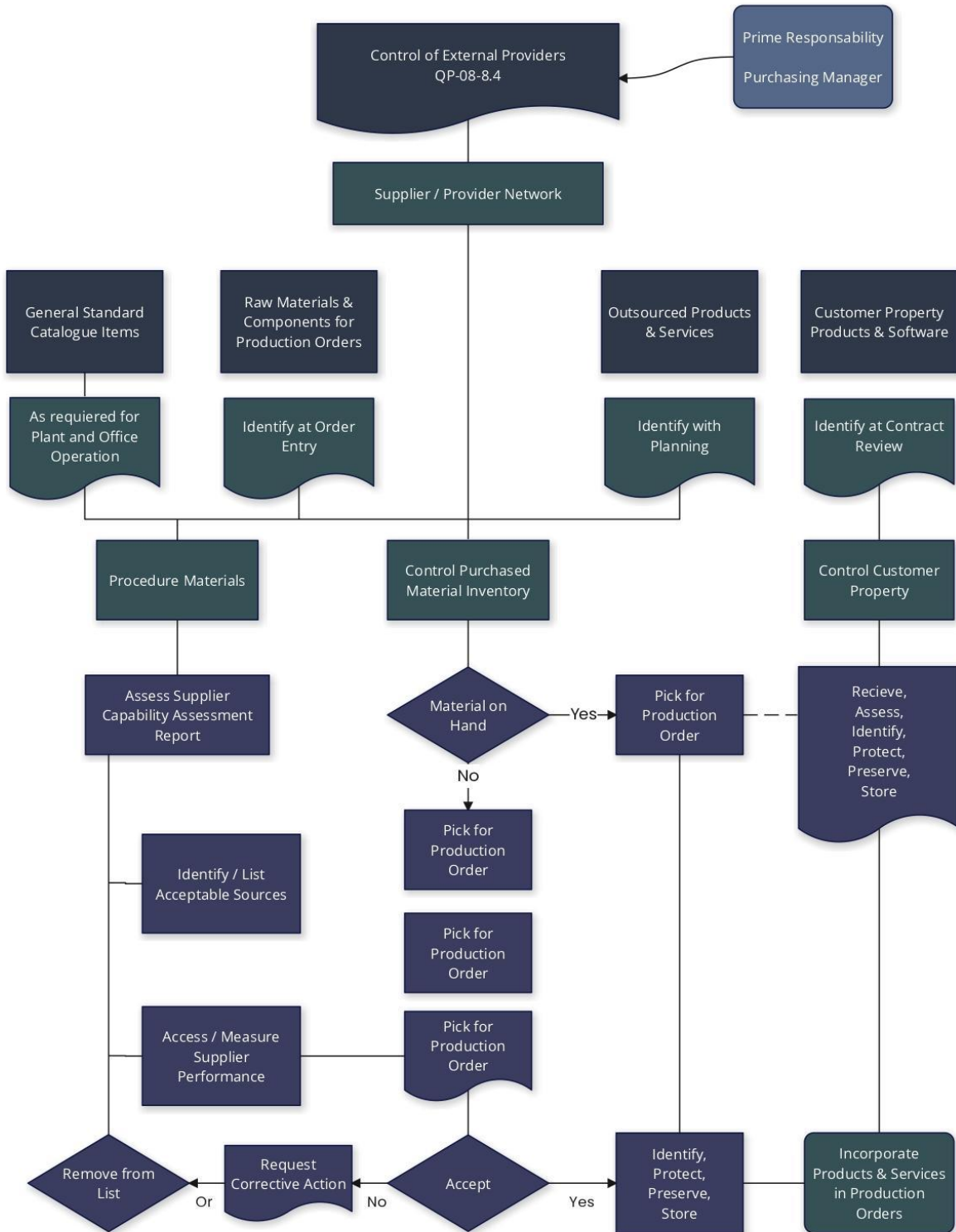
Hasten Applied CNC shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Hasten Applied CNC shall retain documented information of these activities and any necessary actions arising from the evaluations.

SEE DIAGRAM NEXT PAGE



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EXTERNAL PROVIDER - PURCHASING - FLOW DIAGRAM



Hasten Applied CNC is responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer, ensuring when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used, identifying and managing the risks associated with the external provision of processes, products & requiring that external providers apply appropriate controls to their direct and sub-tier external providers to ensure that requirements are met.

8.4.1.1

- a) Hasten Applied CNC shall ensure that externally provided processes, products, and services conform to requirements.
 - **Purchasing and Quality are responsible for and authorized to make approval status decisions, changes, and set conditions for a controlled use of external providers.**
- b) Maintain a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);
 - **Hasten Applied CNC maintains a register (Approved Vendor List) in its ERP System. The AVL shows; approval status and scope.**
- c) Periodically review external provider performance including process, product and service conformity, and on- time delivery performance;
 - **Purchasing uses the ERP System to monitor external provider performance.**
- d) Define the necessary actions to take when dealing with external providers that do not meet requirements;
 - **Suppliers that fall below the target set by Hasten for Supplier Risk Performance are categorized as “Conditional Approval” and are sent a Supplier Corrective Action Request, (SCAR) as deemed necessary.**
 - **A copy of the SCAR is linked to the supplier in the ERP system.**
 - **Purchasing sends a copy of the SCAR to the supplier for follow-up.**
 - **All follow-up information received from the supplier will be attached to the original SCAR form.**
- e) Define the requirements for controlling documented information created by and/or retained by external providers.
 - **Hasten Applied CNC flows down its documented requirements to providers via Quality Terms and Conditions posted on its website home page.**

8.4.2 Type and extent of control

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

The organization shall:

- a) Ensure that externally provided processes remain within the control of its quality management system;
- b) Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) Take into consideration:



- 1) The potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2) The effectiveness of the controls applied by the external provider;
 - 3) The results of the periodic review of external provider performance;
- d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. (SEE NOTES)
- Quality Terms and Conditions are flowed down to suppliers of externally provided processes.
 - Quality prepares a summary of the Supplier Risk Performance for management review.
 - Supplier Risk criteria is defined as, No Risk = Goals Met, Med Risk = Goals Only Met some of the times, High Risk = Goals not met – Corrective Action Required.
 - For each supplier that falls below the target for Supplier Risk Performance, Quality will summarize the number and type of non-conformances, the OTD and Quality Performance for the time, and any follow-up information or action that was taken on the non-conformances.
 - After preparing the summary, Hasten will link the non-conformances and related information to the supplier in the ERP system.
 - Management will review the summary at management review, following the Management Review Procedure.
 - **Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by the Hasten Applied CNC. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.**
 - **Hasten Applied CNC utilizes Receiving Inspections, NCR's, RMA's, previous SCARS, and periodic supplier evaluations to ensure that the externally provided processes, products and services meet requirements.**
 - **When Hasten delegates verification activities to the external provider, the scope and requirements for delegation shall be defined and a register of delegations shall be maintained. Hasten Applied CNC shall periodically monitor the external provider's delegated verification activities.**
 - **When external provider test reports are utilized to verify externally provided products, Hasten shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or Hasten Applied CNC has identified raw material as a significant operational risk (e.g., critical items), Hasten Applied CNC shall implement a process to validate the accuracy of test reports, as necessary.**

8.4.3 Information for external providers

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

The organization shall communicate to external providers its requirements for:

- a) The processes, products and services to be provided; including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);
- When purchased material has an impact on product or service quality, the suppliers of the material are evaluated and selected based on their ability to supply product that meets requirements.
 - The required processes products or services to be provided **including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions); via , Blueprints** and Hasten Applied CNC Quality Terms and Conditions.
- b) The approval of:
- 1) Products and services;
 - 2) Methods, processes and equipment;
 - 3) The release of products and services;
- Purchased product is verified before use. Receiving checks the order against purchasing documents to verify the identification, quantity and condition of the items in the order.
- Verification may include: Obtaining objective evidence of the quality of the product from suppliers through documentation, certificate of conformity, test reports etc.
 - Inspection or audit at the supplier's premises
 - Review of required documentation
 - Inspection of products upon receipt
 - Delegation of verification to the supplier or supplier certification.
- c) Competence, including any required qualification of persons;
- Supplier Terms and Conditions contain; Requirements for qualification of personnel.
- d) The external providers' interactions with the organization;
- Interactions between Hasten and external providers are communicated via Purchasing Terms and Conditions Form F-843-001.
- e) Control and monitoring of the external providers' performance to be applied by the organization;
- Data is collected on Suppliers "on time delivery" plus "Supplier Quality" which is based on the number of orders delivered on time and the number of orders that meet Hasten quality requirements.
- f) Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.
- If verification is to be performed at the suppliers' premises the verification arrangements and method of product release will be documented on the purchasing documents.
- Where specified in the contract the customer or their representative is given the right to verify subcontracted product at the supplier's premises.
- g) Design and development control; (Customer Controlled)

Hasten Applied CNC Supplier Terms and Conditions include:

- **Hasten with Customers consent reserves the right to approve or specify any designs, tests, inspection plans, verifications, use of statistical techniques for product acceptance, and any applicable critical items, including key characteristics.**

h) Special requirements, critical items, or key characteristics;

Hasten Applied CNC Supplier Terms and Conditions include:

- **Hasten Applied CNC reserves the right to “Customer Consent approval” of any designs, tests, inspection plans, verifications, use of statistical techniques for product acceptance, and any applicable critical items, including key characteristics.**

i) Test, inspection, and verification (including production process verification);

Hasten Applied CNC Supplier Terms and Conditions include:

- **Hasten Applied CNC reserves the right to approve or specify any designs, (Customer concession) tests, inspection plans,**

j) The use of statistical techniques for product acceptance and related instructions for acceptance by the organization;

- **Hasten Applied CNC Supplier Terms and Conditions include use of statistical techniques for product acceptance.**

k) The need to:

1. Implement a quality management system;
 2. Use customer-designated or approved external providers, including process sources (e.g., special processes);
 3. Notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;
 4. Prevent the use of counterfeit parts (see 8.1.4);
 5. Notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization’s approval;
 6. Flow down to external providers applicable requirements including customer requirements;
 7. Provide test specimens for design approval, inspection/verification, investigation, or auditing;
 8. Retain documented information, including retention periods and disposition requirements;
- **Contained within the body of the Hasten Applied CNC Terms and Conditions.**

l) The right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;

- **Hasten Applied CNC Supplier Terms and Conditions include: Our organization reserves the right of final approval of product, procedures, processes, and equipment.**

m) Ensuring that persons are aware of:

1. Their contribution to product or service conformity;
 2. Their contribution to product safety;
 3. The importance of ethical behavior.
- **Hasten Applied CNC Supplier Terms and Conditions include: Hasten reserves the right to require and request evidence of External Providers ensuring that their personal are aware of:**
 - o **Their contribution to product or service conformity.**
 - o **Their contribution to product safety.**
 - o **The importance of ethical behavior.**

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

a) The availability of documented information that defines:

- 1) The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
- 2) The results to be achieved;

Processes are performed under controlled conditions and include the following:

Production process verification.

- Use a representative item from the first production run to verify that the process and tooling can produce a conforming product.
- Planned instructions such as Travelers, Work Instructions, Drawings, and Routing Instructions are used to ensure product requirements / characteristics are identified, verified, and documented.
- Critical Items including Key Characteristics are inspected and/or tested, as applicable, when specified by drawings, test plans, Traveler, instructions, or inspection instructions.

b) The availability and use of suitable monitoring and measuring resources;

- Hasten Applied CNC employees are provided with the appropriate tools to assure that the inspection of the product and verification of product acceptance is completed with tools that are traceable to NIST.

c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

- Quality Assurance ensures that appropriate monitoring and control guidelines and inspection and test requirements are documented in travelers, or work instructions.

- **Ensuring that documented information for monitoring and measurement activity for product acceptance includes: a) criteria for acceptance and rejection, b) where in the sequence verification operations are to be performed, c) measurement results to be retained (indication of acceptance or rejection), specific monitoring and measurement equipment required and instructions and their use.**
 - **When sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).**
- d) The use of suitable infrastructure and environment for the operation of processes;
- The infrastructure for the quality management system has been set up in such a manner to assure that customer requirements are met and conformity to the product is achieved.
 - Safety Inspections are carried out to ensure a safe work environment for all Employees.
 - Building workspaces, and associated utilities are properly managed to assure conformity to the product.
- e) The appointment of competent persons, including any required qualification
- Managers review personnel needs: Reviewing the need for additional employees to meet the customer requirements. The review is based on the customer and internal needs. If additional personnel are needed the request is processed. Competency of employees is assessed based on appropriate education, training, skills, and experience by using Training Summary form F-720-004 and the On-The Job Training form F-720-001
- f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- Processes where resulting output cannot be verified by subsequent monitoring or measurement are validated to demonstrate the ability of the process to achieve planned results.
 - The need for validation is identified during the Planning of Product Realization Processes. If the planning identifies the need for validation, responsibility is assigned to a qualified employee, and performed according to applicable work instructions procedures or drawings.
- g) The implementation of actions to prevent human error;
- Hasten Applied CNC ensures that all production employees are properly trained provided with correct tooling and make use of Work Instructions to prevent human error.
- h) The implementation of release, delivery and post-delivery activities.
- Travelers and Quality Records provide evidence that all manufacturing, test and inspection operations have been completed as planned prior to product release.
 - Trained delivery personnel, following written work instructions and documented customer delivery requirements, provide all Hasten delivery services.

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- Hasten Applied CNC does not engage in any post-delivery activities.
- i) The establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
 - **Criteria for workmanship, expressed as product specifications or characteristics are documented in the Traveler or specification sheet for the product. (May Include written standards, representative samples, illustrations);**
- j) The accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
 - **The Traveler provides accountability of product parts, split orders, serial numbers, and non conformances.**
- k) The control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
 - **Critical Items including Key Characteristics are inspected and/or tested, as applicable, when specified by drawings, test plans, Traveler, instructions, or inspection instructions.**
- l) The determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
 - **Methods to measure variable data are included as part of the production package.**
- m) The identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
 - **Travelers and Quality Records provide evidence that all manufacturing, test, and inspection operations have been completed as planned.**
- n) The availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
 - **Travelers and Quality Records provide evidence that all manufacturing, test and inspection operations have been completed as planned.**
- o) The provision for the prevention, detection, and removal of foreign objects;
 - **Prevention, detection, and removal of loose foreign objects is performed as applicable prior to final product acceptance. In process FOD instructions are documented in available work instructions.**
- p) The control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);
 - **See QP-07 Support Procedure in regards to utilities**



- q) The identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

Hasten Applied CNC products are identified, and traceability is provided through material receipt, production and delivery to include recall and replacement where necessary by the following requirements:

- o **Product identification and traceability requirements are defined by Customer Contractual requirements.**
- o **Materials and parts received by Hasten are verified and identified upon receipt by means of individual part marking or container marking. Identification is maintained through the production process and point of delivery as required by Travelers, Production Plans, & customer drawings.**
- o **Hasten traceability is provided through production documentation, including Travelers, Production Plans, configuration data information for control of product manufacture, and inspection.**
- o **Product information includes part numbers, drawing revision levels, parts list revision (as applicable), the job order number and serialization as required.**
- o **Production documentation provides a record of operation sequences including assembly, test, and acceptance Inspection.**
- o **Product serialization control, when required, is defined by customer requirements and/or contracts.**
- o **A record of subassemblies and parts contained in the end item product are identified and maintained as Quality Records.**
- o **A unique identification is applied to individual Hasten's product providing traceability of processing records which are maintained as Quality Records.**
- o **Product processing steps including acceptance test and inspection, are annotated by authorized and controlled stamps and signatures.**

8.5.1.1 Control of Equipment, Tools, and Software Programs: Equipment, tools, and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release for production and shall be maintained.

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

- **Production Traveler documentation controls production equipment and tools.**
- **Department Leads performs machine setup prior to starting the job and validates by 1st article inspection.**
- **Tooling is visually inspected prior to being returned to storage and any defective tooling is reported to quality for replacement.**

- Tooling is reviewed and verified before and after they are used. The verification is based on visual appearance reviewing the condition of the tool.
- Tooling is properly stored to prevent any damage.

8.5.1.2 Validation and Control of Special Processes: For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organization shall establish arrangements for these processes including, as applicable:

- a) Definition of criteria for the review and approval of the processes;
- b) Determination of conditions to maintain the approval;
- c) Approval of facilities and equipment;
- d) Qualification of persons;
- e) Use of specific methods and procedures for implementation and monitoring the processes;
- f) Requirements for documented information to be retained.

Processes where resulting output cannot be verified by subsequent monitoring or measurement are validated to demonstrate the ability of the process to achieve planned results.

- The need for validation is identified during the Planning of Product Realization Processes.
- If the planning identifies the need for validation, responsibility is assigned to a qualified employee, and performed per applicable procedures.
- Outsourced processes are validated by the receiving of purchased product processes.
- All applicable documentation requirements shall be retained.

8.5.1.3 Production Process Verification: The organization shall implement production process verification activities to ensure the production process is able to produce products that meet requirements.

NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans.

The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).

NOTE: This activity can be referred to as First Article Inspection (FAI).

The organization shall retain documented information on the results of production process verification.

- The use of a representative item from the first production run to verify that the process and tooling can produce a conforming product.
- Planned instructions such as Travelers, Work Instructions, Drawings, and Routing Instructions are used to ensure product requirements / characteristics are identified, verified, and documented.
- Control of Production Process Changes

- **Changes to production process instructions are controlled by the following:**
- **The President and Managers have the authority to approve all changes to production processes and sign/date any such changes.**
- **Applicable personnel are trained when processes are changed.**
- **Customer or statutory and regulatory authority approvals are obtained as required by contracts or regulations.**
- **Changes are recorded on the traveler documentation and retained.**
- **Production Process changes are verified following implementation by inspection to assure changes have been implemented and the changes meet the desired effect, without adverse effect on product quality.**
- **Internal Production Risks are identified during the RFQ review and planning.**
- **New Products are subjected to First Article Inspection to validate customer design/specification requirements and use of equipment used to measure/test the product.**

8.5.2 Identification and Traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish controls for the media.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

NOTE: Traceability requirements can include:

- 1) The identification to be maintained throughout the product life;
 - 2) The ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);
 - 3) For an assembly, the ability to trace its components to the assembly and then to the next higher assembly;
 - 4) For a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.
- Hasten Applied CNC products are identified and traceability (as required) is provided through lot control of material receipts, production, and delivery dates.
 - Product identification and traceability requirements are defined by Hasten Applied CNC using serial numbers as required by customer and or Hasten Applied CNC Lot control.
 - Materials and parts received by Hasten Applied CNC are verified and identified upon receipt by means of individual part marking or container marking.

- **Initial Identification is maintained through the production process and point of delivery as required by Travelers, job folders, Process Plans, and applicable drawings.**

Production Traveler documentation provides a record of operation sequences including assembly, test, and acceptance Inspection.

Hasten Applied CNC traceability is provided through production documentation, including Job Folders, configuration data information for control of product manufacture, and inspection.

- Product information includes part numbers, drawing revision levels, BOM's, the job project/Manufacturing order number and serialization as required.
- Production documentation provides a record of operation sequences including assembly, test, and acceptance Inspection.
- Product serialization control, when required, is defined by Hasten requirements. A record of subassemblies and parts contained in the end item product are identified and maintained as Quality Records.
- A unique identification is applied to individual Hasten products providing traceability of processing records which are maintained as Quality Records.
- Product processing steps including acceptance test and inspection are annotated by recorded & controlled by the Electronic Media.

8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

All property provided by customers is identified, protected and preserved from damage
Intellectual property is protected according to customer confidentiality agreements.

- All property damaged, lost or unsuitable for use is reported to the customer.
- A record of Customer property is recorded in the Customer Property log.

8.5.4 Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

- **Production Planning and Managers provide for product preservation that may include specifications and applicable statutory and regulatory requirement provisions for:**
- **Cleaning; Prevention, Detection, and removal of Foreign Objects; Special handling and storage for sensitive products; marking and labeling, Including safety warnings and cautions; Shelf life control and stock rotation and special handling and storage for hazardous materials.**

8.5.5 Post-delivery activities

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

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

When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.

- Hasten Applied CNC Post-delivery activity is limited to the control of conforming products process and subsequent corrective action activity after delivery and return.
- **Post Delivery problems shall be considered when: statutory and regulatory requirements not met, customer requirements imposed were not met, product/customer support regarding warranties and possible replacement parts.**

8.5.6 Control of Changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve production or service provision changes shall be identified.

NOTE: Production or service provision changes can include the changes affecting processes, production equipment, tools, or software programs.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

- **Management Personnel that are authorized to approve production or service provision changes shall be identified.**
- **Production Control changes are controlled by Document Control Rep. (Eng. Chg. Order) form (F-750-002-003) and (Doc. Chg. Order) form (F-750-002).**
- The production configuration control is recorded in Sec 8.1.2 of this procedure.
- Results are verified through first article inspections.

8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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

The organization shall retain documented information on the release of products and services. The documented information shall include:

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

- Hasten Applied CNC submits Factory Acceptance Test Reports which include customer criteria and results achieved during Hasten testing of the product for customer approval prior to shipment, as required.
- Spare parts are inspected and tested as required by Hasten criteria prior to packaging and a certificate of conformance and test results are provided as per customer request for approval prior to shipment.
- All Shipments to customers are authorized by QA and communicated to Hasten logistics.
- **When required to demonstrate product qualification, Hasten Applied CNC shall ensure that retained documented information provides evidence that the products and/or services meet the defined product requirements.**
- **The final acceptance of the product is traceable to an authorized Inspection & Acceptance Inspector.**

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

The organization shall ensure that all documented information required to accompany the products and services are present at delivery.

- **Hasten Applied CNC shall ensure that all documented information required to accompany the products and /or services are present at delivery. This may include supplies and the certificates of compliance with all products shipped.**
- **If a customer requires any additional information. (UL CSA or RoHs compliance)**
- **Hasten Applied CNC will provide any additional documentation as requested by the customer, when available.**

8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization's nonconformity control process shall be maintained as documented information including the provisions for:

- Defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
- Taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;
- Timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;

- Defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).

NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.

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

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

Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:

- After approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;
- After authorization by the customer, if the nonconformity results in a departure from the contract requirements. Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.

Conformity to the requirements shall be verified when nonconforming outputs are corrected

This process is used to ensure that a product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

Detection

- All personnel handling Hasten Applied CNC parts or equipment shall immediately notify management who in turn shall notify the Quality Department, when material, processing or parts fail to meet the specified requirements.
- Identification
- Upon detecting and/or receiving notification of a nonconformance occurrence, the Quality Dept. shall document the nonconformance on a "Rejection Tag". The inspector shall enter the actual description of the non-conformance using the most precise and specific wording that best describes the condition including Hasten assigned Job Number, Vendor Name, and PO #, P/N, Qty., Inspector Name/Stamp and Date.
- The completed "Rejection Tag" shall be attached to the nonconforming items.

Segregation

- After a nonconformance has been documented on a rejection tag the nonconforming item shall be immediately delivered to the designated hold area and will remain on hold until an approved disposition is made. The hold area will be accessible only to personnel approved by Quality Control.

Notification

- The applicable department manager shall be notified of the non-conformances so that provisions for dispositions may be made or to advise the vendor in case the items are to be submitted for vendor disposition.

Customer Returned/Rejected Parts

- Upon receipt of returned or rejected parts, the Receiving Dept. shall move the parts and all related paperwork to the Quality Control Dept.
- The Quality Control Manager shall initiate an investigation detailing all available information pertinent to the returned parts.
- Quality Control will screen all paperwork for accuracy and for possible corrective/preventive action. When necessary, action will be taken to assure compliance of future orders.

Dispositions of use-as-is for the acceptance of nonconforming products shall only be implemented after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent re-entry into the supply chain.

Management is responsible for review and authority for disposition of nonconforming product in Hasten Applied CNC.

- The QA is responsible for disposition of material.
- The President is responsible for contacting customers for concession if nonconforming product is to be used.

8.7.2 The organization shall retain documented information that:

- a) Describes the nonconformity;
 - b) Describes the actions taken;
 - c) Describes any concessions obtained;
 - d) Identifies the authority deciding the action in respect of the nonconformity.
- Hasten Applied CNC uses NCR/CAR System supported by records and Logs to retain information of:
 - a) Describe the nonconformity;
 - b) Describe the actions taken;
 - c) Describe any concessions obtained;
 - d) Identifies the authority deciding the action in respect of the nonconformity.