



Quality Manual ISO 9001-2015

Cedarburg, Wisconsin

Revision: V (2/5/2024)

West Tooling Facility



North Machining Facility



East Machining Facility

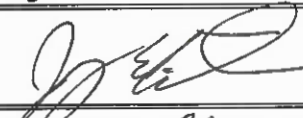
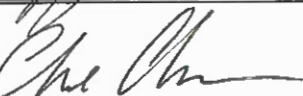


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Management Rep. Chris Andersen	President/CEO Jerry Edquist	Effective Date: 2/5/2024

(CHANGES ARE MARKED IN RED ITALIC TEXT)

SECTION NUMBER	DESCRIPTION
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Approval			
Name	Title	Signature	Date
Jerry Edquist	President/CEO		2/5/2024
Chris Andersen	Director of Quality & Engineering		2/5/2024

SECTION NUMBER	DATE	CHANGE DESCRIPTION	Revision
Section 4.0 Quality Management System	2/5/2024	4.2 Understanding the Needs and Expectation of Interested Parties - Carlson Tool & Manufacturing Corp's internal and external issues and the needs of interested parties are <i>identified during management review and planning meeting</i> , issues can also be identified <i>using</i> risk analysis tools. The outcome is to identify risk facing Carlson Tool & Manufacturing Corp. and/or its interested parties. Such issues are monitored and updated as appropriate and discussed during Management Review Meetings.	V
Section: 5.0 Leadership and Commitment	2/5/2024	Members of Carlson Tool & Manufacturing Corp's Management Team include, <ul style="list-style-type: none"> • President • CFO Chief Financial Officer • Director of Operation • Director of New Customer Development • <i>Human Resource Manager</i> • Director of Quality and Engineering 	V
Section 6.0 Planning	2/5/2024	Planning, Risk and Opportunities - Carlson Tool & Manufacturing Corp. uses the strategic and <i>tactical</i> planning process to evaluate the mission and vision of the company. Furthermore, this process affords us with ability to analyze markets and our competitors, which in turn, allows us to identify strengths, weaknesses, opportunities, and threats while developing key strategic goals. The outcome of these activities is to not only develop a business plan for the near future, but to identify measurements for objectives, develop plans to achieve objectives, and define the direction of the company. Planning activities for the Quality Management System will focus on how to effectively meet quality objectives, customer, <i>statutory and regulatory requirements</i> . In addition, planning activities will also identify risk, opportunities and define actions to assure that:	V
Section 8.0	2/5/2024	8.1 Operational Planning and Control - <i>Quality plans are created by Quality Personnel and when required a cross-functional team lead by the Director of Quality and Engineering or when appropriate the Quality Coordinator., as described in Operating Procedure (OP54001), Quality Planning.</i>	V
Section: 9.0 Performance Evaluation	2/5/2024	9.2 Internal Audit Comprehensive, planned, and documented Quality Audits are carried out. Audits are	V

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		scheduled based on a risk assessment. The Management Representative establishes an Internal Audit Plan and Schedule. At least all elements of the quality management system, including suitable working conditions, are audited over a three-year period. However, more frequent Audits may be scheduled if required.	
Section 11.0 Quality Management System Procedures	2/5/2024	Consolidate Customer Property (West Plant) OP7541 with Customer Property OP7542 Delete reference to Preventive Action	V
Section 4 Quality System	12/13/2021	Added interaction of process step for machining and tooling internal to the quality manual.	U
Section 8 Operations	12/13/2021	8.2.4 Natural occurrences that cannot be controlled can affect Carlson Tool & Manufacturing Corp's ability to meet contractual requirement. In the event of such occurrences the Management Team shall initiate the HW62010 Business Continuation Plan and as required HW62011 Infectious Diseases Business Continuation Plan. The Business Continuation Plan identifies and mitigates the associated risk and includes strategies to protect the interest of all parties involved. 8.4.1 Evaluations of subcontractors are performed as specified in Operating Procedure (OP74101), Evaluation of External Providers. Detailed rules and instructions for the evaluation, re-evaluation, and assessment of subcontractors are given in Operating Procedure (OP74101), Evaluation of External Providers. 8.10 For AS9001 projects, as specified by the contract actions will be taken to prevent foreign object and debris (FOD) contamination or damage.	U
Section 4 Quality System	6/10/2021	The Quality Management System applies to all processes, activities and employees within the organization. This includes the East Plant, North Plant and West Plant operation located at:	T
Section 8 Operations	6/10/2021	For AS9100 projects during all stages of processing actions will be taken to prevent foreign object and debris (FOD) contamination or damage.	T
Section 2 Amendment Description	2/3/2021	Added Approval Table	S
Section 11 Quality Management System Procedures	2/3/2021	Updated listing of operational procedures.	S
Section 8 Operations	11/2/2020	During all stages of processing actions will be taken to prevent foreign object and debris (FOD) contamination or damage.	R
Section 5 Leadership and Commitment	4/18/2019	Updated Management Team Members and Titles to address combining of the Quality and Engineering Management role.	O
Section 5 Leadership and Commitment	7/10/2018	Updated Management Team Members and Title as required.	P
Section 5 Leadership and Commitment	6/12/2018	As required, the customer will be notified of any changes to the Supplier's Quality Management System affecting the loss of registration from a certifying organization, inspection, conformity, and/or airworthiness. In addition, any changes to company ownership, name, location, significant facility change, or changes in Senior and/or Quality Management, shall also be submitted in writing.	O
Section 5 Leadership and Commitment	5/4/2018	Added clause as shown below. 5.3 Customer Notification As required, the customer will be notified of any changes to the Supplier's Quality Management System affecting inspection, conformity, and/or airworthiness. In addition,	N

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		<p>any changes to company ownership, name, location, significant facility change, or changes in Senior and/or Quality Management, shall also be submitted in writing.</p> <p>5.4 Customer Access Carlson Tool and Manufacturing Corp shall grant access to duly authorized customer representatives, appropriate Government or Regulatory Agency Authority to applicable areas of all facilities at any level of the supply chain and to all applicable records pertaining to work performed associated with the respective purchase order.</p> <p>5.5 Source Inspection Carlson Tool & Manufacturing Corp shall support Customer, and/or Government, Regulatory Agency performance of product verification at the Carlson's facility (source inspection) as defined/required by the applicable purchase order. This source inspection may include any one or all of the following, aircraft induction inspection, in-process inspection, and final inspection.</p>	
Section 8 Operation	5/4/2018	<p>Added Clause - 8.6 Frozen Planning - When required, a methodology by which Carlson Tool & Manufacturing Corp will control the manufacturing/production processes to achieve consistent results, by example but not limited to the production of aviation CSI designated features/characteristics of parts and assemblies. This means "freezing" or prohibiting changes to the agreed process plan without appropriate approval.</p> <p>Changed clause for clarification. - 8.14 Control of Nonconforming Outputs -When problems/nonconformities are detected after delivery, Carlson will take appropriate action including investigation in accordance with Operating Procedure (OP85201) Corrective and Preventative Action. The customer will be notified in a timely manner.</p>	N
Section 10 Improvement	5/4/2018	<p>Added Clause - 10.1 Corrective Action and Nonconformity - Corrective Action Request from the Customer, Government and/or Regulatory Agency will be process in accordance with Operating Procedure (OP85201), Corrective and Preventive Action, and the requirements specified by the purchase order.</p>	N
Section 5 Leadership	11/20/2017	<p>Added the following based on outcome of a document audit. Section 5.3 Add these items to list. Company Website, Feedback to external providers, status reports to customers.</p>	M
Section 7 Support	11/20/2017	<p>Changed made to clarify based on the outcome of the documents audit. Section 7.11 Carlson Tool & Manufacturing Corp's Quality Management System will include information required by the ISO 9000-2015 Standard and documented information determined to be required for the effective operation of the company.</p>	M
Section 8 Operation	11/20/2017	<p>Deleted clause based on outcome of the document audit. Section 8.5 - Servicing is not applicable to our business at this time.</p> <p>Modified Clause to make reference to property supplied by external sources Section 8-8 Customer's intellectual property is protected through the means of confidentiality agreements with customers, employees, supplier, and subcontractors. Records of confidentiality are maintained. Other measures to safeguard intellectual property are taken as required.</p> <p>Customer products used for incorporation into finished products or for related activities are handled in the same manner as other purchased products. When specified in a contract, special handling instructions from customers will take precedent over Carlson Tool & Manufacturing Corp's standard procedures. Loss, damage or unsuitability of a customer's products is recorded and reported to the customer.</p>	M
Section 9 Performance Evaluation	11/20/2017	<p>Updated management review inputs per document audit. Section 9.3 Process and product performance. Customer Satisfaction, feedback from interested parties. Nonconformity and corrective action. Results of internal and external audits. Changes to the quality management system. Assessment of the quality management system.</p>	M

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		<p>Improvement. The effectiveness of actions taken to address risk and opportunities. Adequacy of resources. Follow-up on open items from last meeting.</p> <p>Management Review Outputs. Added reference to management review outputs. Output from Management Reviews may lead to actions that address; Opportunities for improvement. Need for changes to the quality management system. Identify resources needs.</p>	
Section 10 Improvement	11/20/2017	<p>Deleted the following clause based on outcome of documents audit. 10.2 Preventive Actions Preventive action is initiated as a result of analysis of appropriate sources of information, such as process and work operations which affect product quality, concessions, audit results, quality records, and customer complaints. Preventive actions may also arise as a result of a corrective action on a similar product or process. Each corrective and preventive action is followed-up to the degree necessary to determine if the corrective action has been implemented and if it is effective. The process of issuing a Corrective Action Request, documenting the proposed action and the follow-up are governed by Operating Procedure (OP85201), Corrective and Preventive Action.</p>	M
Section 1 Table of Contents	11/1/2017	Updated to comply with ISO 9001-2015	
Section 2 Amendment Description	11/1/2017	Updated to comply with ISO 9001-2015	
Section 3 Forward	11/1/2017	Updated to comply with ISO 9001-2015	
Section 4 Quality Management System	11/1/2017	Updated to comply with ISO 9001-2015	
Section 5 Leadership	11/1/2017	Updated to comply with ISO 9001-2015	
Section 6 Planning	11/1/2017	Updated to comply with ISO 9001-2015	
Section 7 Support	11/1/2017	Updated to comply with ISO 9001-2015	
Section 8 Operation	11/1/2017	Updated to comply with ISO 9001-2015	
Section 9 Performance Evaluation	11/1/2017	Updated to comply with ISO 9001-2015	
Section 10 Improvement	11/1/2017	Updated to comply with ISO 9001-2015	
Section 11 Quality Management System Procedures	11/1/2017	Updated to comply with ISO 9001-2015	
Section: 5 Title: Management Responsibility	12/9/2016	Updated Section 5.5 Meeting requirements of the standard, the company's quality policy, stated objectives, customer satisfaction, And by providing the resources and personnel necessary to maintain the system. Clarified Meeting Names –Responsibility	
Title: Quality Management System Procedures Section: 9	12/9/2016	Added reference to Infrastructure OP63001 Lockout/Tag-out Procedure OP63002 General Machine Guarding Requirements for all Machines OP63003 Safety Policy and Procedures for East Plant OP63004 Preservation of Product (Handling – Storage -Packaging & Delivery) OP75501	
Section: 8 Title: Measurement, Analysis and Improvement	12/9/2016	Added reference to OP83003 10 CFR Part 21: Reporting Defects & Non-compliance.	
Section: 4 Management System Section Resource Management	11/13/20104	Change from OP42101 to Operating Procedure (OP42001) Quality System Documentation. Eliminated reference to safety follow up form that is now being tracked on report. Eliminated Reference to Grid Mold Manufacturing. Eliminated Reference to 10 CFR part 21 and urgent release of product.	
Section: 8	3/15/2012	Added reference to OP83003 10 CFR Part 21: Reporting Defects & Non-compliance and	

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Title: Measurement, Analysis and Improvement		document number changes to OP41301 to OP83001 and OP41302 TO OP83002.	
Title: Quality Management System Procedures Section: 9	11/5/2011	Added reference to OP75402 Customer Property (East Plant)	
Section: 5 Title: Management Responsibility	11/5/2011	Added reference to exe management team Tile Change East Plant General Manager and addition of Director of Sales and Marketing.	
Section: 7 Title: Product Realization	11/5/2011	Added reference to OP75402 Customer Property (East Plant)	
Section: 8 Title: Measurement, Analysis and Improvement	11/5/2011	Added reference to OP83002 Control of Nonconforming Material (East Plant).	
Section: 5 Title: Management Responsibility	6/8/2010	Update the Quality Policy to incorporate First Time Correct performance.	
Section: Title 4 Quality Management System	09/18/2009	Update to address ISO 900-2008 requirements.	
Section: 8 Title: Measurement, Analysis and Improvement	09/18/2009	Update to address ISO 900-2008 requirements and clarify monitoring and measurement of processes.	
Section 6.0 Title: Resource Management	09/18/2009	Update reference to business continuation planning.	
Section: 3.0 Title: Foreword	09/18/2009	Update the Vision and Mission Statements.	
Section: 3.0 Title: Foreword	03/09/2009	Update the Quality Policy to incorporate First Time Correct performance.	
Section: 5 Title: Management Responsibility	1/31/2009	Update management review to address meeting attendees, and input and output including first time correct status.	
Section 4 Quality System	11/20/03	Added Clauses to address exclusions and review, updating and re-approval of documents. Documents are subject to review during internal auditing. Documents will be updated as required and re-approved by the issuing authority. Service Provision as define in section 7.5.1 is not applicable to our business.	
Section 5 Management Responsibility	11/20/03	Added Clauses to address Management Review Input and Outputs	
Section 7 Product Realization	11/20/03	Added Clauses to address re-evaluation of subcontracts and service provision.	
All sections replaced.	9/01/03	All section replaced by revision to address conversion to ISO 9001 -2000	
Section 4.10	5/8/2000	Add reference to name change to Deep hole Gun drilling Procedures to eliminate Contract Machining Procedures for in process and final inspection.	
Section 4.4	4/14/2000	Add reference to Design Control (Grid Molds)	
Section 4.3	3/20/2000	Add reference to new structure	

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3.0 Introduction

From the beginning, people have made the difference at Carlson Tool & Manufacturing Corp. When its' founder, Carl Edquist, first opened the doors in 1958, his business philosophy was simple, give customers the best value in tooling by merging skilled and dedicated people with the most up-to-date technology. That philosophy is still reflected today in Carlson Tool & Manufacturing Corp's Mission Statements.

Carlson was originally founded as a tool and die job shop that specialized in building plastic injection molds and aluminum die-cast dies where commitment to high standards, quality, and customer satisfaction was always at the forefront of every job. Since its inception, Carlson has remained dedicated to these standards and guidelines. As our company and business has grown, our services have expanded to include gun-drilling, deep-hole boring, contract machining, contract CMM inspection services, and design/engineering assistance. Never content to be complacent, we continue to innovate and improve what we offer. Throughout the years, we have consistently Gone the Distance to do more than merely meet our customers' demands and specifications. Instead, we make a commitment to not only exceed expectations, but to truly get to know and understand our customers' needs and provide them with quality products and services. Our dedication drives our daily activities, and we strive to provide our clients with exactly what that they need and when they need it. Every day we seek to build strong relationships based on quality products and service and continuously strive to demonstrate why at Carlson Tool, Made in the USA-Starts Here.

One of the key strategies that Carlson Tool & Manufacturing Corp. has invested in is the development, implementation, and operation of an effective Quality Management System across all areas of the organization. The Quality Management System is intended to improve and sustain the overall performance of the business, products and services.

The expected outcomes of the Quality Management System are:

- The ability to consistently provide products and services that meet the customer and applicable statutory and regulatory requirements.
- To facilitate opportunities to enhance customer satisfaction.
- To identify and address opportunities for improvement.
- To foster an approach, where process planning, and their interactions incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking; and
- The ability to demonstrate conformity to relevant quality management system requirements.

Carlson Tool & Manufacturing Corp. utilizes Quality Management Principles in the daily operation of the business. These Quality Management Principles provide an underlying basis to provide on-going improvement of the business.

The Quality Management Principles are:

- Customer focus.
- Leadership.
- Engagement of people.
- Process approach.
- Improvement.
- Evidence-based decision making.
- Relationship management.

The purpose of the Quality Manual is to:

- Communicate the organization's Quality Policy, procedures, and requirements.
- Describe and implement an effective quality system.
- Provide improved control of practices and facilitate assurance activities.
- Provide the documented basis for auditing the quality system.

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- Provide continuity of the quality system and its requirements during changing circumstances.
- Train personnel in the quality system requirements and methods of compliance.
- Present the quality system for external purposes, such as demonstrating compliance with ISO 9001-2015; and
- Demonstrate compliance of the quality system with quality requirements in contractual situations.

3.1 Process Approach

Carlson Tool & Manufacturing Corp. fosters the use of a process approach during the development, implementation and while improving the effectiveness of the Quality Managements System.

The application of the process approach enables:

- Understanding and consistency in meeting requirements.
- The consideration of the processes in terms of adding value.
- The achievement of effective process performance; and
- Improvement activity based on the evaluation of data and information.

3.2 Plan-Do-Check-Act Cycle

The operation of the Quality Management System is achieved by using the Plan-Do-Check-Act (PDCA) cycle with a focus on risk-based thinking, leveraging opportunities and preventing undesirable results.

(PDCA) Closed Loop Cycle can be briefly described as follows:

- **Plan:** Establish the Quality Objectives relevant to Quality Management System and its processes, plan for the resources needed to deliver results in accordance with customers' requirements and organizational policies, identify and address business risks and opportunities.
- **Do:** Implement what was planned.
- **Check:** Monitor and (where applicable) measure the processes, the resulting products and services against policies, objectives, requirements, and planned activities, and report the results; and
- **Act:** Close the loop by taking actions to improve the Quality Management System's performance, as necessary.

3.3 Risk-Based Thinking

Risk-based thinking is integral to operation of an effective Quality Management System. Planning and implementation of actions to address both risks and opportunities creates a basis that increases the effectiveness of the Quality Management System, by achieving improved results and prevent negative effects.

3.4 Normative References

The following documents in whole or in part, are normatively referenced in this document. Only edited content in its latest edition applies including any amendments. ISO 9000:2015, Quality Management Systems — Fundamentals and vocabulary.

3.5 Terms and Definitions

For the purpose of this Quality Manual, the terms and definitions given in ISO 9000:2015 apply to this document.

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3.6 Commitment and Support

The Quality Management System has the support of Carlson Tool & Manufacturing Corp. Management. Compliance with the Quality Management System requirements as defined in manuals, procedures and instructions are developed to support it is mandatory for all functions and personnel of Carlson Tool & Manufacturing Corp.

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4.1 Context of the Organization

Through the strategic and operational planning process, Carlson Tool & Manufacturing Corp. identifies external and internal issues that are relevant to the purpose and direction of the organization and identifies how they affect the ability to achieve intended results.

The Organizational Context involves:

- Understanding Carlson Tool & Manufacturing Corp's core products and services.
- Identifying "interested parties" (stakeholders) as those who receive our products, may be impacted by them, or parties who may otherwise have a significant interest in the organization.
- Identifying and understanding the needs and expectations of interested parties; and
- Determining the scope of the quality management system.

Carlson Tool & Manufacturing Corp. identifies interested parties as follows:

- Customers
- Owners
- Employees
- Suppliers
- Community

4.2 Understanding the Needs and Expectation of Interested Parties

Carlson Tool & Manufacturing Corp's internal and external issues and the needs of interested parties are **identified during management review and planning meeting**, issues can also be identified *using* risk analysis tools. The outcome is to identify risk facing Carlson Tool & Manufacturing Corp. and/or its interested parties. Such issues are monitored and updated as appropriate and discussed during Management Review Meetings.

4.3. Scope of the Quality Management System

Management determines the boundaries and application of Quality Management System to establish its' scope by considering:

- The external and internal issues referred to in Clause 4.1 of the ISO 9001:2015 Standard.
- The requirements of relevant interested parties referred to in Clause 4.2 of the ISO 9001:2015 Standard.
- Consistency in the quality of the applicable products and services of our Company.
- Customer satisfaction through effective application of the Quality Management System.
- All statutory, regulatory and/or legal requirements; and
- Establishment of suitable processes for improvement of the Quality Management System.

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, Carlson Tool & Manufacturing Corp. has determined the scope of the Management System as follows:

Scope: Product design services; design and manufacture of molds and tooling for the plastics/metals industries; and contract machining services.

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4.3. Scope of the Quality Management System (Cont.)

Facilities within the Scope of the Quality Management System

The Quality Management System applies to all processes, activities, and employees within the organization. This includes the East Plant, North Plant and West Plant operation located at:

W57 N14386 Doerr Way

Cedarburg, WI 53012-0085

Phone: (262) 377-2020

www.CarlsonTool.com

4.4 Quality Management System and it's Processes.

Operating Procedure (OP42001), Quality System Documentation defines a Quality Management System that complies with ISO 9001-2015 requirements, regulatory requirements, for certifying agencies, to ensure planning, operation, and control of processes is maintained.

The Quality Management System defines:

- The processes needed.
- Their sequence of interactions.
- Performance indicators.
- Resources needed.
- Responsibilities/authorities.
- How risk and opportunities are determined.
- How processes and changes implemented achieve their intended results; and
- How a Quality Management System processes are improved.

Quality Management System Structure includes:

- Quality Policy.
- Quality objectives.
- Quality manual.
- Operating procedures.
- Work instructions, process procedures and internal standards.
- Applicable national, international, and industry standards.
- Product technical specifications and drawings.
- Production and quality plans; and
- Customer supplied documentation such as drawings, specifications, test procedures, work instructions, inspection instructions, etc.

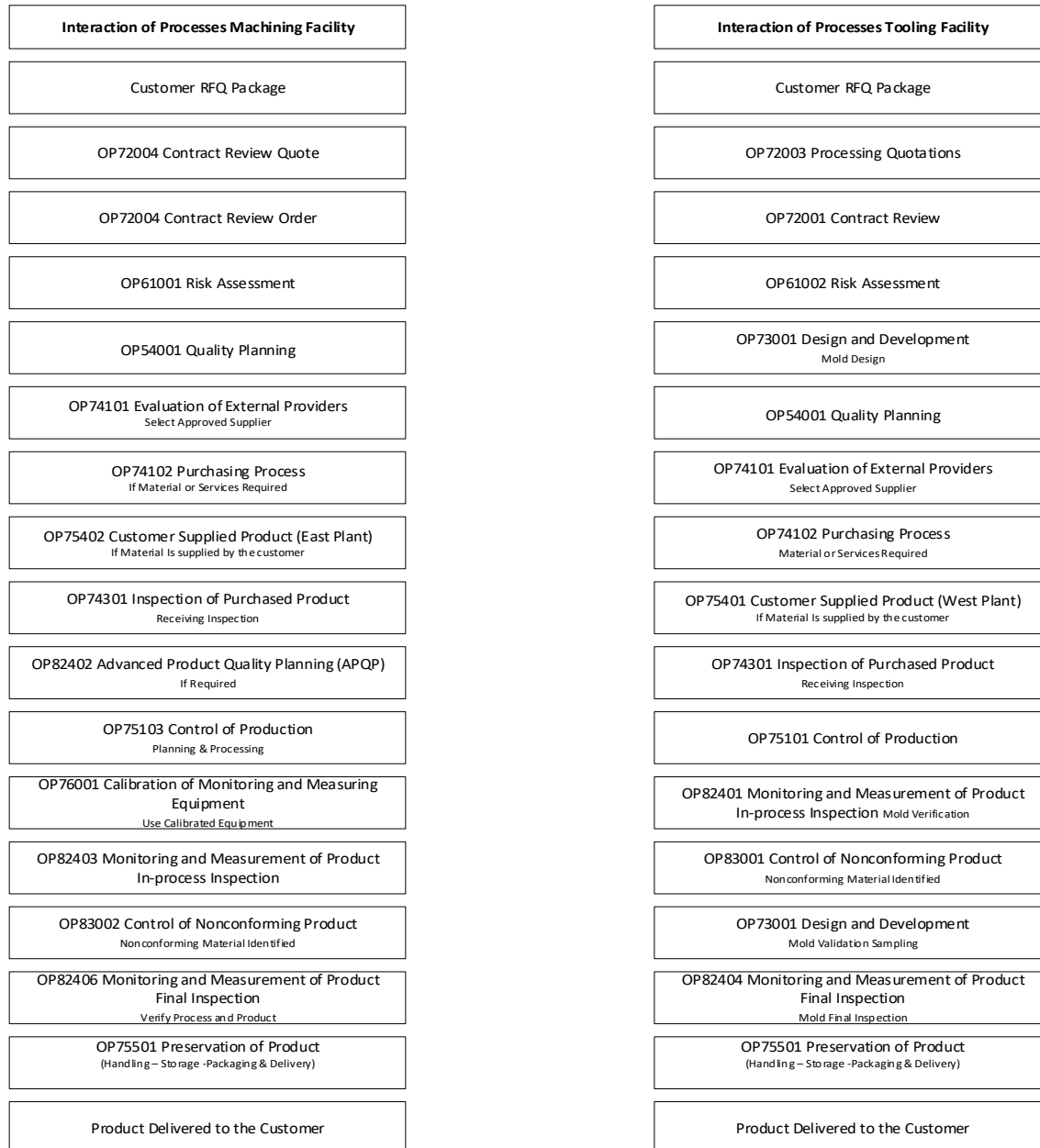
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4.5 Quality Manual

The Management Team shall establish and maintain the Quality Manual to:

- Define the scope of the quality system including justification for any exclusion.
- Identify and reference operating procedures established for the Quality Management System.
- Define the sequence and interaction of the processes within the quality system as shown below.

The Quality System is process based. A process is a series of activities that supply a deliverable product or a service to a customer (internal or external) of the process. A process has a beginning (input data) and an end (output data).



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Title: Leadership and Commitment

5.1 Leadership and Commitment

The Management Team shall provide evidence of its leadership and commitment to the development and implementation of the Quality Management System and continually improve its effectiveness by:

- Ensuring the integration of the Quality Management System in the organizations business process.
- Being accountable for the effectiveness of the Quality Management System.
- Establishing the Quality Policy and Quality Objectives that are in alignment with context and strategic direction of the organization.
- Promoting the use of the process approach and risk-based thinking.
- Communicating to the organization the importance of compliance with the Quality Management System, meeting customer, statutory and regulatory requirements.
- Ensuring the availability of resources.
- Ensuring that the Quality Management System achieves its' intended results.
- Engaging, directing and supporting personnel to contribute to the effectiveness of the Quality Management System.
- Promoting and supporting improvement initiatives; and
- Supporting Management roles to demonstrate leadership in their areas of responsibility.

5.2 Customer Focus

The Management Teams demonstrates leadership and commitment by ensuring that customer requirements are determined, understood and met with the objective of enhancing customer satisfaction.

For all order types, contract review is comprised of verification that the customer's requirements are adequately defined, documented, understood, can be agreed to, and that the Carlson Tool & Manufacturing Corp. has the capacity to meet the contractual requirements. Any differences between the contract and those in the quotation are resolved. Contract reviews are governed by Operating Procedure (OP72001), Contract Review – West Plant, and Operating Procedure (OP72004), Contract Review – East Plant.

5.3 Customer Notification

As required, the customer will be notified of any changes to the Supplier's Quality Management System affecting the loss of registration from a certifying organization, inspection, conformity, and/or airworthiness. In addition, any changes to company ownership, name, location, significant facility change, or changes in Senior and/or Quality Management, shall also be submitted in writing.

5.4 Customer Access

Carlson Tool and Manufacturing Corp shall grant access to duly authorized customer representatives, appropriate Government or Regulatory Agency Authority to applicable areas of all facilities at any level of the supply chain and to all applicable records pertaining to work performed associated with the respective purchase order.

5.5 Source Inspection

Carlson Tool & Manufacturing Corp shall support Customer, and/or Government, Regulatory Agency performance of product verification at the Carlson's facility (source inspection) as defined/required by the applicable purchase order. This source inspection may include any one or all of the following, aircraft induction inspection, in-process inspection, and final inspection.

5.6 Quality Policy

The Management Team establishes implements and maintains a Quality Policy that:

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- Is appropriate for the purpose, context and supports the strategic direction of the organization.
- Provides a framework for setting quality objectives.
- Includes a commitment to customer satisfaction; and
- Includes a commitment to continual improvement.

Quality Policy - We define quality as conformance to requirements. Our objective is to achieve customer satisfaction by providing **First Time Correct** products and services. This is achieved through the continuous improvement of our people and processes.

Communicating the Quality Policy and Objectives

Carlson Tool & Manufacturing Corp's Management Team shall provide communication to the organization regarding the effectiveness of the Quality Management System. Internal and external communication is provided through the media and forums shown below.

- Quality Policy,
- Quality Performance Charts,
- Customer Satisfaction Results,
- Operational Meetings,
- Planning Meetings,
- Management Reviews,
- Company Website,
- Feedback to external providers,
- Status reports to customers,
- Intranet, and
- Postings.

5.4 Roles, Responsibility and Authorities

Interrelation of personnel who lead, perform, and verify work-affecting quality is defined as shown below.

Members of Carlson Tool & Manufacturing Corp's Management Team include,

- President
- CFO Chief Financial Officer
- Director of Operation
- Director of New Customer Development
- *Human Resource Manager*
- Director of Quality and Engineering

The Management Team and authorized designees have the organizational freedom and authority to:

- Formulate the Quality Policy, business plan and objectives.
- Define organizational interfaces.
- Assign authorities and responsibilities.
- Appoint the Management Representative.
- Foster continuous improvement through corrective actions.
- Cultivate teamwork and cooperation at all levels creating a positive work environment.
- Periodically reviewing the quality system's effectiveness.
- Provide internal communication relative to effectiveness of the Quality Management System.

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- Meet requirements of the industrial standard, the Carlson Tool & Manufacturing Corp's Quality Policy, stated objectives and customer satisfaction.
- Provide the resources and personnel necessary to maintain the system.

Management Representative

Carlson Tool & Manufacturing Corp's Management Team appoints as the Management Representative the Quality Manager. The Quality Manager has the authority and responsibility to:

- Ensure that the Quality System is established, implemented, and maintained in accordance with the requirements of the ISO 9001 - 2015 standard.
- Report on the performance of the quality system to the Management Team.
- Retain the organizational freedom to identify problems related to quality and consequently correct, initiate action for their correction, or stop any work or activity that violates the established quality standards.

Section: 6.0	Revision: V	Title: Planning
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6.1 Planning

Planning, Risk and Opportunities

Carlson Tool & Manufacturing Corp. uses the strategic and *tactical* planning process to evaluate the mission and vision of the company. Furthermore, this process affords us with ability to analyze markets and our competitors, which in turn, allows us to identify strengths, weaknesses, opportunities, and threats while developing key strategic goals. The outcome of these activities is to not only develop a business plan for the near future, but to identify measurements for objectives, develop plans to achieve objectives, and define the direction of the company.

Planning activities for the Quality Management System will focus on how to effectively meet quality objectives, customer, *statutory and regulatory requirements*. In addition, planning activities will also identify risk, opportunities and define actions to assure that:

- Actions are integrated and implemented into processes.
- The Quality Management System can achieve its intended results.
- Desirable effects will be enhanced.
- Undesired effects will be reduced or prevented.
- Improvement is fostered.
- Effectiveness of actions is evaluated.

Carlson Tool & Manufacturing Corp's Business and Quality Management System planning process is governed by Operating Procedure (OP54002) Business Planning.

6.2 Quality Objectives

The Management Team shall ensure that quality objectives including those needed to meet product requirements are established at relevant functions and levels within the organization. Quality Objectives shall be measurable, monitored, communicated, and support the Quality Policy and needs of the Carlson Tool & Manufacturing Corp. Quality Objectives are updated as required.

When Quality Objectives are established, the following will be taken into consideration:

- The current and future needs of the business, industry and interested parties.
- Findings from internal audits and management reviews.
- Product and process performance such as (effectiveness, efficiency, and conformance).
- Customer satisfaction.
- Results of Strategic Planning and
- Quality performance.

When planning how to achieve a Quality Objective the following actions will be determined:

- What needs to be done.
- What resources are required.
- Who will be responsible or the owner of the objective.
- When will the objective be completed; and
- How will the results be measured and evaluated.

Activity associated with development, monitoring and measuring of quality objectives for the Quality Management System are described in Operating Procedure (OP82301), Monitoring & Measurement of Processes.

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Title: Planning

6.3 Planning of Changes

Changes to the Quality Management System will be developed and implemented in a planned manner.

During the change process the following will be taken into consideration:

- The reason for the change and the potential effects.
- The integrity of the quality management system.
- The availability of resources; and
- The assignment or reassignment of responsibilities and authorities.

Planning activities for product specific quality plans are described in Operating Procedure (OP54001), Quality Planning.

Section: 7.0

Revision: V

Title: Support

7.1 Resources

The Management Team considers the capabilities and constraints on internal resources when determining the competency and training requirements necessary for effective management, product realization, and verification activities, which includes internal audits. In addition, management evaluates resources needed from external providers. The Management Team will provide adequate resources to achieve Carlson Tool & Manufacturing Corp's objectives and conformity to product requirements.

The methods used to identify and provide necessary resources include strategic planning, annual budget planning, weekly staff meetings, and production meetings.

Management will communicate to all employees the relevance and importance of their work and contributions to achieving quality objectives and required product conformity.

7.2 People

The Management Team will determine and provide personnel necessary for the effective implementation and operation of the Quality Management System processes to achieve Carlson Tool & Manufacturing Corp's objectives and conformity product requirements.

7.3 Infrastructure

The Management Team identifies the infrastructure necessary to meet the needs of the business. Resources and personnel will be provided to develop and maintain the infrastructure to assure that needs of the Carlson Tool & Manufacturing Corp's, quality objectives and product requirements are achieved. The infrastructure includes:

- Building, workspace, and associated utilities.
- Process equipment, including both hardware and software.
- Supporting services like transportation resources; and
- Communications and information technology.

Consideration will be made for environmental issues associated with the infrastructure such as conservation, waste, and pollution and recycling as required.

Natural occurrences that cannot be controlled can affect the infrastructure. In the event of such occurrences the Management Team shall initiate the EW40900 Business Continuation Program. The Business Continuation Plan identifies and mitigates the associated risk and includes strategies to protect the interest of all interested parties involved.

7.4 Environment for the Operation of Processes

Management Team shall determine, provide, and manage the environment that is suitable for the operation to achieve, quality objectives and conformity to product requirements. Factors considered determining the type of environment required is based on the:

- Business culture, social and psychological needs.
- Processing performed in the location.
- Equipment requirements.
- Level of skill, number of employees working in the area.
- Type of environmental conditions, e.g., lighting, heat, humidity, sound levels, and air quality.
- Risk associated with processing or equipment operation regarding safety.
- Ergonomics.

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7.4 Environment for the Operation of Processes (Cont.)

The Management Team identifies and establishes safety initiatives. The Human Resources coordinates safety initiatives with and through the Emergency Response Team.

Safety inspections are conducted to identify unsafe work conditions. The Emergency Response Team performs safety inspections and findings are recorded on form (HF63001) Carlson Tool & Manufacturing Corp's Safety and Housekeeping Worksheet. Issues identified during safety inspection are recorded and findings and action are reported to Management.

All personnel are expected to report work environment changes to Management that could result in unsafe conditions. These conditions may inhibit the ability to achieve Carlson Tool & Manufacturing Corp's objectives or conformity to product requirements. Corrective action shall be taken to restore the work environment back to its intended function.

The following Operating Procedures define the requirements to assure that infrastructure and environment will allow Carlson Tool & Manufacturing Corp. to achieve organization objectives.

Infrastructure	OP63001
Lockout/Tag-out Procedure	OP63002
General Machine Guarding Requirements for all Machines	OP63003
Safety Policy and Procedures for East Plant	OP63004
Human Resources (Competence, training and awareness)	OP62001
Control of Production (West Plant Molds)	OP75101
Control of Production (East Plant)	OP75103
Preservation of Product (Handling – Storage -Packaging & Delivery)	OP75501

7.5 Monitoring and Measuring Resources

The Quality Group manages the equipment calibrations system to ensure that monitoring and measurement activities to verify product conformity are valid and reliable.

The Quality Group ensures that measuring and test equipment is provided to those performing the measuring activity. Moreover, the equipment will be suitable for the monitoring and measurement activities and that it is maintained and calibrated to appropriate standards.

Records of equipment calibration are maintained in accordance with Operating Procedure (OP76001), Control of Monitoring and Measuring Equipment; and Operating Procedure (OP42401), Record Control.

7.6 Measurement Traceability

All equipment used for inspection, measuring, and testing of products is identified and calibrated under suitable environmental conditions, and at prescribed intervals with traceability to measurement standard provided by the National Institute of Standards and Technology. When standards do not exist, record for the basis used for calibration will be retained.

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7.6 Measurement Traceability (Cont.)

The process employed for calibration is defined by Work Instructions and the Equipment Control Database. These include the equipment:

- Type,
- Identification,
- Location,
- Frequency of checks,
- Check method, and
- Acceptance criteria.

Calibration stickers or colored dots are affixed to equipment to identify their calibration status.

Measuring and test equipment is handled, preserved, stored, and safeguarded from adjustments to preserve its accuracy and fitness for use.

When measuring and test equipment is found to be out of tolerance/calibration, an assessment of the validity of previous measurements of effected products is assessed and action will be taken as required.

Operating Procedure (OP76001), Control of Monitoring and Measuring Equipment, regulates all activities associated with the monitoring, control and calibration of measuring and test equipment.

7.7 Organizational Knowledge

Carlson Tool & Manufacturing Corp. determines the knowledge necessary for the operation of its processes and to achieve conformity of products and organizational objectives. This may include knowledge and information obtained from:

Internal sources, such as:

- Intellectual property,
- Feedback and lessons learned,
- On the job and cross training,
- Project and design reviews,
- Product noncompliance,
- Continuous improvement activity, and
- Internal and External Audit results.

External sources such as:

- Customer standards,
- Industrial standards,
- Statutory and regulatory requirements,
- Subject matter experts,
- Conferences,
- Academia, and
- Third party audit results.

Organizational knowledge is retained and made available through reports, spreadsheets, databases, work instructions, procedures and standards.

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7.7 Organizational Knowledge (Cont.)

When addressing changing needs and trends, Carlson Tool & Manufacturing Corp. will consider its' current knowledge and determine if additional knowledge is required and if so, how it will be acquired or accessed.

Operating Procedure (OP71002), Knowledge Management, defines activities associated with the assessment, storage, accessing and acquiring organizational knowledge.

7.8 Competence

The Human Resources Group shall:

- Determine competency requirements by role.
- Document competency requirements in the job description.
- Ensure personnel performing specific roles are qualified on the basis of appropriate education, training and/or experience.
- Evaluate an employee's competency through an annual management assessment and performance evaluation process.
- Take actions to acquire the necessary competence when gaps or needs are identified.
- Evaluate the effectiveness of action taken; and
- Retain records to provide evidence of competence.

The Human Resource Group and respective manager identifies training required for person's performing activities affecting quality and provides the required training to satisfy competency needs. Records of personnel training are maintained.

Carlson Tool & Manufacturing Corp. provides new employee orientation and training. Other training is provided as required. There is also a reimbursement program for employees who desire to upgrade their competence through external education or training.

Effectiveness of training is evaluated. Indications of successful training would be such things as passing grades for course work, reduced error rates, better understanding of the role of an operation or process in providing customer satisfaction, and reduced processing or cycle time.

Records of internal and external training provided to employees are maintained in the Training Manager Database.

Operating Procedure (OP62001), Human Resources (Competence, Training and Awareness), describes in detail the processes used for the identification of competency/training needs, programs and makes reference to training policies of Carlson Tool & Manufacturing Corp.

7.9 Awareness

Carlson Tool & Manufacturing Corp. ensures that employees are aware of:

- The Quality Policy.
- Quality objectives and results.
- Their contribution to the effectiveness of the Quality Management System.
- The benefits of improved Quality System Management Performance.
- The significance of nonconformance with the Quality Management System requirement; and
- Safety procedures, goals, and results.

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7.10 Communication

Carlson Tool & Manufacturing Corp's Management shall provide communication to the organization regarding the effectiveness of the Quality Management System. Communication is provided by example, through the media and forums shown below:

- Operational meetings,
- Planning meetings,
- Safety meetings,
- Management reviews,
- One on one meetings,
- Performance reviews,
- Resource group meeting,
- Intranet, and
- Screen savers and postings.

7.11 Documented Information

Carlson Tool & Manufacturing Corp's Quality Management System will define the documented information required by the ISO 9000-2015 Standard to assure effective operation of the company.

7.11.1 Creating and Updating Documented Information

Documents required for the Quality Management System are controlled; processes have been established and implemented for maintenance of documents and data as described in Operating Procedure (OP42301), Control of Documents. These documents outline controls for:

- Approving documents for adequacy prior to issue.
- Reviewing, updating when necessary, and re-approving, by the same function, such documents, and identify revisions.
- Ensuring that relevant versions of applicable documents are available at point of use.
- Ensuring that documents remain legible, readily identifiable and retrievable.
- Preventing the unintended use of obsolete documents and their retention period.
- Maintaining suitable identification of obsolete documents as necessary.
- Establishing and maintaining a master index to identify current revision of all procedures.

Documents and document changes may be initiated by anyone in the organization but may only be issued by an authorized department manager as defined in Operating Procedure (OP42001), Quality System Documentation, and Operating Procedure (OP42301), Control of Documents. All documents are reviewed and approved prior to issue. Documents and data are distributed to personnel and locations where they are used. When appropriate and relevant, a distribution list is maintained. Document placement is regulated.

Document changes are reviewed and authorized by the same authority that issued the original document. Customer design changes and modifications are processed per the Contract Review Procedures. Engineering Team reviews and approves the changes, and processes any changes required in Carlson Tool & Manufacturing Corp's documentation. Revised portions of documents are distributed with a change brief, and obsolete documents are removed. A Master List is maintained specifying the latest issues and revisions of its' documents.

At a minimum, documents are subject to review during internal auditing. Documents will be updated as required and re-approved by the issuing authority.

Obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified.

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7.11.2 Control of Documented Information (Records)

Controls relevant to Documented Information (Records) required for the Quality Management System are established and implemented for maintenance of documents and data as described in Operating Procedure (OP42401), Record Control.

- Record control is established, implemented, and maintained for storage, protection, retrieval, retention period, and disposal as defined in Operating Procedure (OP42401), Record Control, of the records.
- The records shall be identifiable to the product or process involved.
- When required documents of external origin will be controlled.
- They shall be stored in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss.
- Records are to be maintained and retained as defined in the record index or as specified by applicable industry standard.

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Title: Operation

8.1 Operational Planning and Control

Quality plans are created by Quality Personnel and when required a cross-functional team lead by the Director of Quality and Engineering or when appropriate the Quality Coordinator., as described in Operating Procedure (OP54001), Quality Planning.

Inspections and tests are performed with controlled and calibrated equipment. Records of inspections are established and maintained to provide evidence that products comply with stated requirements.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Carlson Tool & Manufacturing Corp's communication with customers may include:

- Providing information related to the products and services offered.
- Addressing inquiries, contract, or order changes.
- Obtaining customer feedback related to products and/or services offered, including customer complaints.
- Handling and controlling customer property; and
- Establishing requirements for contingency actions, when relevant.

8.2.2 Customer Feedback

Customer feedback activity is monitored, and records are maintained as described in Operation Procedure (OP82101), Customer Satisfaction. Feedback measurements include customer complaint count/cost, warranty claims/cost, account debits/back charges and customer compliments. Customer feedback data is used to identify areas within Carlson Tool & Manufacturing Corp. that require improvement. Results are reported during Management Review.

8.2.3 Customer Property

Customer's intellectual property is protected through the means of confidentiality agreements with customers, employees, supplier, and subcontractors. Records of confidentiality are maintained. Other measures to safeguard intellectual property are taken as required.

8.2.4 Contingency Actions

Natural occurrences that cannot be controlled can affect Carlson Tool & Manufacturing Corp's ability to meet contractual requirement. In the event of such occurrences the Management Team shall initiate the HW62010 Business Continuation Plan and as required HW62011 Infectious Diseases Business Continuation Plan. The Business Continuation Plan identifies and mitigates the associated risk and includes strategies to protect the interest of all parties involved.

8.2.5 Determining Requirements for Products and Services

Reviews of customer information typically provided in the form of a request for quotation (RFQ) is evaluated to determine the requirements that need to be achieved. These include determining statutory and regulatory requirements, those requirements necessary to the company for order fulfillment and that the claims for the product and services can be achieved.

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8.2.6 Review of Requirements for Product and Services

Reviews of customer information comprises of a verification to determine that the customer's requirements are adequately defined, documented, understood, can be agreed to, and that the company has the capacity to meet contractual requirements. Any differences between the contract and those in the Quotation are resolved.

Input requirements, including applicable statutory and regulatory requirements, are identified, documented, and reviewed for adequacy. Incomplete, ambiguous, or conflicting requirements are resolved. The results of proposal, tender and contract review activities are taken into consideration.

8.2.7 Changes to Requirements for Products and Services

Changes made to contracts and/or products are reviewed to assure that requirements are adequately defined, documented, understood, can be agreed to, and that the company has the capacity to meet such. Departments affected by the change are notified.

Persons conducting reviews shall make a record of each review. Details for the review process including the establishment and maintenance of contract review records are provided in Operating Procedure (OP72001), Contract Review – West Plant, and Operating Procedure (OP72004), Contract Review – East Plant.

8.3 Design and Development

All product design services, and design control activities are specified and governed as indicated in Operating Procedure (OP70301), Design and Development (Molds) (West Plant). The activities included those listed below.

8.3.1 Design and Development Planning

Plans are prepared for each design and development activity, which describe the activity, and define the responsibility for their implementation. The activities are assigned to qualified personnel equipped with adequate resources. The plans are updated as necessary, as the design evolves.

The organizational and technical interfaces between different groups, which provide input into the design process, are defined and the necessary information documented, transmitted, and regularly reviewed.

8.3.2 Design and Development Inputs

Design input requirements, including applicable statutory and regulatory requirements, are identified, documented, and reviewed for adequacy. Incomplete, ambiguous, or conflicting requirements are resolved. The results of proposal, tender and contract review activities are taken into consideration.

8.3.3 Design and Development Controls

Formal reviews of the design are planned and conducted at appropriate stages of the design. Participants include representatives of all functions concerned with the design stage being reviewed, as well as other specialist as required. Records of the reviews are maintained.

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8.3.4 Design and Development Verification

The design is verified at appropriate stages to ensure that the outputs meet the input requirements. Design verifications may include:

- Performing alternative calculations.
- Undertaking tests and demonstration.
- Reviewing the design-stage documents before release.
- Comparing the new design with a similar proven design, if available; and
- Records of the design verification measures are maintained.

8.3.5 Design and Development Outputs

The design output is documented and expressed in terms that are verified against the design-input requirements and are validated (see 4.4.8). The responsible engineer assures that the design output:

- Meets the design input requirements.
- Contain or *refer* to acceptance criteria.
- Identify characteristics that are crucial to safe and proper functioning of the product; and
- Design output documents are reviewed prior to release.

8.3.6 Design and Development Validation

Design validations are performed to ensure that the product conforms to the defined user needs and requirements. Validations are performed after successful design verification and under defined operating conditions. Multiple validations are performed if warranted. Design validation for product design services provided by Carlson Tool & Manufacturing Corp. is the customer's responsibility.

8.3.7 Control of Design and Development Changes

All design changes and modifications are identified, documented, reviewed, and approved by authorized personnel before they are implemented.

8.4 Control of Externally Provided Processes, Products and Services (Purchasing)

Carlson Tool & Manufacturing Corp. evaluates its' subcontractors and purchases only from those that can satisfy our quality requirements. Subcontractors are encouraged to seek quality improvement opportunities through prevention, not detection. This is emphasized through the Corrective and Preventive Action System. Purchasing documents clearly and completely describes ordered products, including quality requirements. Purchasing documents are reviewed and approved prior to release.

8.4.1 Purchasing Process

Evaluations of subcontractors are performed as specified in Operating Procedure (OP74101), Evaluation of External Providers.

Quality performance of all subcontractors is monitored. Subcontractors showing inadequate performance are asked to implement corrective actions and are discontinued if there is no improvement.

The type and extent of control exercised over subcontractors is dependent upon the impact of the subcontracted product on the quality of the final product, and the subcontractors' prior quality performance.

An approved subcontractor list is maintained. Orders may only be placed with subcontractors that are on the list.

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Title: Operation

8.4.1 Purchasing Process (Cont.)

Re-evaluation of subcontractors is performed as specified in Operating Procedure (OP74101), Evaluation of Suppliers.

Detailed rules and instructions for the evaluation, re-evaluation, and assessment of subcontractors are given in Operating Procedure (OP74101), Evaluation of External Providers.

8.4.2 Purchasing Information

The Buyer prepares purchasing documents. The documents clearly and completely describe ordered products. They include precise identification of the products, reference applicable standards and state quality requirements. The Buyer reviews and approves all purchasing documents prior to release.

Rules applicable to preparation, review, and approval of purchasing documents are provided in Operating Procedure (OP74102), Purchasing Process.

8.4.3 Verification of Purchased Product

Purchased products are subjected to either a Level One or a Level Two Receiving Inspection. First, all products are inspected visually, and then designated products are subjected to a more detailed and technical inspection. Nonconforming products are segregated and are prevented from use in production.

Operating Procedure (OP74301), Inspection of Purchased Product, sets forward detailed rules for performing and recording the receiving inspections.

8.5 Production and Service Provision

Production operations are planned and documented. Personnel performing complex or critical operations are provided with work instructions and workmanship standards. Special processes are controlled and performed in accordance with written procedures. Process capability studies are used to evaluate and approve production processes and changes. Production areas are clean and provide a suitable working environment.

The Manufacturing Plan is created by the Project Leaders. The Shop Floor Routing, Dispatch List determines all production and inspection operations necessary to manufacture and verify a product.

Operating Procedure (OP75101), Control of Production (West Plant Molds); Operating Procedure (OP75102), and Operating Procedure (OP75103), Control of Production (East Plant) specifies the requirements and responsibilities for controlling processes.

When the complexity or importance of an activity warrants it, production personnel are provided with work instruction. Production equipment and preventive maintenance, processes, product characteristics, and production environment are controlled and/or maintained in accordance with Operating Procedure (OP75101), Control of Production (West Plant Molds), and Operating Procedure (OP75103), Control of Production (East Plant).

After the final inspection, products are protected and stored in adequate conditions to prevent damage and deterioration. If delivery is specified, protection of the product is extended to include delivery to the destination.

Operating Procedure (OP75501), Preservation of Product (Handling – Storage -Packaging & Delivery), governs the activities of preservation, packaging, and delivery.

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8.6 Frozen Planning

When required, a methodology by which Carlson Tool & Manufacturing Corp will control the manufacturing/production processes to achieve consistent results, by example but not limited to the production of aviation CSI designated features/characteristics of parts and assemblies. This means "freezing" or prohibiting changes to the agreed process plan without appropriate approval.

8.6.1 Validation of Process for Production and Service Provision

Carlson Tool & Manufacturing Corp. shall validate any processes, production and service provision where subsequent monitoring or measurement cannot the resulting output. This includes process where deficiencies only become apparent after product is in use or the service has been delivered. This type of process is defined as "Special Processes". Special Processes are controlled and performed in accordance with written procedures as defined in Operating Procedure (OP75201), Validation of Special Processes.

8.7 Identification and Traceability

All purchased and manufactured materials and parts are identified with part numbers assigned by the customer or vendor. The part numbers provide for a correlation between a part and its technical documentation.

When required by contract, material traceability is provided per the customer's requirements. Quality Assurance maintains records of material certifications.

Operating Procedure (OP75301), Product Identification and Traceability, regulate activities pertaining to this section of the quality system.

8.8 Monitoring and Measurement of Product (In-process Inspection)

In-process inspections are specified on the Inspection Instruction for the product. The inspections are normally carried out by the production personnel. In addition, Quality personnel perform product audits to verify the effectiveness of the production quality system. Activities related to the in-process inspections are regulated by:

- Operating Procedure (OP82401), In-process Inspection (Mold Making), and
- Operating Procedure (OP82403), Monitoring and Measurement of Product In-process Inspection (East Plant).

These types of inspections are recorded and signed off by the personnel performing the inspection. The records identify the inspection authority responsible for release of the product. Instructions for establishing the inspection records are described in Operating Procedures shown above while filing and maintenance of the records are regulated by Operating Procedure (OP42401), Record Control.

8.9 Property owned by external providers (Customers, Suppliers)

External provider's property is protected through the means of confidentiality agreements with customers, employees, supplier, and subcontractors. Records of confidentiality are maintained. Other measures to safeguard intellectual property are taken as required.

Property provided from external sources that are used for processing or for incorporation into products are handled in the same manner as other purchased products. When specified in a contract, special handling instructions from customers will take precedent over Carlson Tool & Manufacturing Corp's standard procedures. Loss, damage, or unsuitability of a customer's products is recorded and reported to the customer.

Customer supplied products are reviewed, inspected, tested, marked, and stored in the same manner as other purchased products. Operating Procedure (OP75402), Customer Property contains detailed instructions in this regard. In the event of loss, damage, deterioration or unsuitability of products, a record is made, and the customer is contacted.

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Revision: V

Title: Operation

8.10 Preservation

The Shipping and receiving groups are responsible for product handling and ensuring that material containers are adequate and clean. Moreover, they ensure that equipment used for internal transportation of product is well maintained and operators are trained in use of the equipment, and that product is protected during production and storage.

Raw material and in-process storage areas and their operation are the responsibility of the Project Manager. Only products that are properly identified and that have passed the required inspections are authorized to enter and leave the storage areas. The storage areas are assessed at appropriate intervals to determine the condition of stock.

For AS9001 projects, as specified by the contract actions will be taken to prevent foreign object and debris (FOD) contamination or damage.

Packaging and labeling requirements are identified during contract review and/or based upon customer specifications. The specifications are communicated to personnel in the form of drawings and work instructions. Packaging is designed for the intended means of delivery.

Product is preserved as necessary to provide adequate protection while under the Company's control including while being transported to the customer.

Operating Procedure (OP75501), Preservation of Product (Handling – Storage -Packaging & Delivery), governs activities associated with these processes.

8.11 Post-Delivery Activities

Carlson Tool & Manufacturing Corp. shall determine the requirements for post-delivery activities during the contract review process. In addition, post-delivery activity maybe associated with actions outside the scope of the contract.

While determining the extent of post-delivery activities that are required, Carlson Tool & Manufacturing Corp. shall take into consideration:

- Statutory and regulatory requirements.
- The potential undesired consequences associated with products and services.
- The nature, use and intended lifespan of products and services.
- Customer requirements; and
- Customer feedback.

Examples of post-delivery activities include:

- Engagement with customers to determine if the products or services were to their satisfaction.
- On-site installation of equipment and technical support.
- Contractual arrangements such as warranties or technical support.
- Collection and analysis of in-service data.
- Creation of technical documentation and revision; and
- Spare parts supply.

8.12 Control of Changes

Carlson Tool & Manufacturing Corp shall manage changes associated with production and service provision. This is accomplished through planning, review, implementation, and verification of the change to ensure conformity with requirements.

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Title: Operation

Documented Information (Records) will be maintained describing the results of the reviews, the person(s) authorizing change, and any actions arising from the review.

8.13 Release of Products and Services (Final Inspection)

All inspections are recorded and signed off by the personnel performing the inspection. The records identify the inspection authority responsible for release of the product. Instructions for establishing the inspection records are described in Operating Procedures shown above while filing and maintenance of the records are regulated by Operating Procedure (OP42401), Record Control.

Purchased products are subjected to either a Level One or a Level Two receiving inspection. First, all products are inspected visually, and then designated products are subjected to a more detailed and technical inspection. Operating Procedure (OP74301), Inspection of Purchased Product, governs the activities associated with inspection of purchased product.

In-process inspections are specified on the inspection instruction or production traveler. These inspections are normally carried out by the production personnel. In addition, quality personnel perform product audits to verify the effectiveness of the production quality system. Acceptance is denoted with a sign-off of in-process inspections records, this is the authorization to release product for the next operation. Activities related to the in-process inspections are governed by:

- Operating Procedure (OP82401), In-process Inspection (Mold Making), and
- Operating Procedure (OP824030, Monitoring and Measurement of Product In-process Inspection (East Plant).

A final inspection is performed at the completion of processing to determine that all operations are complete and to assure all requirements have been met. Product that passes final inspection is released for transport to the customer. The activities and process for performing and recording the final inspection is governed by:

- Operating Procedure (OP82404), Monitoring and Measurement of Product Final Inspection (West Plant Molds), and
- Operating Procedure (OP82406), Monitoring and Measurement of Product Final Inspection (East Plant).

8.14 Control of Nonconforming Outputs

Carlson Tool & Manufacturing Corp's Policy is to identify all suspect products and document all nonconformities. Nonconforming products are identified with a Caution Tag or specified container and are segregated where possible. The nonconformity is recorded in the Nonconforming Material Report in the NCR Database. Responsibility for disposition of nonconforming product is defined and concerned functions are notified. When required, the customer is contacted for concession. Repaired or reworked product is re-inspected.

When problems/nonconformities are detected after delivery, Carlson will take appropriate action including investigation in accordance with Operating Procedure (OP85201) Corrective and Preventative Action. The customer will be notified in a timely manner.

The process for control of nonconformity is governed by Operating Procedure (OP83001), Control of Nonconforming Material, and Operating Procedure (OP83002), Control of Nonconforming Product (East Plant).

Section: 9.0

Revision: V

Title: Performance Evaluation

9.0 Monitoring, Measurement, Analysis and Evaluation

To determine the effectiveness and suitability of the Quality System the data from the following objectives will be measured, analyzed, and evaluated:

- Management Objectives.
- Price of Nonconformance.
- Customer Complaints and Warranty Claims.
- Performance and effectiveness of the quality system (Internal Audit Results).
- The need for changes and improvements to the Quality Management System.
- Effective implementation of planning activities.
- Effectiveness of Corrective/Preventive Actions,
- Effectiveness of actions taken to address risk and opportunities; and
- The performance of suppliers and subcontractors.

Operating Procedures: (OP84001), Analysis of Data; (OP56001), Management Review; and (OP82301), Monitoring and Measuring of Processes, govern activity associated with Monitoring, measurement, analysis, and evaluation of the business.

9.1 Customer Satisfaction

Carlson Tool & Manufacturing Corp. measures customer satisfaction through the measurement of complaints and warranty claims. Customer satisfaction results are reported to Management. Customer satisfaction measures are used to identify areas within the company that require improvement. Operating Procedure (OP82101), Customer Satisfaction, governs activities associated with monitoring and measurement.

9.2 Internal Audit

Comprehensive, planned, and documented Quality Audits are carried out. Audits are scheduled based on a risk assessment. The Management Representative establishes an Internal Audit Plan and Schedule. At least all elements of the quality management system, including suitable working conditions, are audited over a three-year period. However, more frequent Audits may be scheduled if required.

The Management Representative selects and leads an Audit Team. Areas of the business that are the responsibility of the Management Representative are audited by personnel independent of these responsibilities. Qualified auditors are used to perform internal audits. Audit preparation includes the review of applicable standards, operating procedures, work instructions and quality records. The auditor creates questionnaires and checklists to be used during the audit.

When an audit noncompliance is identified, the auditor will record the noncompliance in the Audit Noncompliance Database. The audit noncompliance is issued and the respective manager responsible for the area where the finding is identified and notified. An investigation of the cause of the nonconformance and propose a correction to the noncompliance will be performed. A corrective action will be made to eliminate the cause of the noncompliance. Implementation and effectiveness of the action is verified by a follow-up audit. The results of internal audits and subsequent corrective actions are submitted as an agenda item for the management review meetings. Activities associated with the auditing process are governed by Operating Procedure (OP82201), Internal Audits.

9.3 Management Review

The Management Team reviews the Quality System at least once a year. The purpose of the reviews is to assess the effectiveness and continuing suitability of the Quality Policy, system, objectives, and preventative actions. The Management Representative is responsible for scheduling and conducting the reviews. Conclusions of the reviews are recorded. Detailed instructions for scheduling, conducting, and recording the reviews are provided in Operating Procedure (OP56001), Management Review.

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9.3 Management Review (Cont.)

Management Review Inputs Include:

- Process and product performance.
- Customer Satisfaction, feedback from interested parties.
- Nonconformity and corrective action.
- Results of internal and external audits.
- Changes to the quality management system.
- Assessment of the quality management system.
- Improvement.
- The effectiveness of actions taken to address risk and opportunities.
- Adequacy of resources.
- Follow-up on open items from last meeting.
- Management Review Outputs.

Output from Management Reviews may lead to actions that address:

- Opportunities for improvement.
- Need for changes to the quality management system.
- Identify resources needs.

Section: 10.0

Revision: V

Title: Improvement

10.0 Continuous Improvement

A comprehensive continuous improvement philosophy is deployed throughout Carlson Tool & Manufacturing Corp. Quality and service, which includes timing and delivery, shall be continuously improved. This requirement does not replace the need for innovative improvements.

Carlson Tool & Manufacturing Corp. develops specific action plans for continuous improvement in processes that are most important to the customer in accordance with Operating Procedure (OP85101), Continual Improvement. For characteristics that can only be evaluated using attributes data, continuous improvement means perfection of process methods to ensure that the requirement is always met.

Opportunities for quality and productivity improvements are identified and appropriate improvement projects initiated. The methods used to identify projects, and the knowledge and use of the methodologies required for continuous improvement projects are specified in Operating Procedure (OP85101), Continual Improvement.

10.1 Corrective Action and Nonconformity

Processes, work operations, quality records, and customer complaints are analyzed to detect any sources of potential quality problems and determine preventive actions if required. Causes of nonconformity's are investigated using disciplined problem-solving methods, and corrective actions are requested to prevent recurrence. Controls are applied to ensure that corrective and preventive actions are implemented and that they are effective, which results in continuous improvement.

Corrective and preventive actions are taken to a degree appropriate to the magnitude of problems and commensurate with the risks encountered. When appropriate, a cross-functional team is utilized to provide for participate problem solving.

A disciplined problem-solving method is used when a nonconformance to a specification or requirement occurs. When an external nonconformance occurs, the customer is responded to in the prescribed manner. Operating Procedure (OP85201), Corrective and Preventive Action, describes in detail the instructions that apply to initiation of corrective actions.

Changes to documented procedures are recorded and implemented and the relevant information on actions taken, including these changes, are submitted for management review as specified in Operating Procedure (OP56001), Management Review.

Corrective Action Request from the Customer, Government and/or Regulatory Agency will be process in accordance with Operating Procedure (OP85201), Corrective and Preventive Action, and the requirements specified by the purchase order.

Corrective actions are initiated because of:

- Identification of product nonconformity.
- Process and quality problems.
- Noncompliance's observed during audits.
- Customer complaints, and/or return analysis; and
- Nonconforming deliveries from suppliers or subcontractors.

Section: 11.0	Revision: V	Title: Quality Management System Procedures
Procedure Name		Document No.
Quality Planning		OP54001
Business Planning		OP54002
Management Review		OP56001
Quality System Documentation		OP42001
Contract Review - (West Plant)		OP72001
Processing Quotations - (Tooling Facility West Plant)		OP72003
Contract Review-East Plant		OP72004
Design and Development (Molds) (West Plant)		OP73001
Awareness, Access and Communication		OP73002
Control of Documents		OP42301
Organizational Knowledge		OP71601
Evaluation of External Providers		OP74101
Purchasing Process		OP74102
Customer Property		OP75402
Identification & Traceability		OP75301
Control of Production (West Plant Molds)		OP75101
Control of Production (East Plant)		OP75103
Processing of Controlled Items (Bell Helicopter)		OP75104
Validation of Special Processes		OP75201
Infrastructure		OP63001
Lockout/Tag-out Procedure		OP63002
General Machine Guarding Requirements for all Machines		OP63003
Safety Policy and Procedures for East Plant		OP63004

Inspection of Purchased Product	OP74301
Monitoring and Measurement of Product In-process Inspection (West Plant)	OP82401
Advanced Product Quality Planning (APQP)	OP82402
Monitoring and Measurement of Product In-process Inspection (East Plant)	OP82403
Monitoring and Measurement of Product Final Inspection (West Plant Molds)	OP82404
Monitoring and Measurement of Product Final Inspection (East Plant)	OP82406
Calibration of Monitoring and Measuring Equipment	OP76001
Control of Nonconforming Product	OP83001
Control of Nonconforming Product (East Plant)	OP83002
10 CFR Part 21: Reporting Defects & Non-compliance	OP83003
Corrective Action	OP85201
Preservation of Product (Handling – Storage -Packaging & Delivery)	OP75501
Record Control	OP42401
Internal Audits	OP82201
Risk Assessment (East Plant)	OP61001
Risk Assessment (West Plant)	OP61002
Human Resources (Competence and Training)	OP62001
Servicing – N/A	N/A
Analysis of data	OP84001
Improvement	OP85101
Customer Satisfaction	OP82101
Monitoring & Measurement of Processes	OP82301