Quality Manual ISO 9001-2015

Cedarburg, Wisconsin

Revision: W (11/11/2024)

West Tooling Facility

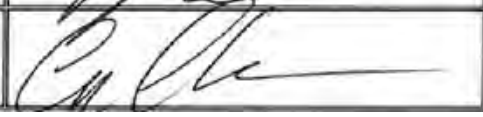
North Machining Facility

East Machining Facility

1.0 Table of Contents

2.0 Approvals & Amendments

2.1 Approvals

Name	Title	Signature	Date
Jerry Edquist	President/CEO		11/11/2024
Chris Andersen	Director of Quality & Engineering		11/11/2024

2.2 Amendments

SECTION NUMBER	DATE	CHANGE DESCRIPTION	Revision
	10/18/2024	Update the manual format consolidated all sections into document, added paragraph clause numbering and page numbers. *Customer Focus - 5.5 Source Inspection - 5.5.2 Activities associated with customer notification, access and source inspection are defined in Operating Procedure (OP73002), Awareness, Access and Communication.* 5.8 Roles, Responsibility and Authorities - 5.8.2 Members of Carlson Tool & Manufacturing Corp's Management Team include, *added Sales Manager*. *6.0 Planning - 6.2 Product and Process Planning - 6.2.1 Planning activities for product specific quality plans are described in Operating Procedure (OP54001), Quality Planning.* *6.2.2 Planning activities for product specific quality plans that are associated with by example, fight safety or critical components are described in Operating Procedure (OP54003), Frozen Process Planning.* *6.2.3 Planning activities for products that require advanced product quality planning (APQP) are described in Operating Procedure (OP82402), Advanced Product Quality Planning (APQP) .* 7.0 Support - 7.3 Infrastructure - 7.3.3 Natural occurrences that cannot be controlled can affect the infrastructure. In the event of such occurrences the Management Team shall initiate the HW62010 Business Continuation Program, and as required, *HW62011 Infectious Diseases Business Continuation Plan.* The objective of these plans is to identify and mitigate the associated risk and include strategies to protect the interest of all interested parties involved. 7.4 Environment for the Operation of Processes - 7.4.2 The Management Team identifies and establishes the Safety Team. *The Director of Operations leads* the Safety Team and coordinates safety initiatives with and through the Emergency Response Team. 7.4 Environment for the Operation of Processes - 7.4.5 The following Operating Procedures define the requirements to assure that infrastructure and environmental conditions will allow Carlson Tool & Manufacturing Corp. to achieve organizational	W

		objectives. • *Carlson Safety Program OP63005* • *Maintainece (Facility Equipment and Vehicles) OP63007* 7.7 Organizational Knowledge - .7.2 Organizational knowledge is retained and made available through reports, spreadsheets, databases, work instructions, procedures and standards as *defined in Operating Procedure (OP71601) Organizational Knowledge.* *8.0 Operation - 8.1 Operational Planning and Control - 8.1.1 Quality planning activity is facilitated by Quality and when required a cross-functional team may be utilized as described in the following operating procedures. - OP54001 Quality Planning, OP54003 Frozen Process Planning, OP82402 Advanced Product Quality Planning (APQP* 8.5 Contingency Actions - 8.5.1 Natural occurrences that cannot be controlled can affect Carlson Tool & Manufacturing Corp's ability to meet contractual requirements. In the event of such occurrences the Management Team shall initiate the HW62010 Business Continuation Plan 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 8.19 Purchasing Information -8.19.1The Buyer prepares purchasing documents. The documents clearly and completely describe ordered products. They include precise identification of the products, reference applicable standards, *flow down* and quality requirements. The Buyer reviews and approves all purchasing documents prior to release. 8.22 Frozen Planning - *8.22.2 The development, approval, control and changes to frozen processes are described in Operating Procedure (OP54003) Frozen Process Planning.* 8.27.4 Packaging and marking requirements are identified during contract review. These requirements are based upon company or customer specifications. These requirements are communicated to personnel in the form of drawings, work instructions or notations on the *production traveler*. Packaging is designed for the intended means of delivery. 8.30 Release of Products and Services - 8.30.1 A final inspection is performed at the completion of processing to determine that all operations are complete, *all deliverables are comple*te and to assure all requirements have been met. Products 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: 8.31 Control of Nonconforming Outputs - 8.31.1 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 products is defined and concerned functions are notified. When required, *the customer is contacted for disposition actions.* Repaired or reworked product is re-inspected 8.31 Control of Nonconforming Outputs - *8.31.3 The process for control of nonconformity is governed by Operating Procedure (OP83001), Control of Nonconforming Product* ,~~and Operating Procedure (OP83002), Control of Nonconforming Product (East Plant).~~ *Combine procedures.*	

3.0 Forword

3.1 Introduction

3.1.1 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 and machining services 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 Statement.

3.1.2 Carlson was originally founded as a tool and die job shop that specialized in building plastic injection molds and aluminum diecast 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 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 requirements. Instead, we make a commitment to not only exceeding 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 they need and when they need it. Every day we seek to build strong relationships based on quality products and services, by continuously striving to demonstrate why at Carlson Tool, Made in the USA-Starts Here.

3.1.3 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.

3.1.4 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.

3.1.5 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.

3.1.6 The Quality Management Principles are:

- Customer focus.
- Leadership.
- Engagement of people.
- Process approach.
- Improvement.

3.0 Forword (Cont.)

- Evidence-based decision making.
- Relationship management.

3.1.7 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.
- 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.
- Demonstrate compliance of the quality system with quality requirements in contractual situations.

3.2 Process Approach

3.2.1 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.

3.2.2 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.

3.3 Plan-Do-Check-Act Cycle

3.3.1 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.

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

- **Plan:** Establish the Quality Objectives relevant to the 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 measure the processes, the resulting products and services against policies, objectives, requirements, and planned activities, and report the results.
- **Act:** Close the loop by taking actions to improve the Quality Management System's performance, as necessary.

3.4 Risk-Based Thinking

3.4.1 Risk-based thinking is integral to the 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 preventing negative effects.

3.5 Normative References

3.5.1 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.

3.6 Terms and Definitions

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

3.7 Commitment and Support

3.7.1 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. Compliance to the requirements of the Quality Management System is mandatory for all functions and personnel of Carlson Tool & Manufacturing Corp.

4.0 Quality Management System

4.1 Context of the Organization

4.1.1 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.

4.1.2 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.

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

- Customers
- Owners
- Employees
- Suppliers
- Community

4.2 Understanding the Needs and Expectations of Interested Parties

4.2.1 Carlson Tool & Manufacturing Corp identifies internal, external issues and the needs of interested parties during management reviews and planning meetings, 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

4.3.1 Management determines the boundaries and applications of the 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.

4.3.2 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:

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

4.4 Facilities within the Scope of the Quality Management System

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

Carlson Tool & Manufacturing Facilities		
West Facility (Tooling)	East Facility (Machining)	North Facility (Machining)
W57 N14386 Doerr Way Cedarburg, WI 53012	5545 Pioneer Road Mequon, WI 53092	W60 N171 Cardinal Ave Cedarburg, WI 53012
Phone: 262-377-2020	Phone: 262-377-2020	Phone: 262-377-2020
Fax: 262-377-1751	Fax: 262-376-1018	Fax: 262-376-1018
Website: Carlsontool.com	Website: Carlsontool.com	Website: Carlsontool.com

4.5 Quality Management System and it's Processes.

4.5.1 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.

4.5.2 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.
- How Quality Management System processes are improved.

4.5.3 Quality Management System Structure includes:

- Quality Policy.
- Quality Objectives.
- Quality Manual.
- Operating Procedures.
- Work Instructions.
- Forms, Tags and Labels.
- Process Procedures and Internal standards.
- Applicable national, international, and industry standards.
- Product technical specifications and drawings.
- Production and quality plans.
- Customer provided documents and data.

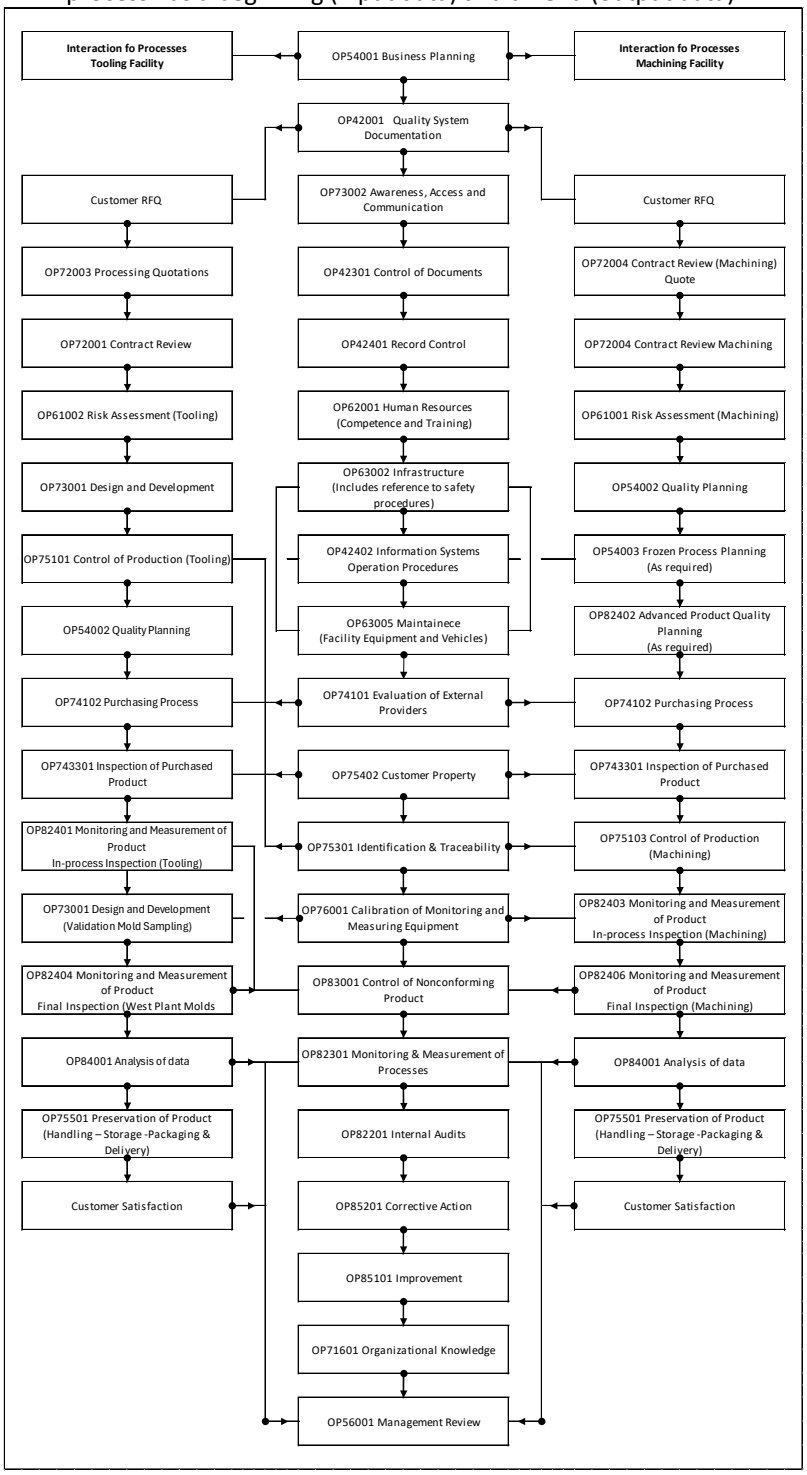
4.6 Quality Manual

4.6.1 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

4.7 Interaction of Processes

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



5.0 Leadership

5.1 Leadership and Commitment

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

- Ensuring the integration of the Quality Management System in the organizations business processes.
- 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.
- Supporting Management roles to demonstrate leadership in their areas of responsibility.

5.2 Customer Focus

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

5.2.3 For all order types, contract review is comprised of verification that the customer's requirements are adequately defined, documented, understood, and can be agreed to, and that 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

5.3.1 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

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

5.5 Source Inspection

5.5.1 Carlson Tool & Manufacturing Corp shall support Customers, and/or Government, Regulatory Agencies performance of product verification at Carlson's facilities (source inspection) as defined by the contract. Source inspections may include but is not limited to, by example, any one or all of the following, aircraft induction inspection, in-process inspection, and final inspection.

5.5.2 Activities associated with customer notification, access and source inspection are defined in Operating Procedure (OP73002), Awareness, Access and Communication.

5.6 Quality Policy

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

- 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.
- Includes a commitment to continual improvement.

5.6.2 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.

5.7 Communicating the Quality Policy and Objectives

5.7.1 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.
- Postings.

5.8 Roles, Responsibility and Authorities

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

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

- President
- Chief Financial Officer
- Director of Operations
- Director of New Customer Development
- Human Resource Manager
- Director of Quality and Engineering
- Sales Manager

5.8.3 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.
- Appointing the Management Representative.
- Foster continuous improvement through corrective actions.
- Cultivate teamwork and cooperation at all levels, creating a positive work environment.
- Periodically review the quality system's effectiveness.
- Provide internal communication relative to the effectiveness of the Quality Management System.
- 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.

5.9 Management Representative

5.9.1 Carlson Tool & Manufacturing Corp's Management Team appoints as the Management Representative, the Director of Quality & Engineering. The Director of Quality & Engineering has 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.

6.0 Planning

6.1 Planning, Risk and Opportunities

6.1.1 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 the 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.

6.1.2 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 and 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 will be fostered.
- Effectiveness of actions are evaluated.

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

6.2 Product and Process Planning

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

6.2.2 Planning activities for product specific quality plans that are associated with by example, fight safety or critical components are described in Operating Procedure (OP54003), Frozen Process Planning.

6.2.3 Planning activities for products that require advanced product quality planning (APQP) are described in Operating Procedure (OP82402), Advanced Product Quality Planning (APQP) .

6.3 Quality Objectives

6.3.1 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.

6.3.2 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).

6.3 Quality Objectives (Cont.)

6.3.2 When Quality Objectives are established, the following will be taken into consideration: (Cont.)

- Customer satisfaction.
- Results of Strategic Planning.
- Quality performance.

6.3.3 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.
- How will the results be measured and evaluated.

6.3.4 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.

6.4 Planning of Changes

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

6.4.2 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.
- The assignment or reassignment of responsibilities and authorities.

7.0 Support

7.1 Resources

7.1.1 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 include 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.

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

7.1.3 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

7.2.1 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 to product requirements.

7.3 Infrastructure

7.3.1 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 ensure 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.

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

7.3.3 Natural occurrences that cannot be controlled can affect the infrastructure. In the event of such occurrences the Management Team shall initiate the HW62010 Business Continuation Program, and as required, HW62011 Infectious Diseases Business Continuation Plan. The objective of these plans is to identify and mitigate the associated risk and includes strategies to protect the interest of all interested parties involved.

7.4 Environment for the Operation of Processes

7.4.1 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.

7.4.2 The Management Team identifies and establishes the Safety Team. The Director of Operations leads the Safety Team and coordinates safety initiatives with and through the Emergency Response Team.

7.4.3 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 inspections are recorded and findings and actions are reported to Management.

7.4 Environment for the Operation of Processes (Cont.)

7.4.4 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 should be taken to restore the work environment back to its intended function.

7.4.5 The following Operating Procedures define the requirements to ensure that infrastructure and environmental conditions will allow Carlson Tool & Manufacturing Corp. to achieve organizational objectives.

Document Title	Document Number
Infrastructure	OP63001
Lockout/Tag-out Procedure	OP63002
General Machine Guarding Requirements for all Machines	OP63003
Safety Policy and Procedures for East Plant	OP63004
Carlson Safety Program	OP63005
Maintainece (Facility Equipment and Vehicles)	OP63007
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

7.5.1 The Quality Group manages the calibrations system to ensure that measuring and test equipment utilized for verification of product provides valid and reliable results.

7.5.2 The Quality Group maintains and calibrates measuring and test equipment to appropriate standards.

7.5.3 The Quality Group ensures that measuring and test equipment is available for those performing measuring activity.

7.5.4 Equipment shall be suitable for measurement activities based on the outcome of a gage repeatability and reproducibility analysis.

7.5 Monitoring and Measuring Resources (Cont.)

7.5.5 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

7.6.1 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 standards provided by (NIST) National Institute of Standards and Technology. When standards do not exist, records for the basis used for calibration will be retained.

7.6.2 The process employed for calibration is defined by Work Instructions and the Equipment Control Database (Gage-Pak). The following criteria is utilized for equipment calibration and inventory control:

- Type.
- Identification.
- Location.
- Frequency of Calibration.
- Calibration method.
- Acceptance criteria.

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

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

7.6.5 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.

7.6.6 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

7.7.1 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:

7.7.1.1 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.
- Internal Audit results.

7.7 Organizational Knowledge (Cont.)

7.7.1.2 External sources such as:

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

7.7.2 Organizational knowledge is retained and made available through reports, spreadsheets, databases, work instructions, procedures and standards as defined in Operating Procedure (OP71601) Organizational Knowledge.

8.0 Operation

8.1 Operational Planning and Control

8.1.1 Quality planning activity is facilitated by Quality and when required a cross-functional team may be utilized as described in the following operating procedures.

Document Number	Document Title
OP54001	Quality Planning
OP54003	Frozen Process Planning
OP82402	Advanced Product Quality Planning (APQP

8.1.2 As specified in the quality plan 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 Customer Communication

8.2.1 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.

8.3 Customer Feedback

8.3.1 Customer feedback is monitored, and records are maintained as described in Operation Procedure (OP82101), Customer Satisfaction. Feedback measurements include the following:

- Customer complaints.
- Warranty Claims.
- Account debits related to quality.
- External Cost of Poor Quality.
- Customer compliments.

8.3.2 Customer feedback is used to identify areas within Carlson Tool & Manufacturing Corp. that require improvement. Results are reported during Management Review.

8.4 Customer Property

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

8.5 Contingency Actions

8.5.1 Natural occurrences that cannot be controlled can affect Carlson Tool & Manufacturing Corp's ability to meet contractual requirements. In the event of such occurrences the Management Team shall initiate the HW62010 Business Continuation Plan 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.

8.6 Determining Requirements for Products and Services

8.6.1 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.

8.7 Review of Requirements for Product and Services

8.7.1 Reviews of customer information comprise of a verification to determine that the customer's requirements are adequately defined, documented, understood, and 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.

8.7.2 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.

8.8 Changes to Requirements for Products and Services

8.8.1 Changes made to contracts and/or products are reviewed to ensure 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.

8.1.2 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.

8.9 Design and Development

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

8.10 Design and Development Planning

8.10.1 Design plans are prepared for each design and development activity, the design plan describes the stages, milestone dates, responsibilities for their implementation. These activities are assigned to qualified personnel equipped with adequate resources. The plans are updated as necessary, as the design evolves.

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

8.11 Design and Development Inputs

8.11.1 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.

8.12 Design and Development Controls

8.12.1 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 specialists as required. Records of the reviews are maintained.

8.13 Design and Development Verification

8.13.1 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 demonstrations.
- Reviewing the design documents and data before release.
- Comparing the new design with a similar proven design.
- Records of the design verification activities are maintained.

8.14 Design and Development Outputs

8.14.1 The design output is documented and expressed in terms that are verified against the design-input requirements and are validated. The engineer responsible assures us that the design output:

- Meets the design input requirements.
- Contains or refers to acceptance criteria.
- Identifies characteristics that are crucial to safe and proper functioning of the product.
- Design output documents are reviewed prior to release.

8.15 Design and Development Validation

8.15.1 Design validations are performed to ensure that the product conforms to the defined user's 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.

8.16 Control of Design and Development Changes

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

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

8.17.1 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.

8.18 Purchasing Process

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

8.18.2 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.

8.18.3 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.

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

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

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

8.19 Purchasing Information

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

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

8.20 Verification of Purchased Product

8.20.1 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 being used in production.

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

8.21 Production and Service Provision

8.21.1 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. As required, process capability studies are used to evaluate and approve production processes and changes. Production areas are clean and provide a suitable working environment.

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

8.21.3 Operating Procedure (OP75101), Control of Production (West Plant Molds),and Operating Procedure (OP75103), Control of Production (East & North Plants) specifies the requirements and responsibilities for controlling processes.

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

8.22 Frozen Planning

8.22.1 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 review and approval.

8.22.2 The development, approval, control and changes to frozen processes are described in Operating Procedure (OP54003) Frozen Process Planning.

8.23 Validation of Process for Production and Service Provision

8.23.1 Carlson Tool & Manufacturing Corp. shall validate any processes, production and service provision where subsequent monitoring or measurement cannot verify the resulting output. This includes processes where deficiencies only become apparent after the 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.

8.24 Identification and Traceability

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

8.24.2 When required, material traceability is controlled and maintained as specified by the Engineering Group or the customer. The Quality Group manages records of material certifications.

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

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

8.25.1 In-process inspections are performed as specified. These inspections are normally carried out by production personnel. In addition, the Quality Group may conduct product audits to verify the effectiveness of the production quality system. Activities related to the in-process inspections are regulated by:

- Operating Procedure (OP82401), Monitoring and Measurement of Product In-process Inspection (West Plant).
- Operating Procedure (OP82403), Monitoring and Measurement of Product In-process Inspection (East & North Plant).

8.26.1 In process inspection results are recorded on the appropriate documents and signed off by personnel performing the activity. These records identify the status of the product and the inspection authority responsible for release of the product. Instructions for establishing the inspection records are described in Operating Procedures shown above. Inspection records are controlled and maintained in accordance with Operating Procedure (OP42401), Record Control.

8.26 Property owned by external providers. (Customers)

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

8.26.2 Property that is provided by external sources will be controlled and when the specified customer requirement will take precedent over Carlson Tool & Manufacturing Corp's standard procedures.

8.26 Property owned by external providers. (Customers) (Cont.)

8.26.3 Supplied products from External Providers (Customers) 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.

8.27 Preservation

8.27.1 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.

8.27.2 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.

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

8.27.4 Packaging and marking requirements are identified during contract review. These requirements are based upon company or customer specifications. These requirements are communicated to personnel in the form of drawings, work instructions or notations on the production traveler. Packaging is designed for the intended means of delivery.

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

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

8.28 Post-Delivery Activities

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

8.28.2 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.

8.28 Post-Delivery Activities (Cont.)

8.28.3 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.
- Supply of spare parts.

8.29 Control of Changes

8.29.1 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.

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

8.30 Release of Products and Services

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

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

8.31 Control of Nonconforming Outputs

8.31.1 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 products is defined and concerned functions are notified. When required, the customer is contacted for disposition actions. Repaired or reworked products are re-inspected.

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

8.31.3 The process for control of nonconformity is governed by Operating Procedure (OP83001), Control of Nonconforming Product.

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

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

- Management Objectives.
- Price of Nonconformance.
- Customer Complaints.
- Warranty Claims.
- Audit Results.
- Effective implementation of planning activities.
- Effectiveness of Corrective Actions.
- Effectiveness of actions taken to address risk and opportunities.
- The performance of external providers.
- Opportunity for Improvements.

9.1.2 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.

9.2 Customer Satisfaction

9.2.1 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 being used to identify areas within the company that require improvement. Operating Procedure (OP82101), Customer Satisfaction, governs activities associated with monitoring and measurement.

9.3 Internal Audit

9.3.1 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.

9.3.2 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.

9.3.3 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, a correction to the noncompliance will be initiated.

9.3 Internal Audit (Cont.)

Corrective action will be generated 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.

9.4 Management Review

9.4.1 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 actions taken. 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.

9.4.2 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.

9.4.3 Output from Management Reviews may lead to actions that address:

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

10.0 Improvement

10.1 Continuous Improvement

10.1.1 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.

10.1.2 Carlson Tool & Manufacturing Corp. develops specific action plans for continuous improvement in processes that are most important to the business in accordance with Operating Procedure (OP85101), 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.

10.1 Continuous Improvement (Cont.)

10.1.3 Opportunities for quality and productivity improvements are identified and appropriate improvement projects have 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), Improvement.

10.2 Corrective Action and Nonconformity

10.2.1 Processes, work operations, quality records, and customer complaints are analyzed to detect any sources of potential quality problems and determine if action is 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 actions are implemented and that they are effective, which results in continuous improvement.

10.1.2 Corrective 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 for problem solving.

10.1.3 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 Action, describes in detail the instructions that apply to initiation of corrective actions.

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

10.1.5 Corrective Action Request from the Customer, Government and or Regulatory Agency will be processed in accordance with Operating Procedure (OP85201), Corrective Action, and the requirements specified by the contract.

10.1.6 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.

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