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ISO 9001 QUALITY SYSTEM MANUAL

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INTRODUCTION

Stimpson Co., Inc. has developed and implemented a quality management system to better satisfy the needs of its customers and to continually improve the Quality Management System of the company. The quality system complies with the international standards ISO 9001 (2000). The system covers the design, production and shipping of the company's products.

The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel affected by the system, and to provide general procedures for all activities comprising the quality system.

Another purpose of this manual is to present the quality system to our employees, customers and other interested parties, and to inform them what specific controls are implemented to assure product quality.

This manual has been approved by the President:

Ralph E. Rau Jr.

And authored by the Management Representative:

Peter Kaplan

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1. QUALITY POLICY

The policy of the Stimpson, Co., Inc. is to produce quality products that satisfy requirements. Management is committed to work with and provide each employee with the resources and training necessary to continually improve the effectiveness of the Quality System.

This policy has been formulated by the President of Stimpson Co., Inc. The policy is explained and discussed at the general orientation training given to all existing and new employees. The policy is also posted in conspicuous locations throughout the company.

2. References

2.1 ISO 9001:2000 – Quality Management System Requirements

3. Definitions

Top Management- Group of people that direct and control the company at the highest level.

ERP- Enterprise Resource Planning- The software manufactured by JD Edwards used for Accounting, Customer Service, Production, Purchasing and Shipping processes

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4. Quality Management System

4.1 General Requirements

- a) Identify the processes needed for the quality management system and their applications throughout Stimpson Co., Inc.
- b) Determine the sequence and interaction of these processes
- c) Determine criteria and methods needed to ensure both the operation and control of the processes are effective,
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) Monitor, measure and analyze these processes, and
- f) Implement actions necessary to achieve planned results and continual improvement of these processes

4.2 Documentation Requirements

4.2.1 General

The quality management system shall include

- a) Documented statements of a quality policy and quality objectives,
- b) A quality manual
- c) Documented procedures required by the ISO 9001:2000 International Standard

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- d) Documents needed by the Stimpson Co., Inc. to ensure the effective planning, operation and control of its processes.
- e) Records requested by the ISO 9001:2000 International Standard

4.2.2 Quality manual

A quality manual is established and maintained that includes the following:

- a) The scope of the quality management system, including details of, and justification for, any exclusions.
- b) The documented procedures established for the quality management system, or reference to them
- c) A description of the interaction between the process of the quality management system

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled as well.

A document procedure shall be established to define the controls needed

- a) To approve documents for adequacy prior to issue,
- b) To review and update as necessary and re-approve documents
- c) To ensure that changes and the current revision status of documents are identified
- d) To ensure that relevant versions of applicable documents are available at points of

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use

- e) To ensure that documents remain legible and readily identifiable
- f) To ensure that documents of external origin are identified and their distribution controlled, and
- g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure is established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5 Management responsibility

5.1 Management commitment

Top management provides evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- a) Communicating to Stimpson Co., Inc the importance of meeting customer as well as regulatory and legal requirements
- b) Establishing the quality policy
- c) Ensuring that quality objectives are established

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- d) Conducting management reviews
- e) Ensuring the availability of resources

5.2 Customer Focus

Top management ensures that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction. This will include the process for establishing the criteria and the prioritization of customer's requirements. The process will also be maintained and reviewed for adequacy and effectiveness in the planning of projects and programs for the continual improvement of the system and the ability to remain focused on the customer.

Stimpson Co., Inc. maintains documented processes that govern the identification and control of significant quality attributes of its products. These are identified as any element of Stimpson Co., Inc.'s activities or products that may affect quality.

The management review team evaluates the relationship and identification of quality characteristics and their impacts on the system objectives by clarifying and prioritizing them for program/project development.

5.3 Quality Policy

Top management ensures that the quality policy:

- a) Is appropriate to the purposes of Stimpson Co., Inc.;
- b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;
- c) Provides a framework for establishing and reviewing quality objectives;

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d) Is communicated and understood within Stimpson Co., Inc.

e) Is reviewed for continuing suitability

5.4 Planning

5.4.1 Quality Objectives

Top management ensure that quality objectives are established at relevant functions and levels within Stimpson Co., Inc. The quality objectives are measurable and consistent with the quality policy. Quality objectives include those needed to meet requirements for product.

Quality objectives are established, documented and may be issued as a result of management review meetings.

5.4.2 Quality Management System Planning

Top management ensures that:

- a) The planning of the quality management system is carried out in order to meet the requirements as specified in 4.1 of the ISO 9000:2000 Standard, as well as the quality objectives, and
- b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented

5.5 Responsibilities, authority and communication

5.5.1 Responsibility and Authority

Responsibilities, authorities and their interrelations are defined and communicated

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within Stimpson Co., Inc. An organization chart is available upon request.

5.2.2 Management Representative

The President appoints the management representative. He shall have authority that includes

- a) Ensuring that processes needed for the quality management system are established, implemented and maintained
- b) Reporting to top management on the performance of the quality management system and any need for improvement, and
- c) Ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE: The responsibility of the management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal Communication

Top management ensures that appropriate communication processes are established within Stimpson Co., Inc. and that communication takes place regarding the effectiveness of the quality management system. This may be accomplished through bulleting board postings, company training and meetings.

5.6 Management Review

5.6.1 General

Top management reviews the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing

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opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained.

5.6.2 Review Input

The input to management shall include information on

- a) Results of audits,
- b) Customer feedback,
- c) Process performance and product conformity,
- d) Status of preventive and corrective actions,
- e) Follow-up actions from previous management reviews,
- f) Changes that could affect the quality management system, and
- g) Recommendations for improvement

5.6.3 Review Output

The output from management review shall include and decisions and actions related to

- a) Improvement of the effectiveness of the quality management system and its processes,
- b) Improvement of product related to customer requirements, and

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c) Resource needs

6. Resource Management

6.1 Provision of resources

Management determines and provides the resources needed

- a) To implement and maintain the quality management system and continually improve its effectiveness, and
- b) To enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting product shall be competent on the basis of appropriate training, skills and experience

6.2.2 Competence, awareness and training

Stimpson Co., Inc. shall

- a) Determine the necessary competence for personnel performing work affecting product quality,
- b) Provide training or take other actions to satisfy these needs
- c) Evaluate the effectiveness of actions taken,
- d) Ensure that is personnel are aware of the relevance and importance of their

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activities and how they contribute to the achievement of the quality objectives, and

- e) Maintain appropriate records of education, training, skills and experience

6.3 Infrastructure

Stimpson Co., Inc. shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

- a) Buildings, workspace and associated utilities,
- b) Process equipment (both hardware and software), and
- c) Supporting services (both contracted and in-house)

6.4 Work environment

Stimpson Co., Inc. determines and manages the work environment needed to achieve conformity to product requirements.

7. Product realization

7.1 Planning of product realization

Stimpson Co., Inc. shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

In planning product realization Stimpson Co., Inc. shall determine the following, as appropriate:

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- a) Quality objectives and requirements for the product;
- b) The need to establish processes, documents, and provide resources specific to the product;
- c) Required verification, validation, monitoring and inspection activities specific to the product and the criteria for product acceptance;
- d) Records needed to provide evidence that the realization processes and resulting product meet requirements

The output of this planning shall be in a form suitable to Stimpson Co., Inc.'s method of operations

7.2 Customer-related processes

Stimpson Co., Inc. is an Original Equipment Manufacturer and does not permit the use of customer supplied product as all items manufactured are the sole, unique design of the Stimpson Company. Inc.

7.3 Design and development

7.3.1 Design and development planning

Stimpson Co., Inc shall plan and control the design and development of product.

During the design and development planning, Stimpson Co., Inc. shall determine

- a) The design and development stages,
- b) The review, verification and validation that are appropriate to each design and development stage, and
- c) The responsibilities and authorities for design and development

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Stimpson Co., Inc shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained. These inputs shall include

- a) Functional and performance requirements
- b) Applicable statutory and regulatory requirements
- c) Where applicable, information derived from previous similar designs, and
- d) Other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against design and development input and shall be approved prior to release.

Design and development outputs shall

- a) Meet the input requirements for design and development,
- b) Provide appropriate information for purchasing, production and for service provision,
- c) Contain or reference product acceptance criteria, and
- d) Specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and development review

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At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements

- a) To evaluate the ability of the results of design and development to meet requirements, and
- b) To identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development inputs requirements. Records of the results of the verification and any necessary actions shall be maintained.

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and products already delivered if applicable.

Records of the results of the review of changes and any necessary actions shall be maintained.

7.4 Purchasing

7.4.1 Purchasing process

Stimpson Co., Inc. shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

Stimpson Co., Inc. shall evaluate and select suppliers based on their ability to supply product in

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accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

7.4.2 Purchasing information

Purchasing information shall describe the products to be purchased, including where appropriate

- a) Requirements for approval of produce, procedures, processes and equipment
- b) Requirements for qualification of personnel, and
- c) Quality management system requirements

Stimpson Co., Inc. shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

Stimpson Co., Inc. shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the Stimpson Co., Inc. or its customer intends to perform verification at their supplier's premises, the organization shall state the intended verification arrangements and method of production release in the purchasing information.

7.5 Production and service provision

7.5.1 Control of production and service provision

Stimpson Co., Inc. plans and carries out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

- a) The availability of information that describes the characteristics of the product
- b) The availability of work instructions, as necessary

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- c) The use of suitable equipment
- d) The availability and use of monitoring and measuring devices
- e) The implementation of monitoring and measurement, and
- f) The implementation of release, delivery and post delivery activities.

7.5.2 Validation of processes

Stimpson Co., Inc. validates any process and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any process where deficiencies become apparent only after the product is in use or has been delivered.

Validation shall demonstrate the ability of these processes to achieved planned results

Stimpson Co., Inc. establishes arrangements for these processes including, as applicable

- a) Defined criteria for review and approval processes,
- b) Approval of equipment and qualification of personnel,
- c) Use of specific methods and procedures,
- d) Requirements for records, and
- e) Revalidation.

7.5.3 Identification and traceability

Where appropriate, Stimpson Co., Inc. identifies the product by suitable means throughout product realization.

Stimpson Co., Inc. identifies the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, Stimpson Co., Inc. shall control and record the unique

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identification of the product.

7.5.4 Customer property

Stimpson Co., Inc. exercises care with customer property while it is under Stimpson Co., Inc.'s control or being used by Stimpson Co., Inc. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.

7.5.5 Preservation of product

Stimpson Co., Inc. preserves the conformity of product during internal processing and delivery. The preservation includes identification, handling, packing, storage and protection. This also applies to the constituent parts.

7.6 Control of monitoring and measuring devices

Stimpson Co., Inc. determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determine requirements.

Processes are established to ensure that monitoring and measurement can be and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

- a) Be calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
- b) Be adjusted or readjusted as necessary;
- c) Be identified to enable the calibration status to be determined;
- d) Be safeguarded from adjustments that would invalidate the measurement result;
- e) Be protected from damage and deterioration during handling, maintenance and storage.

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The validity of previous measuring results when the equipment is found not to conform to requirements is assessed and recorded. Appropriate action is taken on the equipment and any product affected.

Records of the results of calibration and verification are maintained.

8.0 Measurement, analysis and improvement

8.1 General

Stimpson Co., Inc. plans and implements the monitoring, measurement, analysis and improvement processes needed

- a) To demonstrate conformity of the product,
- b) To ensure conformity of the quality management system, and
- c) To continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, Stimpson Co., Inc. monitors information relating to customer perception as to whether Stimpson Co., Inc. has fulfilled the customer requirements. The methods used for determining customer satisfaction are documented.

8.2.2 Internal audits

Stimpson Co., Inc. conducts internal audits at planned intervals to determine whether the quality management system

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- a) Conforms to planned arrangements, to the requirements of the ISO 9000:2000 International Standard and to the quality management system requirements established by Stimpson Co., Inc., and
- b) Is effectively implemented and maintained

Stimpson Co., Inc. plans the audit program taking into consideration the status and importance of the processes and areas to be audited as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Auditors are selected and audits are conducted to ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.

A documented procedure includes the responsibility and requirements for planning and conducting audits, and for recording results and maintaining records.

The management responsible for the area being audited ensures the actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of the verification results.

8.2.3 Monitoring and measurement processes

Stimpson Co., Inc applies suitable methods for monitoring, and where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product

Stimpson Co., Inc monitors and measures the characteristics of the product to verify that requirements for the product are fulfilled. This is carried out at appropriate stages of the product realization process in accordance with the planned processes, procedures and instructions.

Evidence of conformity with the acceptance criteria is documented. Records indicate the person (s) authorizing the release of product.

Product releases do not proceed until all the specified activities have been satisfactorily completed,

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unless otherwise approved by a relevant authority, and where applicable by the customer.

8.3 Control of nonconforming product

Stimpson Co., Inc. ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in a documented procedure.

Stimpson Co., Inc. deals with nonconforming product by one or more of the following ways:

- a) By taking action to eliminate the detected nonconformity
- b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
- c) By taking action to preclude its original intended use or application

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained are maintained.

When nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, Stimpson Co., Inc. takes action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of data

Stimpson Co., Inc. collects and analyzes appropriate data to determine the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

Stimpson Co., Inc. analyzes the data to provide information on:

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- a) Customer satisfaction
- b) Conformance to product requirements
- c) Characteristics and trends of processes and products including opportunities for preventive action, and
- d) Suppliers

8.5 Improvement

8.5.1 Continual improvement

Stimpson Co., Inc. continually improves the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews.

8.5.2 Corrective action

Stimpson Co., Inc takes corrective action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

The documented procedure for corrective action defines the requirements for:

- a) Reviewing nonconformities (including customer complaints);
- b) Determining the causes of nonconformity;
- c) Evaluating the need for action to ensure that nonconformities do not recur;
- d) Determining and implementing the action needed;
- e) Recording of the results of action taken;
- f) Reviewing corrective action taken

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8.5.3 Preventive action

Stimpson Co., Inc. determines action taken to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions taken are appropriate to the effects of the potential problems.

The documented procedure for preventive action defines the requirement for:

- a) Determining potential nonconformities and their causes;
- b) Evaluating the need for action to prevent occurrences of nonconformities;
- c) Determining and implementing action needed;
- d) Recording results of action taken; and
- e) Reviewing of preventive action.

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Appendix A:

Interrelationships Matrix

ISO Manual Section	ISO 9000:2000 Element	Procedure No	Procedure Title
4.0	Quality Management System	QM 4.0	Quality Manual
4.1	General Requirements	QM 4.1	Quality Manual
4.2	Documentation Requirements		Quality Manual
4.2.1	General	QM 4.2.1	Quality Manual
4.2.2	Quality Manual	QM 4.2.2	Quality Manual
4.2.3	Control of Documents	QWP05	Document and Data Control
4.2.4	Control of Quality Records	QWP10	Quality Records
5.0	Management Responsibility	MWP01	Management Responsibility
5.1	Management Commitment	QM 5.1	Quality Manual
5.2	Customer Focus	QM 5.2	Quality Manual
5.3	Quality Policy	MF04	Quality Policy
5.4	Planning	QM 5.4	Quality Manual
5.4.1	Quality Objectives	QM 5.4.1	Quality Manual

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5.5	Responsibility, authority and communication	QM 5.5	Quality Manual
5.5.1	Responsibility and Authority	QM 5.5.1	Quality Manual
5.5.2	Management Representative	QM 5.5.2	Quality Manual
5.5.3	Internal Communication	QM 5.5.3	Quality Manual
5.6	Management Review	MWP01	Management Responsibility
5.6.1	General	MWP01	Management Responsibility
5.6.2	Review Input	MWP01	Management Responsibility
5.6.3	Review Output	MWP01	Management Responsibility
6.0	Resource Management	QM 6.0	Quality Manual
6.1	Provision of Resources	QM 6.1	Quality Manual
6.2	Human Resources	QM 6.2	Quality Manual
6.2.1	General	QM 6.2.1	Quality Manual
6.2.2	Competence, awareness, and training	QWP07	Training
6.3	Infrastructure	QM 6.3	Quality Manual
6.4	Work Environment	QM 6.4	Quality Manual
7.0	Product Realization	QM 6.0	Quality Manual
7.1	Planning of Product Realization	QM 7.1	Quality Manual
7.2	Customer Related Processes	QM 7.2	Quality Manual
7.2.1	Determining Requirements Related to Product	CSWP04	Order Entry

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7.2.2	Review of Requirements Related to Product	CSWP04	Order Change
7.2.3	Customer Communication	CSWP01/02	Custom/Standard Products
7.3	Design and Development	QWP01	Die Design
7.3.1	Design and Development Planning	QWP01	Die Design
7.3.2	Design and Development Inputs	QWP01	Die Design
7.3.3	Design and Development Outputs	QWP01	Die Design
7.3.4	Design and Development Review	QWP01	Die Design
7.3.5	Design and Development Verification	QWP01	Die Design
7.3.6	Design and Development Validation	QWP01	Die Design
7.3.7	Design and Development Changes	QWP01	Die Design
7.4	Purchasing	QM 7.4	Quality Manual
7.4.1	Purchasing Process	PUWP01	Supplier Evaluation
7.4.2	Purchasing Information	PUWP02	Purchasing
7.4.3	Verification of Purchased Product	INWP01	Receiving Inspection
7.5	Production	QM 7.5	Quality Manual
7.5.1	Control of Production	PWP01	Power Press Scheduling
7.5.2	Validation of Production Processes	QM 7.5.2	Quality Manual
7.5.3	Identification and Traceability	QWP09	Product Identification
7.5.4	Customer Property	QM 7.5.4	Quality Manual
7.6	Control of Monitoring and Measuring Devices	INWP04	Calibration

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8.0	Measurement, Analysis and Improvement	QM 8.0	Quality Manual
8.1	General	QM 8.1	Quality Manual
8.2	Monitoring and Measurement	QM 8.2	Quality Manual
8.2.1	Customer Satisfaction	CSWP06	Customer Satisfaction
8.2.2	Internal Audits	QWP06	Internal Audits
8.2.3	Monitoring and Measurement of Processes	QM 8.2.3	Quality Manual
8.2.4	Monitoring and Measurement of Product	INWP05	First Piece Inspection
		INWP02	In-Process Inspection
		INWP03	Final Inspection
8.3	Control of Nonconforming Product	QWP02	Nonconformance Memos
		QWP03	Nonconforming Raw Materials
8.4	Analysis of Data	QM 8.4	Quality Manual
8.5	Continual Improvement	QM 8.5	Quality Manual
8.5.1	Continual Improvement	QM 8.5.1	Quality Manual
8.5.2	Corrective Action	QWP08	Corrective and Preventive Action
8.5.3	Preventive Action	QWP08	Corrective and Preventive Action