PRISMIER

Manufacturing Simplified

PRISMIER, LLC
Quality Manual

Revision D– 7/11/2018

Conforms to ISO 9001:2015
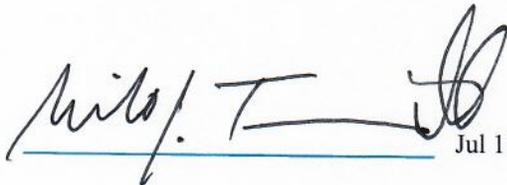
Jul 11th,2018

Mike Tummillo
Vice President of Sales & Marketing

Jul 11th,2018

Dave Low
Vice President of Engineering & Operations

TABLE OF CONTENTS

0.0   Welcome to Prismier, LLC

Prismier is a leading vertically-integrated Mechanical Contract Manufacturer (MCM). Service offerings include Engineering Assistance, Rapid Prototype through Production of Sheet Metal Fabrication & Stamping, Plastic Injection Molding, CNC Machining, Die Casting, and Assembly. Prismier's Corporate Headquarters and New Product Introduction (NPI) Center is conveniently located in Woodridge, IL, just outside of Chicago and have global production partners located throughout the USA, China, and Mexico.

Prismier serves the MCM needs of the individual entrepreneur or small business to the fortune 500 Original Equipment Manufacturer (O.E.M.) by providing comprehensive global manufacturing solutions, control and reduce total costs, and create flexible supply chains that are responsive to volume variability.

At Prismier, our Core Values define the common philosophy shared throughout all levels of our organization. They are critical to our success in conducting business and building relationships with our stakeholders.

- *Be Nice* - We uphold the highest possible standards of ethical behavior characterized by openness, candor, and honesty. At the same time, we expect that all employees will foster an inclusive work environment that celebrates diversity of people, perspectives and ideas.
- *Grow On* - We never stand still; we are never satisfied. Individually, and as teams, we constantly look at what we do, and ask, "How can we do this better?" Then, we use a systematic approach to take action. Equally as important is personal growth; we want each employee to grow personally in their position and keep current with latest manufacturing practices and/or technologies.
- *Appreciate Ya* - We make a difference. We feel rewarded, personally and as a team, because what we do in our jobs is consistent with our goals and dreams. We seek to recognize and to enjoy the good qualities of our employees and their efforts.
- *Own it* - We don't say, "It's not my fault," or "It's not my job." We take responsibility for meeting our commitments — our personal ones as well as those of the entire organization. We take ownership of the results. We are committed to creating value for all of Prismier's key stakeholders. We set high performance standards and hold ourselves personally and collectively accountable to meeting our objectives.

1.0   Prismier: Who We Are

1.1   Determining Our Strategic Direction

Prismier has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This involves:

- Understanding our core products and services, and scope of management system (see 2.2 below).

- Identifying "interested parties" (stakeholders) as those who receive their parts and/or assemblies, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company.

- Understanding internal and external issues that are of concern to Prismier and its interested parties; identified in the document **Vision/Traction Organizer** (VTO)**.** Many such issues are identified through an analysis of risks facing either Prismier or the interested parties. Such issues are monitored and updated as appropriate, and discussed as part of management reviews.

This information is then used by senior management to determine the company's strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

1.2   Scope of the Management System

1.2.1   Scope Statement

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, Prismier has determined the scope of the management system as follows:

The sale and precision manufacturing of prototype and production of metal and polymeric components and assemblies to customer expectations.

1.2.2   Facilities Within the Scope

The quality system applies to all processes, activities and employees within the company. The facility is located at:

10216 Werch Drive, Suite 118
Woodridge IL, 60517
Phone: 630.592.4515
Fax: 630.214.4099
Web: www.prismier.com

1.2.3   Permissible Exclusions

The following clauses of ISO 9001 were determined to be not applicable to Prismier.

- 8.3 Design and development of product and services. – Prismier is a contract manufacturer which specializes in the manufacture of parts, components, and assemblies designed by our customer base.

1.2.4   Scope of the Quality Manual

This manual is prepared for the purpose of defining the company's interpretations of the ISO 9001:2015 international standard, as well as to demonstrate how the company complies with that standard.
This manual does not strictly follow the numbering structure of ISO 9001. Instead, Appendix B presents a cross reference between the sections of this manual and the clauses of ISO

9001:2015.
This manual presents "Notes" which are used to define how Prismier has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in ISO 9001:2015. *Notes appear in italics, with gray background.*
Where subordinate or supporting documentation is reference in this manual, these are indicated by **bold italics**.

2.0 Quality Policy

The Quality Policy of Prismier is as follows:

It is Prismier's goal to be a high performing organization, as defined by our customers, by providing a flexible and responsive customer experience.

We will achieve this by:

- Consistently meeting, if not exceeding, customer product requirements
- Delivering on-time, every time
- Growing our employees
- Building better processes through continual improvement
- Ethical and environmentally responsible practices

Our quality system is based upon the foundations of ISO 9001, Lean Six Sigma manufacturing practices, and our quality focused employees.

3.0 Management System Structure and Controls

3.1 Process Approach

3.1.1 Process Identification

Prismier has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming parts, components, or assemblies discovered during final processes or after delivery. Instead, nonconformities (NC) and risks are identified in real time, by actions taken within each of the top-level processes.
Note: not all activities are considered "processes" – the term "process" in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the top-level processes identified.
The following top-level processes have been identified for Prismier:
- Improvement

- Leadership

- Operations – Sales

- Operations – Manufacturing

- Operations – Supply Chain

- Performance Evaluation

- Planning

- Quality Management System

- Support

Each process may be supported by other activities; such as tasks or sub-processes. Monitoring and control of top level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process is defined by a turtle diagram style document which lists:

- applicable inputs and outputs

- requirements

- resources

- objectives

- process overview

- defined metrics and reporting

- required forms or supporting formats

- direct reference documents

The sequence of interaction of these processes is illustrated in Appendix A.

Note: Appendix A represents the typical sequence of processes, and may be altered depending on customer or regulatory requirements at the job or contract level, as needed.

3.1.2   Process Controls & Objectives

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one "metric" or key performance indicator (KPI) which is then measured to determine the process' ability to meet the quality objective.

Note: some processes have multiple objectives and multiple metrics. This is determined by the nature of the process, it's impact on the produced parts, components, or assemblies and associated risks.

Note: Whereas ISO 9001 discusses process measurements and "quality objectives" as separate concepts, Prismier combines them; i.e., quality objectives are used to control the processes. Additional objectives for part, component, or assembly manufacturing may be assigned, but these will also be used to measure process effectiveness.

Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, in order to present the data to the Leadership Team. The data is then analyzed by the Leadership Team in order that the Leadership Team may set goals and adjust our long-term continual improvement strategies.

The specific quality objectives for each process are defined in the applicable Turtle diagrams Metrics and Reporting box. Current standings and individual goals for each objective, are

recorded on the actual chart or metric, and are reviewed by the Leadership Team during the management reviews.

When a process is achieving less than 80% of the goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes. This corrective and preventive actions (CPA) are recorded in the quality management software.

3.1.3   Outsourced Processes

Any process performed by a third party is considered an "outsourced process" and must be controlled, as well. The company's outsourced processes, and the control methods implemented for each, are defined in **Operations – Supply Chain**.

The type and extent of control to be applied to the outsourced process take into consideration:

a) the potential impact of the outsourced process on the company's capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared,

c) the capability of achieving the necessary control through the purchasing contract requirements.

3.2   Documentation & Records

3.2.1   General

The management system documentation includes both documents and records.

Note: the ISO 9001:2015 standard uses the term "documented information"; Prismier does not use this term, but instead relies on the terms "document" and "record" to avoid confusion. In this context the terms are defined by Prismier as:

- *Document – written or pictorial information used to describe how an activity is done.*
- *Record – captured evidence of an activity having been done.*

Documents and records undergo different controls as defined herein.

The extent of the management system documentation has been developed based on the following:

a) The size of Prismier

b) Complexity and interaction of the processes

c) Risks and opportunities

d) Competence of personnel

The effective implementation date of the quality management system is April. 28, 2016. This date is also used for grandfathering of suppliers, employees, and records. Records, evidence of process controls, or training is not required for the afore mentioned before this time.

3.2.2   Control of Documents & Records

Documents required for the management system are controlled in accordance with procedure

	TITLE: **Quality Manual**				PAGE 8 OF 21
	APPROVAL: *Dave Low*	AUTHOR: **Phill Miller**	DOCUMENT#: **0-0430-1001**	REV: **D**	RELEASED DATE: **05/24/2016**

PRISMIER Manufacturing Simplified

0-0742-2001 Document and Record Control. The purpose of document and record control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information.

All documented procedures are established, documented, implemented and maintained in the quality management software.

3.2.3   Control of Records

Procedure *0-0742-2001 Document and Record Control* has also been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling records that are created by and/or retained by suppliers.

These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of proper production of parts, components, or assemblies, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

3.3   Change Management

When Prismier determines the need for changes to the management system or its processes, these changes planned, implemented, and then verified for effectiveness; see the document *0-0842-3001 Change Control Procedure*.

Documents are changed in accordance with procedure *0-0742-2001 Document and Record Control.*

3.4   Risks and Opportunities

Note: Prismier deviates slightly from the approach towards risk and opportunity presented in ISO 9001. Instead, Prismier views "uncertainty" as neutral, but defines "risk" as a negative effect of uncertainty, and "opportunity" as a positive effect of uncertainty. Prismier has elected to manage risks and opportunities separately, except where they may overlap. Formal risk management may not be utilized in all instances; instead, the level of risk assessment, analysis, treatment and recordkeeping will be performed to the level deemed appropriate for each circumstance or application.

Prismier considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services.

Risks and opportunities are managed directly in the procedure or process for top or high-level processes only. Significant processes, determined by the process owner and/or by the Quality Director, will be given a score from 1 (low risk) to 5 (high risk). Each score of a process will then be averaged to provide an overall score for the process or procedure. Any score over the score of 3.5 will require that a corrective and/or preventive action be put into place. Once the action has been completed, the process shall be rescored to represent the lower level of risk.

Risks and opportunities which are maintained and managed on a daily basis include:

- Customer onboarding and order entry.
  - o Prismier utilizes our web presence and ever-changing marketing practices to bring in new customers and new projects from existing customers.
- Supply chain activities.
  - o Through the utilization of audits, audit checklists, financial review, ongoing incoming inspection and non-conformance data.
- Manufacturing
  - o Utilizing Process Failure Mode and Effects Analysis, formal and informal internal auditing, in process and final inspection results, and our Corrective and Preventive Action processes.

4.0 Management & Leadership

4.1 Management Leadership and Commitment

The Leadership Team of Prismier provides evidence of its leadership and commitment to the development and implementation of the management system and continually improving its effectiveness by:

a) taking accountability of the effectiveness of the management system;

b) ensuring that the Quality Policy and quality objectives are established for the management system and are compatible with the strategic direction and the context of the organization;

c) ensuring that the quality policy is communicated, understood and applied within the organization;

d) ensuring the integration of the management system requirements into the organization's other business processes, as deemed appropriate (see note);

e) promoting awareness of the process approach;

f) ensuring that the resources needed for the management system are available;

g) communicating the importance of effective quality management and of conforming to the management system requirements;

h) ensuring that the management system achieves its intended results;

i) engaging, directing and supporting persons to contribute to the effectiveness of the management system;

j) promoting continual improvement;

k) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

l) Communicating to the staff through town hall meetings (TLC's), email, and cascading management discussions.

Note: "business processes" such as accounting, employee benefits management and legal activities are out of scope of the QMS.

4.2   Customer Focus

The Leadership Team of Prismier adopts a customer-first approach which ensures that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction.
This is accomplished by assuring:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained.

4.3   Quality Policy

The Leadership Team has developed the *Quality Policy*, defined in section 2.0 above, that governs day-to-day operations to ensure quality.
The *0-0520-1001*-*Quality Policy* is released as a standalone document as well, and is communicated and implemented throughout the organization.

4.4   Organizational Roles Responsibilities & Authorities

The Leadership Team has assigned responsibilities and authorities for all relevant roles in the company. These are communicated through the combination of the *0-0530-4001 – Organizational Chart* and personal communication.
The Leadership Team accepts responsibility and authority for:

a) ensuring that the management system conforms to applicable standards;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of the management system;

d) providing opportunities for improvement for the management system;

e) ensuring the promotion of customer focus throughout the organization;

f) ensuring that the integrity of the management system is maintained when changes are planned and implemented.

4.5   Internal Communication

The Leadership Team of Prismier ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods include:

a) regularly scheduled *town hall* styled meetings

b) use of corrective and preventive action processes to report nonconformities or suggestions for improvement

c) use of the results of analysis of data

d) meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS

e) use of the results of the internal audit process

f) internal emails

g) posted memos to employees

h) the Leadership Team's "open door" policy which allows any employee access to the Leadership Team for discussions on improving the quality system

4.6   Management Review

The Leadership Team reviews the management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the *Quality Policy* and quality objectives.

Management review frequency, agenda (inputs), outputs, required members, actions taken and other review requirements are defined in the documented procedure *0-0930-3001 – Management Review – Level 10 Meetings.* Records from management reviews are maintained.

5.0   Resources

5.1   Provision of Resources

Prismier determines and provides the resources needed:

a) to implement and maintain the management system and continually improve its effectiveness

b) to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations.

Resources and resource allocation are assessed during management reviews.

5.2   Human Resources

Senior management ensures that it provides sufficient staffing for the effective operation of the management system, as well its identified processes. See procedure *0-0720-3001 Training, Competence and Awareness.*

Staff members performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience. Training and subsequent communication ensure that staff are aware of:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the management system, including the benefits of improved performance;

d) the implications of not conforming with the management system requirements.

Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.

5.3 Infrastructure

Prismier determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

a) buildings, workspace and associated facilities;

b) process equipment, hardware and software;

c) supporting services such as transport;

d) information and communication technology.

Supporting system software shall be utilized through Prismier's business procedures. The system software will support, but not be limited to, a quality management, enterprise resource planning, accounting and accounts receivables, and a customer relationship management. The software systems and their programmed workflows and processes, which are inherent, shall not be specifically documented. Training provided for these types of software systems will done so on-the-job, and employee competency will be proven by their daily production.

Equipment is validated prior to and maintained during its useful life. All maintenance schema and requirements are setup and recorded in the quality management software.
Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification. All calibration records and requirements will be setup and recorded in the quality management software.
Note: Calibration and measurement traceability is not employed for all measurement devices. Instead, Prismier determines which devices will be subject to calibration based on its processes, products and services, or in order to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.

5.4 Work Environment

Prismier provides a clean, safe and well-lit working environment. The Leadership Team of Prismier manages the work environment needed to achieve conformity to product requirements. Specific environmental requirements for products are determined during quality planning and are documented in subordinate procedures, work instructions, or job documentation. Where special work environments have been implemented, these shall also be maintained per 5.3 above.
Human factors are considered to the extent that they directly impact on the quality of parts, components, or assemblies which are produced for our customers.
Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the management system. Only work environment aspects which can directly affect process efficiency or product and service quality are managed through the management system.

5.5 Organizational Knowledge

Prismier also determines the knowledge necessary for the operation of its processes and to

achieve conformity of products and services. This may include knowledge and information obtained from:

   a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;

   b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained, and made available to the extent necessary.

When addressing changing needs and trends, Prismier shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

6.0   Operation

6.1   Operational Planning and Control

Prismier plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the management system. Such planning considers the information related to the context of the organization (see section 1.0 above), current resources and capabilities, as well as product and service requirements.

Changes to operational processes are done in accordance with the document *0-0842-3001 Change Control Procedures*.

6.2   Customer-Related Activities

6.2.1   Capture of Customer Requirements

During the intake of new business Prismier captures:

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

   b) requirements not stated by the customer but necessary for specified or intended use, where known

   c) statutory and regulatory requirements related to the product;

   d) any additional requirements determined by Prismier.

These activities are defined and recorded in our Customer Relations Management (CRM) software.

6.2.2   Review of Customer Requirements

Once requirements are captured, Prismier reviews the requirements prior to its commitment to supply of parts, components, and/or assemblies. This review ensures that:

   a) product requirements are defined,

   b) contract or order requirements differing from those previously expressed are resolved,

   c) the organization has the ability to meet the defined requirements, and/or the claims for the products and services it offers, and

d) risks have been identified and considered.

These activities are defined in greater detail in the procedures *0-0823-2002 Estimation & Quoting* and *0-0823-2001 Manufacturing Engineering*

6.2.3   Customer Communication

Prismier has implemented effective communication with customers in relation to:
   a) providing information relating to products and services;

   b) handling enquiries, contracts or orders, including changes;

   c) obtaining customer feedback relating to products and services, including customer complaints;

   d) handling or controlling customer property;

   e) establishing specific requirements for contingency actions, when relevant.

6.3   Design and Development

Prismier is a provider of parts, components, and assemblies which are designed by our customers. We prefer to be a part of the design process in conjuncture with our customers, however Prismier recognizes that this will not be the typical case. Regardless of Prismier's involvement with the design process, we take full exception to section 8.3 of the ISO9001 standard.

6.4   Purchasing

Prismier ensures that purchased raw materials, subcomponents, and externally acquired processes or production support services conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent on the effect on subsequent product realization or the final product.
Prismier evaluates and selects suppliers based on their ability to supply product and service in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.
Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received parts, components, and/or assemblies, which are either in a raw state or post an outside service or process are then verified against requirements to ensure satisfaction of requirements. Suppliers who do not providing conforming parts, components, or services may be requested to conduct formal corrective action.

6.5   Provision of Production of Parts, Component, and/or Assemblies

6.5.1   Control of Provision of Production

To control its provision of Production, Prismier considers, as applicable, the following:
   a) the availability of documents or records that define the characteristics of production as well as the results to be achieved;

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

c) the implementation of monitoring and measurement activities;

d) the use of suitable infrastructure and environment;

e) the appointment of competent persons, including any required qualifications;

f) the implementation of actions to prevent human error;

g) the implementation of release, delivery and post-delivery activities.

At this time, Prismier does not utilize any in-house "special processes" where the result of the process cannot be verified by subsequent monitoring or measurement. Any such special processes are sent to outside suppliers, and controlled and an outsourced process per the customer requirements.

6.5.2   Identification and Traceability

Where appropriate, Prismier identifies its parts, components, and assemblies or other critical process outputs by suitable means. Such identification includes the status of production with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection or disposition, or some other similar identifier, all product shall be considered conforming and suitable for use.

If unique traceability is required by contract, regulatory, or other established requirement, Prismier controls and records the unique identification of the part, component, or assembly.

6.5.3   Property Belonging to Third Parties

Prismier exercises care with customer or supplier property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.

For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use. Third party property will be recorded and tracked in the quality management software system.

6.5.4   Preservation

Prismier preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

6.5.5   Post-Delivery Activities

As applicable, Prismier conducts the following activities which are considered "post-delivery activities":

- Preproduction Part Approval Process Documentation

- Customer support of part production inquiry

- Support of customer production move

Post-delivery activities are conducted in compliance with the management system defined herein.

6.5.6 Process Change Control

Prismier reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Process change management is defined in the document *0-0842-3001 Change Control Procedure.*

6.5.7 Measurement and Release of Production

Acceptance criteria for produced parts, components or assemblies are defined in appropriate subordinate or customer documentation. Reviews, inspections and/or tests are conducted at appropriate stages to verify that the product and service requirements have been met. This is done before the parts, components or assemblies are released or services are delivered.

Each process utilizes different methods for measuring and releasing production.

6.5.8 Control of Nonconforming Outputs

Prismier ensures that productions of parts, components or assemblies, or other process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

7.0 Improvement

7.1 General

Prismier uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible.

Improvement shall be driven by an analysis of data related to:

The results of analysis shall be used to evaluate:

    a) conformity of products and services;

    b) the degree of customer satisfaction;

    c) the performance and effectiveness of the management system;

    d) the effectiveness of planning;

    e) the effectiveness of actions taken to address risks and opportunities;

    f) the performance of external providers;

    g) other improvements to the management system.

7.2 Customer Satisfaction

As one of the measurements of the performance of the management system, Prismier monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information include:

- recording customer complaints

- product rejections or returns

- repeat orders for product

- changing volume of orders for product

- trends in on-time delivery

- obtain customer scorecards from certain customers

- customer satisfaction surveys as presented as a part of our emails

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

7.3   Internal Audit

Prismier conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO 9001, and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained. For a further description of the process, see document *0-0920-3001 – Internal Audits.*

7.4   Corrective and Preventive Action

Prismier takes corrective action to eliminate the cause of nonconformity in order to prevent *recurrence.* Likewise, the company takes preventive action to eliminate the causes of potential nonconformities in order to prevent their *occurrence.*

These activities are done through the use of the quality management software. Prismier follows the 8D process to:

1. *Define the action team*
2. *Describe the problem*
3. *Develop an interim containment plan*
4. *Determine root cause and escape points*
5. *Determine permanent corrections to resolve the issue*
6. *Define and implement corrective actions*
7. *Prevent future system problems*
8. *Recognize the team efforts*

TITLE: **Quality Manual**				PAGE 18 **OF** 21
APPROVAL: *Dave Low*	AUTHOR: Phill Miller	DOCUMENT#: **0-0430-1001**	REV: **D**	RELEASED DATE: **05/24/2016**

PRISMIER
Manufacturing Simplified

Appendix A: Overall Process Sequence & Interaction
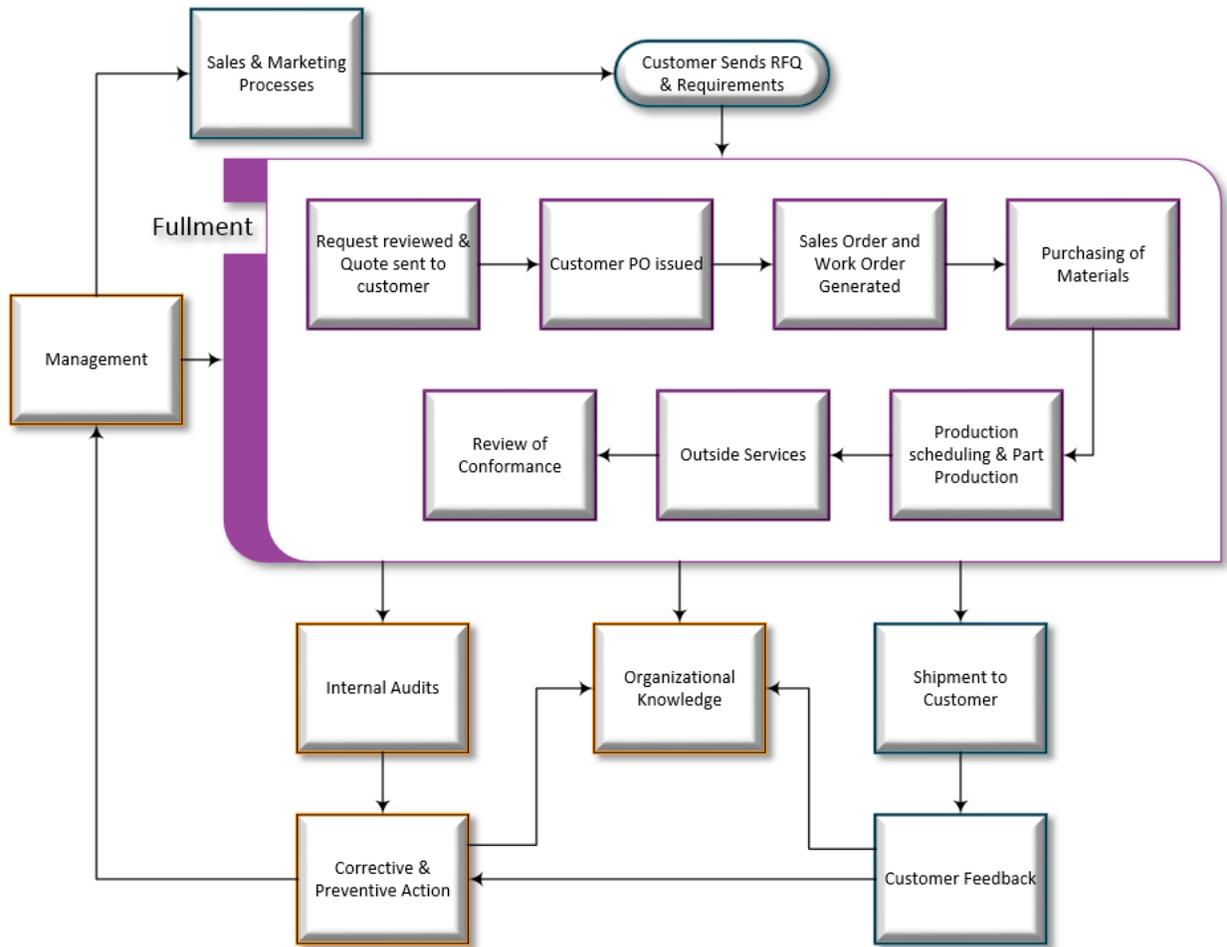
*Reference: **0-0420-3001 Prismier Overall Process***

Appendix B: ISO 9001:2015 Cross Reference

ISO 9001:2015 Clause	Section in Manual
4.0 Context of the Organization (all)	
4.1 Understanding the Organization & Its Context	1.1 Determining Our Strategic Direction
4.2 Understanding the needs & expectations of interested parties	1.0 Who We Are
4.3 Determining the scope of the QMS	1.2 Scope of the Management System
4.4 Management system and its processes	3.1 Process Approach
5.0 Leadership	
5.1 Leadership & Commitment	4.1 Management Leadership and Commitment
5.1.1 General	4.1 Management Leadership and Commitment
5.1.2 Customer focus	4.2 Customer Focus
5.2 Policy	2.0 Quality Policy 2.3 Quality Policy
5.3 Organizational Roles Responsibilities and Authorities	4.4 Organizational Roles and Responsibilities and Authorities
6.0 Planning	
6.1 Actions to address risks and opportunities	3.4 Risks and Opportunities
6.2 Quality objectives and planning to achieve them	3.1.2 Process Controls & Objectives
6.3 Planning of changes	3.3 Change Management
7.0 Support	
7.1 Resources	
7.1.1 General	5.1 Provision of Resources
7.1.2 People	5.2 Human Resources
7.1.3 Infrastructure	5.3 Infrastructure
7.1.4 Environment for the operation of processes	5.4 Work Environment
7.1.5 Monitoring and measuring resources	5.3 Infrastructure
7.1.6 Organizational knowledge	5.5 Organizational Knowledge
7.2 Competence	5.2 Human Resources
7.3 Awareness	4.5 Internal Communication
7.4 Communication	4.5 Internal Communication
7.5 Documented information	3.2 Documentation & Records
8.0 Operation	
8.1 Operational planning and control	6.1 Operational Planning and Control
8.2 Requirements for products and services	
8.2.1 Customer communication	6.2.3 Customer Communication
8.2.2 Determining the requirements related to products & services	6.2.1 Capture of Customer Requirements
8.2.3 Review of requirements related to products & services	6.2.2 Review of Customer Requirements
8.2.4 Changes to requirements for products and services	6.2.2 Review of Customer Requirements

TITLE:
Quality Manual

PAGE 20 **OF** 21

APPROVAL: *Dave Low*

AUTHOR: Phill Miller

DOCUMENT#: 0-0430-1001

REV: D

RELEASED DATE: 05/24/2016

ISO 9001:2015 Clause	Section in Manual
8.3 Design and development of products and services	6.3 Design and Development
8.4 Control of externally provided processes, products & services	6.4 Purchasing
8.5 Production and service provision	
8.5.1 Control of production and service provision	6.5.1 Control of Provision of production
8.5.2 Identification and traceability	6.5.2 Identification and Traceability
8.5.3 Property belonging to customers or external providers	6.5.3 Property Belonging to Third Parties
8.5.4 Preservation	6.5.4 Preservation
8.5.5 Post-delivery activities	6.5.5 Post-Delivery Activities
8.5.6 Control of changes	6.5.6 Process Change Control
8.6 Release of products and services	6.5.7 Measurement and Release of Production
8.7 Control of nonconforming outputs	6.5.8 Control of Nonconforming Outputs
9.0 Performance evaluation	
9.1 Monitoring, measurement, analysis and evaluation	
9.1.1 General	7.1 Improvement: General
9.1.2 Customer satisfaction	7.2 Customer Satisfaction
9.1.3 Analysis and evaluation	7.1 Improvement: General
9.2 Internal audit	7.3 Internal Audit
9.3 Management review	4.6 Management Review
10.0 Improvement	
10.1 General	8.1 Improvement: General
10.2 Nonconformity and corrective action	8.4 Corrective and Preventive Action
10.3 Continual improvement	8.1 Improvement: General