Title: Quality Policy Manual ISO 9001:2015 ISO 13485:2016 AS9100D:2016	**Document: Q1** **Revision: P11** **Date: 12/01/2025** Protomatic Quality Manual Q1 Rev P11 Approved 12-01-25	Original Approval _____ QA Approval _____

Note: Only electronic files and hard copy quality documents containing a signed Control Block are considered controlled.

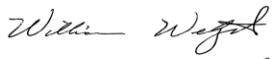
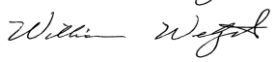
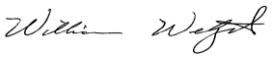
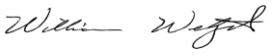
PROTOMATIC

Quality Policy Manual

WEB SITEs:

www.Protomatic.com

Record of Revision History

Revision	Approval	Date	Nature of Change
A		11/17/1997	Initial Release
B		1/7/1998	Changed Scope to ISO9002, not ISO9001; Changed Section 20 to reference procedure PRC-20-01, Statistical Methods
C		5/8/1998	Policy- Added Endorsement of Policy Section 4.6; Addressed 4.6.4 Customer Verification of purchased product; Section 4.10 Addressed urgently released product; Section 4.11 Addressed 4.11.2, b, f and h
D		8/24/1998	Section 14- Removed paragraph 3.4 and 3.5 Reference to Customer Complaint Log.
E		12/30/1998	Introduction- Removed requirement for President Signature of Introduction Quality Policy; Endorsed by new President (Rita Wetzel instead of Bill Wetzel); Section 1- Management review was quarterly; Section 3 Verbal orders are accepted per salesperson discretion.
F		07/29/2002	Revised and rewrote to ISO-9001:2000 standard, excluding Product Design (7.3).
F1		01/18/2005	Added last paragraph to section 6.2.2 to grandfather in skills employees already have before issuance of quality procedure.
F2		02/01/2005	Added PRC-02-01 to 4.2.4.
G		10/17/2005	Added "*Approval*" column to revision history page.
G1		02/21/2007	Added note to all pages on "only blue stamp" indicating controlled documents.
H		06/26/2007	Added the intent commitment for ISO 13485 Medical and AS9100 Aerospace, and some ref procedures.
J		05/12/2008	Modified Title block to include Signoff; Added Mgt. Rep. to Org. chart; modified wording in Section 5.6.3 from Action Items to Decisions and Actions.
K		01/31/2009	Revised and rewrote to ISO 9001:2008 standard.
K1		02/24/2009	Add Exclusion to clarify standards.
K2		02/25/2009	ERRATA Changes; Color coded text to clarify different areas.
K3		02/27/2009	ERRATA Changes; Removed AS9100:2004 and ISO 13485:2003 from Title block.
L		07/16/2009	AS9100:2004 and ISO 13485:2003 were separated by color code; Includes clause number for reference and removed strike outs.
M		07/28/2010	Inserted updated org chart; and added 8.2.4 from ISO9001 to QA Manual.
M1		7/19/2012	Updated org chart page 11.
M2		12/9/2013	Eliminated org chart from Quality Manual.
M3		1/28/2014	Stage 1 ISO 13485:2003 Corrections/Improvement to Exclusions, Vision, Resp. & Authority, Clarification of Procedures
M4		2/10/2014	Table of contents updated; Quality System & Plan updated; Responsibility and Authority matrix updated; 4.2.4 Control of Records clarified retention periods; Corrected typos.

M5	4/29/2014	Modified Responsibility and Authority Matrix to match Position Responsibilities PRC-01-04 making uniform titles with Org Chart, FRM0101
M6	12/2/2014	Removed Special Need Tag Procedure PRC-10-05, replaced with enhanced In-Process Instruction Ins1003, removed Shipping Receiving Instruction Ins0908 (redundant, in Position Responsibilities PRC-01-04)
M7	5/4/2015	Added Conflict Minerals, Counterfeit Product Mitigation, Safety and Health Statements.
M8	11/30/2015	Added Configuration Management Clause 7.1.3, Work Transfer 7.1.4 (Pg26) and referenced procedures. Updated Quality System Plan, PRC-02-02, picture (pg14-15)
M9	2/3/2017	Added Cyber Security Policy and Procedure references (PRC-24-01); Changed Reps. & Authority for 6.3 Infrastructure; Updated PRC-02-01 ref image (L6).
N	3/24/2017	Updated to ISO9001:2015 and ISO13485:2016 requirements.
P	10/13/2017	Updated to AS9100D:2016 requirements.
P1	1/19/2018	Added process interaction sheet.
P2	3/1/18	Updated to AS9100D:2016 requirements after registration audit.
P3	2/6/2020	AS9100D:2016 Improvements Updated 0.1.1 List of Interested Parties improving relevance of Interested parties (AS9100D 4.2.b.) Improved 0.4 Interaction of Processes Graphics (AD9100D 4.4.2.b)
P4	3/25/2020	AS9100D:2016 Improvements Added “Implementation Note” for Section 0.1.1 and 0.4.
P5	1/27/2021	AS9102D:2016 Improvements Added detail for Interested Parties and Implementing Documents In section 0.1.1
P6	11/10/2022	Updated Quality Policy Removed Rita Wetzel as President and added Doug Wetzel as Managing Director.
P7	9/8/2023	Updated Quality System and Plan to include AS9100 Ref. (p. 18-19) Added RoHS and Reach Policy (p. 14). Added Implementing Documents (p.14). Removed www.ProtomaticMedical.com and www.ProtomaticAerospace.com from (p.1).
P8	9/24/2024	Added Climate Change Policy. (p.14). Added Process Interactions For PEARS (p. 18). Added PEAR 1-6 to Qual System & Plan (p. 19-20)
P9	10/28/2025	Updated PEAR map and Core Process interactions.

P10	11-13-25	Revised 8.5.5 Exceptions for post-delivery activities (pg.7&40)
P11	12-01-25	Added to 7.5.1.4 Exceptions for post-delivery activities (pg. 41) Removed PRC-02-01 (Quality System and Plan pg.19-20). Added "All other clauses not listed" to Resp. Matrix (pg. 16)

Text Color Chart

ISO 9001-Black
ISO 13485 Blue
AS9100-Red

Title, Scope and Field of Application

Forward

0.1 General

Protomatic, Inc. has adopted the ISO 9001:2015 Standard as its base quality management system but has also added the additional requirements of ISO 13485:2016 and AS9100D:2016. This decision is reflected in this manual. This document specifies the quality management and related systems that we use. Differences from the base are:

ISO 13485 standards highlighted in Blue
AS9100 standards highlighted in Red

The systems requirements of this manual are aimed at achieving customer satisfaction by consistently providing conforming product and meeting customer requirements through application of the system, continual improvement and the prevention of nonconformity. This Quality Manual conforms to the requirements and elements of the ISO 9001:2015 international standard. Protomatic, Inc. adheres to the policy statements defined for each Clause and sub-clause or element of the aforementioned standard, plus the added requirements. We are a prototype organization primarily serving the automotive, aerospace, and medical device fields but also providing Contract Manufacturing for all industries as we specialize with CNC Vertical Machining Centers, precision CNC Turning, welding, CAD, CAM, CMM, fixtures, and tool and die.

Certain specific requirements, such as those intended only for medical device manufacturers, that are stated in this manual are only met for the intended specific customer base and are noted accordingly.

The processes within Protomatic, Inc. are inter-related and this can be seen by the flow chart diagrams on page 11 of this manual as well as the inputs and outputs listed on all documented procedures, which we have created.

0.1.1 List of Interested Parties

The interested parties that relate to Protomatic business are:

Internal

Interested Party	Relationship/Requirements	Relevance/Risk
Employees	Safe work environment, Consistent compensation	Injury, sickness, human factors Unemployment, Turn-over
Owners/Share Holders Investors	Sustainability Profit and ROI on Investment Reputation	Too much pressure for Short Term Profit Loss of Business Knowledge (Turnover) Unethical Behavior Environmental Damage

External

Interested Party	Relationship/Requirements	Relevance/Risk
Customers	Supplier Requirements Product Quality Contract Requirements	Nonconforming Materials Competitor Pricing pressure Product Lead-time
Suppliers (Raw Material) (Service/Process)	Consistent business stream Contract Requirements & Capabilities for Service	Variable Product Quality & Nonconforming product Price increases Unapproved process changes
Competitor	None	Pricing Pressure Product/service changes
Communities & Schools	Taxes, revenue stream Education- Personnel	New Requirements, Change to Taxes Lack of Competent Personnel

Regulatory Agencies Product compliance Changes/New- Licensing requirements
(US Gov, DOD, FDA, FAA, OSHA, MIOSHA, DDTC, State of MI, City of Dexter, etc.)

Implementing Documents (AS9100D- Standard Section 4.1, 4.2, 4.4.2)

PFEMA- Risk / Mitigation	FRM PFEMA
QMS Policies section for Method	QMS Q1 (This Document, Section 0.4)
Scope of Implementation	QMS Q1 (This Document, Section 0.4)
Responsibility and Authority	QMS Q1 (This Document, Section 0.4)
Customers	QMS Q1 (This Document, Section 0.4),
Opportunities, Competitor	Strategic/Tactical Plan, Sales Meetings
Employees	HR Procedures PRC-01-04, PRC-01-08 Employee Manual, Training (Orientation and Skills), All Procedures, Instructions and Forms
Suppliers	Terms and Conditions INS0603, Purchasing PRC-06-01 and PRC-06-02 PFEMA, NCMR PRC-13-01 and CAPA PRC-14-01
Safety	Employee Manual, Safety Training TRN009, Forklift Training TRN012, Lockout TRN013, Liquid Store age TRN021, Fire Ext TRN033, Employee Evac TRN037, First Response TRN038 Blood borne Pathogen TRN040, Mag Handling TRN041, Cyber Security TRN057, Corona Virus TRN060 Suitable Work Environment PRC-09-03 Visitor Policy PRC-01-06
Regulatory Agencies	Advisory Notice PRC-23-01, IT Cyber Security PRC-24-01, PRC-24-02 Management Review PRC-01-03
Community	Emergency Plan INS0906,
Owners	Business Continuity Plan INS0912 Supplier Code of Ethics INS0607 Tactical and Strategic Plan (See Mang. Review)

0.2 Process Approach

Protomatic, Inc. has adopted the process approach in the development, implementation and improvement of its quality management system. This approach enhances customer satisfaction using a closed-loop methodology.

0.3 Exclusions/Exceptions

Protomatic, Inc. satisfies the requirements of ISO9001:2015, ISO13485:2016 and AS9100D:2016 with the following exclusions/exceptions:

- Product design (7.3), servicing (part of 7.5), installation (7.5.3) and certain sterilization requirements (7.5.2, 7.5.5, 7.5.7) are excluded.

Justification for these exclusions/exceptions:

- 7.3- It is Protomatic, Inc.'s policy not to accept orders or contracts that specify design responsibility for machined parts.
- 7.5- Distribution of completed medical devices - Not performed.
- 7.5- due to the nature of a provider of prototype parts and components, servicing is not part of any contracts we have historically taken
- 7.5.3- due to the nature of a provider of prototype parts and components, installation of the component is not part of any contracts we have historically taken
- 7.5.2, 7.5.5, 7.5.7- Cleanliness and sterilization has never historically been requested of us due to the nature of our business - Not performed.
- 7.5.3- Installation - Not performed.
- 7.5.4- Servicing - Not performed.

All clauses of AS9100D:2016 apply to this QMS with the following exceptions:

- 8.3 Design and Development Planning
- 8.5.5 Post-Delivery Activities
  - a. statutory and regulatory requirements;
  - c. the nature, use and intended lifetime of its products and services.
  - d. customer requirements;
  - f. collection and analysis of in-service data
  - g. control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul
  - h. controls required for work undertaken external to the organization
  - i. product/customer support

See section 7.5.1.4 and 7.5.1.5 of this manual for details.

Clauses stated in section 0.3 come from the international standards.

Current Independent (3rd Party) Auditors audit to ISO 9001:2015, ISO-13485:2016 and AS9100D:2016.

Note: We modified 0.3 exclusions to increase clarity for all Auditors (2nd and 3rd party).

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Quality Manual Distribution

Recipient	(P) – Paper (E) – Electronic
General Manager Office	P #1
Shop Floor - Documentation Board	P #2
Network Server (+Backup)	E #1

0.4 Introduction to the Organization

Company Profile

Protomatic Inc. is a Prototype machining and custom Short-Run Production CNC Mill and Turning Job Shop located in Dexter, Michigan, in a temperature controlled 30,500 square foot facility.

Protomatic offers, prototype, production manufacturing and assembly of custom parts and systems manufactured for Medical, Automotive, Military, Electronic, Aerospace, and Optical OEMs.

Knowledgeable with a variety of materials such as:
Aluminum, Magnesium, Brass, Phosphor Bronze , Aluminum Bronzes, Steels
Stainless Steels; 300 Series, 400 Series , Duplex, 17-4PH (630), MO 13-8PH,
Titanium; 6Al4V Grade 5, Ti pure Grade 2, 6Al4V ELI Grade 23
Plastics; Ultem™, Telfon™, UHMW, Delrin™, Acetel, Vespel™, Nylon, Kapton™, and others
Refractory Metals such as Tungsten, Niobium, Tantalum, Rhenium (Rene), Molybdenum, Super Alloys; Haynes 25™, Kovar™, Invar™, Inconel™, Hastelloy™, Cobalt Steels and Nickel Steels.

Contract Manufacturing for all industries specializing with CNC Vertical Machining Centers, precision CNC Turning, welding, CAD, CAM, CMM, fixtures, and tool and die.
Custom parts made from billet or custom casting are available.

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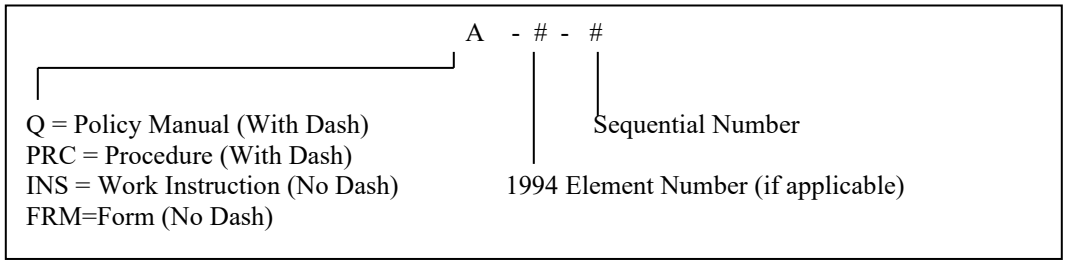
Quality Manual Control

Protomatic, Inc.'s Quality Manual is distributed on paper in a controlled fashion, with very few printed copies. The manual is reviewed periodically and approved by our General Manager or President. One controlled paper copy of this manual is accessible on the shop floor to view. The controlled electronic copy of the manual is stored in the network server and is accessible by limited authorized personnel and can only be modified by personnel the Quality Manager and/or the General Manager authorizes and requires re-approval by the General Manager or President. Uncontrolled versions of the Quality Manual are available to customers upon request. The distribution list on the previous page describes locations of "controlled" copies. Individuals listed in the Responsibility Matrix as primarily responsible for each policy had input in the creation of the policies listed throughout the manual. The General Manager or higher of Protomatic, Inc. approves the entire manual.

Quality Documentation Scheme- Protomatic, Inc.'s Quality documentation is numbered under the following scheme.



Q1 Quality Policy Manual (entire manual is controlled as one document)

Our Policy Statement

QUALITY POLICY

Protomatic, Inc. will continuously improve its products and production processes to better satisfy the needs and expectations of its customers. Protomatic, Inc. is dedicated to on time delivery of defect-free products.

Managing Director: *Doug Wetzel*

This policy has been formulated and is endorsed by the President of Protomatic, 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. Protomatic, Inc.'s Primary Objectives and Goals are also explained and discussed. They are:

To always deliver On-time: On-time Delivery allows customers to meet their scheduling commitments. Protomatic, Inc.'s timely delivery, in support of customer schedules, is mutually beneficial.

To provide fast "Turn-around": Short lead times are a significant strategy of Protomatic, Inc. Providing short lead-time products are an exceptional service and value to customers.

To always deliver Defect Free Products: Delivering defective products is extremely costly. Some costs include: direct product replacement costs, scheduling costs -"ripple effect" in manufacturing, customers missing schedule deadlines and/or Protomatic, Inc. loss of customer. Eliminating and/or controlling defective products is of paramount concern to Protomatic, Inc.

To Exceed Customer Expectations: Protomatic, Inc. strives not only to meet customer expectations, but also to exceed them. Protomatic, Inc. strives to always supply timely products at a price consistent with the most competitive technology available.

Our Mission Statement

Slogan/ Tag Line: "Life-Saving Precision"

Protomatic is a CNC contract manufacturer with consistently high quality and uncompromising precision essential to produce our customer's components that save lives.

Protomatic's
Conflict Mineral Statement

Protomatic Inc. endeavors to not purchase any material that contains "conflict minerals" which directly or indirectly finance or benefit armed groups in the DRC or an adjoining country. We are implementing reasonable due diligence processes to understand where "conflict minerals" are being used in our products and to determine the source and the origin within our supply chain.

Suppliers of tin, tungsten, tantalum and gold to Protomatic are expected to establish their own conflict minerals policies in conformance with the Dodd-Frank Act, due diligence frameworks and management systems that are designed to prevent conflict minerals originating from the DRC or an adjoining country, to the extent that they benefit groups committing human rights violations, from being included in the products sold to Protomatic. In the event Protomatic determines that a supplier has failed to develop and implement reasonable steps to comply with this Policy, Protomatic reserves the right to take appropriate actions per our quality systems procedure Purchase Order PRC-06-02 and Purchasing Requirements Instruction INS0602, which may include discontinuing the business relationship with the supplier.

Protomatic's
Counterfeit Product Mitigation

Protomatic, Inc. recognizes that the counterfeiting of components is a serious problem and affects the economy worldwide. The impact of counterfeit parts cannot be understated - these parts adversely affect the U.S. supply chain by greater costs to companies having to mitigate the risk, replace failed parts, lost sales and lost brand value, as well as damage to the business image. To customers, it means failed products, lower reliability and safety concerns.

Protomatic is committed to provide high quality products on which our customers may rely. In that endeavor, it is our policy and commitment of Protomatic Inc. to ensure that counterfeit parts are not used in the manufacture of Protomatic products per our quality system procedure PRC-06-02 and Instruction INS0602.

We purchase components directly from:

- Manufacturer Direct (OCM)
- Manufacturers Authorized Distributor
- Manufacturers Approved Agent/Rep

The performance of our approved vendors is continuously monitored, internally, by Protomatic, in addition to auditing by outside agencies, in accordance with the ISO 9001, ISO 13485 and AS9100 standards.

Protomatic
Safety and Health Policy

Company policy: It is the policy of this company to ensure a safe, healthful workplace for all its employees. Injury and illness losses from incidents are costly and preventable. This company will employ an effective accident and illness prevention program that involves all its employees in the effort to eliminate workplace hazards.

Management: Management is accountable for preventing workplace incidents, injuries and illnesses. Management will provide top-level support of safety program initiatives. Management will consider all employee suggestions for achieving a safer, healthier workplace. Management also will keep informed about workplace safety and health hazards, and it will regularly review the company safety and health program.

Supervision: Supervisors are responsible for supervising and training workers in safe work practices. Supervisors must enforce company safety rules and work to eliminate hazardous conditions. Supervisors shall lead safety efforts by example.

Safety Officer: The safety officer or any employee representatives may recommend safety and health improvements in the workplace. The officer is responsible for identifying hazards and unsafe work practices, removing obstacles to incident prevention and helping the company evaluate the accident and illness prevention program.

Employees: All employees are expected and encouraged to participate in safety and health program activities including the following: reporting hazards, unsafe work practices and accidents immediately to their supervisors or a safety committee representative; wearing required personal protective equipment; and participating in and supporting safety committee activities.

Protomatic
Cyber Security Policy

Company policy: It is the policy of this company to ensure a safe cyber environment. This involves training employees on security principles. Steps are taken to protect information, computers and network from cyber attacks through the following methods; provide a firewall security for employees Internet connection, control mobile device usage, make backup copies of important business data and information, control physical access to computers, create user accounts for each employee, secure Wi-Fi networks, employ best practices on electronic payments, limit employee access to data and information, limit authority to install software and utilize password and authentication protocols. The company will measure and monitor effectiveness to improve overall security. Protomatic uses NIST SP800-171 as the principle guidelines, additional guidelines will be instituted subject to new threats. These guidelines may change without notification.

Protomatic
RoHS 3 and REACH Policy:

The Directive RoHS 3 on the "Restriction of the use of certain hazardous substances in electrical and electronic equipment" as introduced to the EU in 2002 as directive 2002/95/EC and implemented soon thereafter, is intended to reduce the levels and restrict the use of the stated substances in electrical and electronic equipment (NO GREATER THAN 0.1% OF THE PRODUCT). Protomatic policy, when required by our customers, is to not introduce any of the stated materials into its finished goods as specified in RoHS Directive 2015/863/EU. Exempt materials are specified by customer requirements.

Protomatic also strives to develop manufacturing processes that do not introduce Substances of Very High Concern (SVHC), as specified in EU REACH (European Union), (Registration, Evaluation, Authorization and Restriction of Chemicals) Regulation Article 57.

Implementing Documents:
Quality System and Plan PRC-02-01
Restricted Materials List FRM0609
Purchase Order PRC-06-02
Supplier Approval PRC-06-01
Purchasing Requirements Ins0602
IT and Internal Support Services PRC-24-01
IT Implementation and Reaction PRC-24-02
Suitable Work Environment PRC-09-03

Protomatic
Climate Change Policy:

It is the policy of Protomatic to continually evaluate the internal and external effects of climate change and its ability to achieve the intended results of its quality management system. Climate change is a very important external issue that can significantly impact the quality management system and ultimately the ability of Protomatic to serve its valued customers. Therefore Protomatic is committed to include climate change and its effects as a strategic factor when striving to achieve its intended results: Exceed Customer Expectations; Continuously Improve Products and Processes; On Time Delivery and Defect Free Products; "Life-Saving Precision". Protomatic realizes that climate change is continually evolving and therefore will periodically evaluate its impacts to its business.

See Management Review(s)

Responsibility and Authority Matrix KEY- "P"=Primary "S"= Secondary

Reference Only: **ISO 9001:2015 Sections** **ISO 13485:2016 Sections** **AS9100D:2016 Sections**	**Quality Mgr.**	**Mfg. Mgr.**	**Finance Mgr.**	**Pres.**	**VP of Sales**	**IT Mgr.**	**VP and General Mgr.**	**Engineer Mgr.**
4. Quality Management System								
4.1 General Requirements		S		P			S	
4.2 Documentation Requirements	P	S						
General	S			P				S
Quality Manual	P			S			S	S
Control of Documents	P	S						S
Control of Records	P							S
5. Management Responsibility								
5.1 Management Commitment	S	S	S	P	S	S	S	S
5.2 Customer Focus	S	S	S	S	P	S	S	S
5.3 Quality Policy	S			P				
5.4 Planning	S			P	S			
Quality Objectives		S		P				
QMS Planning	S	S		P				
5.5 Responsibility Authority		S		S			P	
Management Representative	P	S						
Internal communication	P	S			S		S	
5.6 Management Review	S			P				
General	S			P			S	
Review input	P			S			S	
Review Output	S			P			S	
6. Resource Management								
6.1 Provision of Resources	S			P			S	
6.2 Human Resources		S	P					
General		S	P					
Competence, awareness, training		S	P					
6.3 Infrastructure			S	P		P	P	S
6.4 Work Environment		S				P	S	
7. Product Realization								
7.1 Planning of Product Realization	S	S		S	P		S	S
7.2 Customer-Related Processes	S	S		S	P		S	S
Customer communication	S				P		S	
7.3 Design and Development (Not Applicable)				P				
7.4 Purchasing			P				S	
7.5 Production and Service (NA) Provisions	S	P					S	
Control of production servicing provision	S	P					S	
Validation of processes for production/servicing provision	P	S						S
Identification and traceability	S	P						S
Customer property		S			S			P
Preservation of product	P						S	
7.6 Control of Monitoring and Measuring Devices	P							S

Reference Only: **ISO 9001:2015 Sections** **ISO 13485:2016 Sections** **AS9100D:2016 Sections**	**Quality Mgr.**	**Mfg. Mgr.**	**Finance Mgr.**	**Pres.**	**VP of Sales**	**IT Mgr.**	**VP and General Mgr.**	**Engineer Mgr.**
8. Measurement Analysis Improvement								
8.1 General (SPC)	P							S
Customer satisfaction	S				P			
Internal audit	P			S			S	
Monitoring and measurement of processes	S	P						
Monitoring and measuring of product	S	P						
8.3 Control of Nonconforming Product	P	S					S	S
8.4 Analysis of Data	P			S			S	S
8.5 Improvement	P	S						
Continual improvement	S	S					S	P
Corrective action	P	S					S	
Preventative action	P	S					S	
All Other Clauses not Listed, Including applicable post-delivery activities.	S			P				