HARVEY VOGEL MANUFACTURING CO.

Custom Metal Stampings and Assemblies

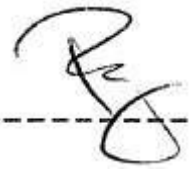
Quality Manual

Endorsement Page

Prepared by: **Patricia Pearson,**
Director of Quality

_____ Date: **06-30-2016**

Approved by: **Bob Verhey,**
President



_____ Date: **06-30-2016**

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Harvey Vogel Manufacturing Company
COMPANY OVERVIEW

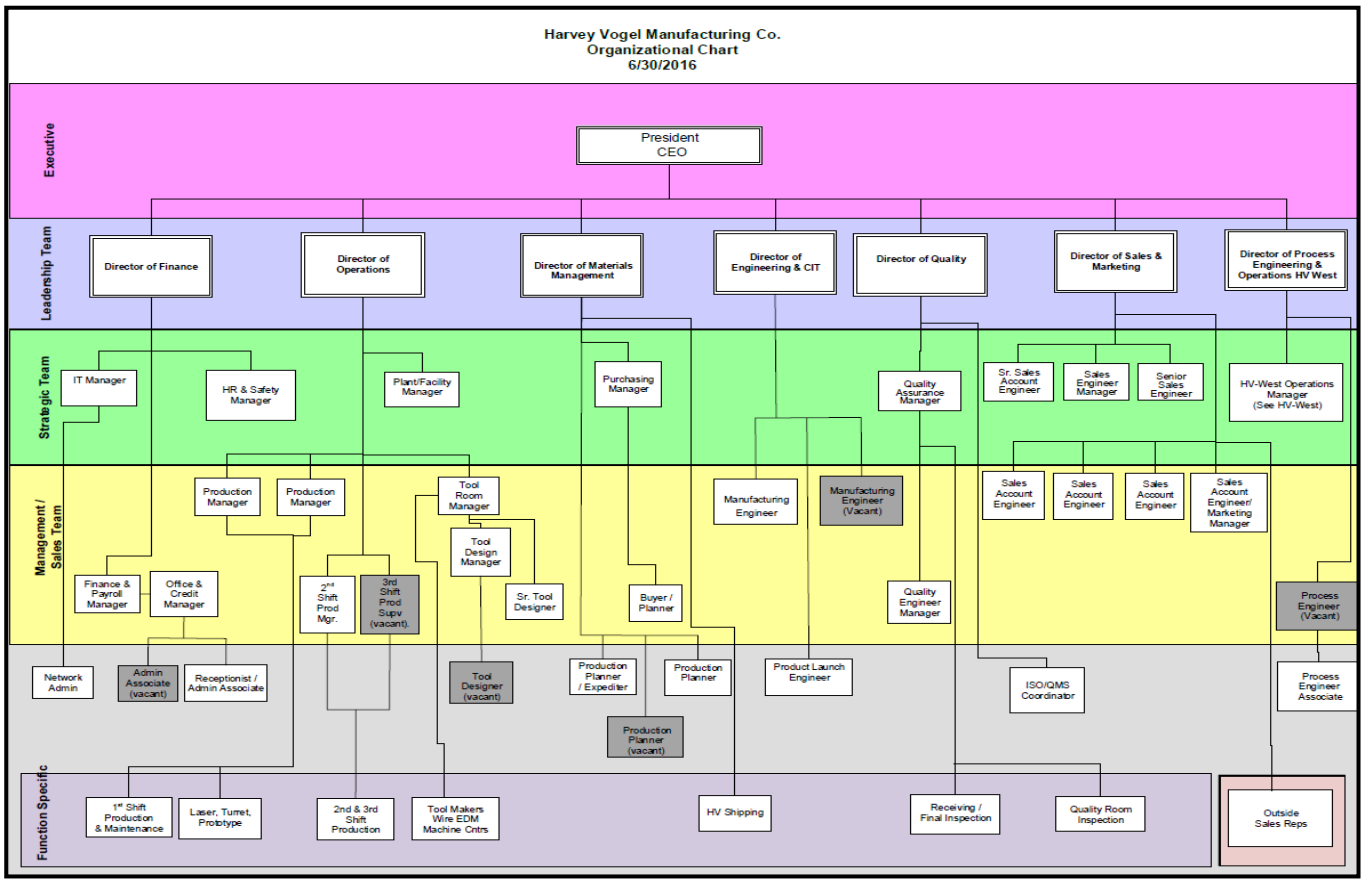
With over 70 years of excellence in manufacturing, Harvey Vogel's team of 180 dedicated professionals is ready to provide the best solutions to all of your metal stamping and fabrication needs. Whether your project demands prototypes, a short run, a long run or a complex assembly, you will find in Harvey Vogel a metal stamping resource that holds your interests first.

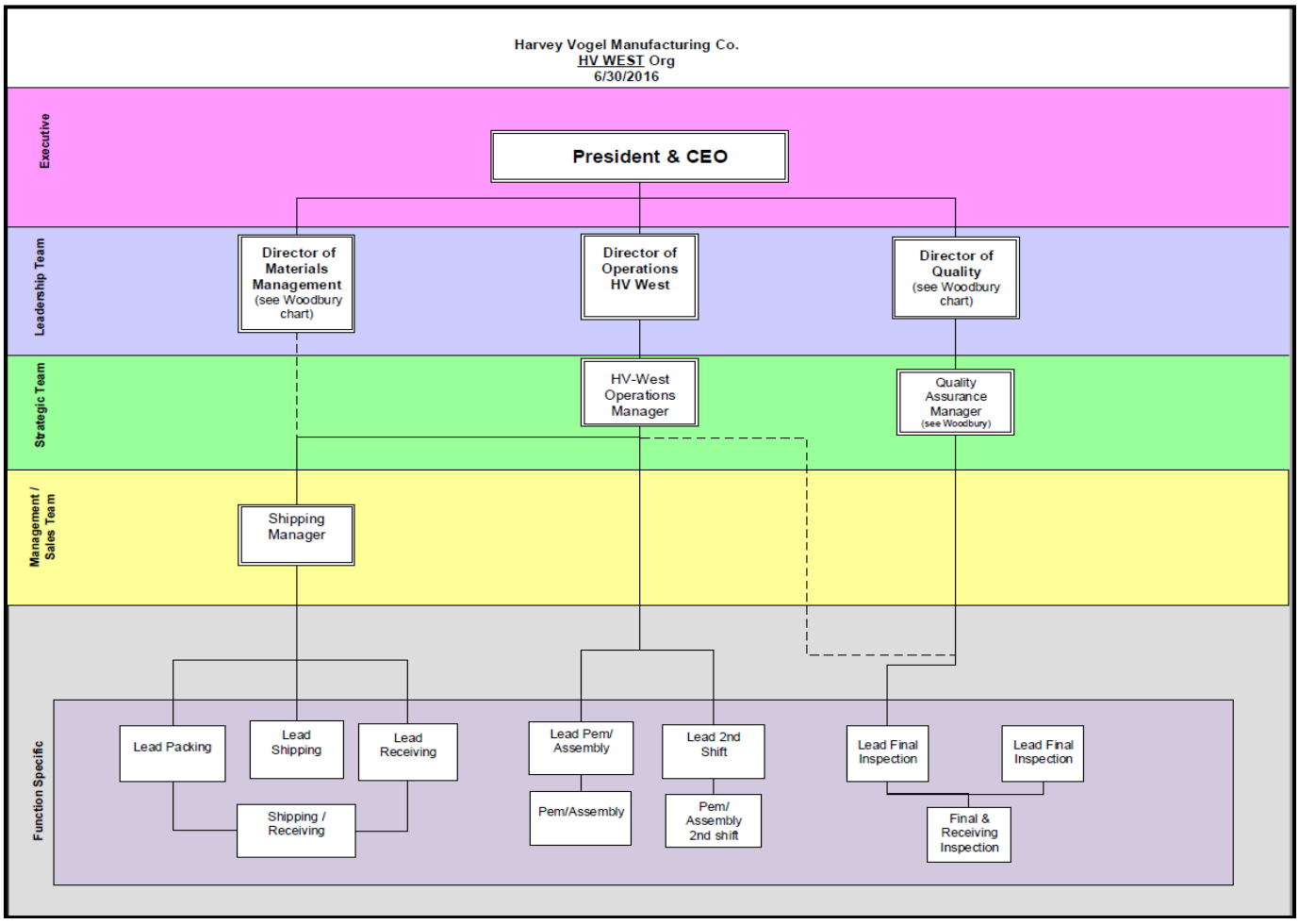
Harvey Vogel has 2 facilities, its corporate headquarters in Woodbury, MN with 132,000 square feet and its HV West facility in Eagan, MN with 71,000 square feet. These state of the art facilities have over 100 metal stamping and fabrication machines offering the ultimate in quality, speed and reliability. With blanking pressure up to 400 tons; as well as water jet cutting and machining capabilities, HV can meet the closest, most exacting tolerances in fabrications from one millimeter to 36" x 72", using almost any metal material.

Harvey Vogel will also provide many other value added services including complete tool room and engineering services, plating, painting, welding, leveling, tapping, reaming, pem setting, assembly and more.

Harvey Vogel commits itself to manufacturing high quality parts, providing strong customer service and delivering parts on time. At Harvey Vogel, we are continually striving to exceed our customer's requirements and expectations.

Harvey Vogel is certified to the ISO 9001 and ISO 14001 standard. Harvey Vogel complies with all required regulatory requirements. Customers determine the specifications to which Harvey Vogel must manufacture and/or inspect, including MIL, ASME, ASTM, ISO and ANSI. The applicability of national and international requirements is dependent on the type and usage of the product. Harvey Vogel also complies with all local, state and federal environmental and safety guidelines in accordance with OSHA and Minnesota EPA.


Harvey Vogel Manufacturing Co.
Organizational Chart
6/30/2016
Executive
President
CEO
Leadership Team
Director of Finance
Director of Operations
Director of Materials Management
Director of Engineering & CIT
Director of Quality
Director of Sales & Marketing
Director of Process Engineering & Operations HV West
Strategic Team
IT Manager
HR & Safety Manager
Plant/Facility Manager
Purchasing Manager
Quality Assurance Manager
Sr. Sales Account Engineer
Sales Engineer Manager
Senior Sales Engineer
HV-West Operations Manager (See HV-West)
Management / Sales Team
Production Manager
Production Manager
Tool Room Manager
Tool Design Manager
Manufacturing Engineer
Manufacturing Engineer (Vacant)
Sales Account Engineer
Sales Account Engineer
Sales Account Engineer
Sales Account Engineer/ Marketing Manager
Finance & Payroll Manager
Office & Credit Manager
2nd Shift Prod Mgr.
3rd Shift Prod Supv (vacant).
Sr. Tool Designer
Buyer / Planner
Quality Engineer Manager
Process Engineer (Vacant)
Network Admin
Admin Associate (vacant)
Receptionist / Admin Associate
Tool Designer (vacant)
Production Planner / Expediter
Production Planner
Product Launch Engineer
ISO/QMS Coordinator
Process Engineer Associate
Production Planner (vacant)
Function Specific
1st Shift Production & Maintenance
Laser, Turret, Prototype
2nd & 3rd Shift Production
Tool Makers Wire EDM Machine Cntrs
HV Shipping
Receiving / Final Inspection
Quality Room Inspection
Outside Sales Reps


Harvey Vogel Manufacturing Co.
HV WEST Org
6/30/2016
Executive
President & CEO
Leadership Team
Director of Materials Management (see Woodbury chart)
Director of Operations HV West
Director of Quality (see Woodbury chart)
Strategic Team
HV-West Operations Manager
Quality Assurance Manager (see Woodbury)
Management / Sales Team
Shipping Manager
Function Specific
Lead Packing
Lead Shipping
Lead Receiving
Shipping / Receiving
Lead Pem/ Assembly
Pem/Assembly
Lead 2nd Shift
Pem/ Assembly 2nd shift
Lead Final Inspection
Lead Final Inspection
Final & Receiving Inspection

Harvey Vogel Manufacturing Company
QUALITY POLICY STATEMENT

Harvey Vogel Manufacturing Co. produces high quality, precision stampings. Quality, in both service and product, is of the utmost importance. It is our goal to provide on time service, and products that meet all specifications and agreed upon standards.

We recognize the need of an effective Quality program to ensure conformance with the exacting requirements of today's highly sophisticated technologies. To achieve this, the Quality Department and its managers will function independently of the Production and Sales Departments. The goal of the Quality Assurance System is to:

- Approach the standard of zero defects and the capability of Six Sigma
- Adhere to customer drawing requirements, train and mentor in the use of statistics
- Provide the knowledge and tools needed to produce a quality product and drive continuous improvement
- Enhance and better position ourselves for any anticipated or future customer needs

To achieve our goal of continuous quality improvement and customer satisfaction, we have applied the methods demonstrated in this manual and in our overall quality system. As a result, we will obtain preventive measures that will result in continued quality improvement at the lowest possible cost.

Harvey Vogel Manufacturing Company
QUALITY POLICY

The HV Quality Policy is fourfold:

- To manufacture products that meet customer specifications.
- To meet our customers' requirements and expectations in quality, service and delivery.
- To implement preventive measures that will result in continued quality improvement that will reduce costs and enhance customer satisfaction.
- To be committed to regulatory requirements and continually improve the effectiveness of the HV quality system.

Scope

1.1 Quality Policy

The quality system described within this manual establishes the total Harvey Vogel Manufacturing Co. quality policy. The quality policy of Harvey Vogel Manufacturing Co. is:

The HV Quality Policy is four-fold:

1. To manufacture products that meet customer specifications.
2. To meet our customers' requirements and expectations in quality, service and delivery.
3. To implement preventive measures that will result in continued quality improvement that will reduce costs and enhance customer satisfaction.
4. To be committed to regulatory requirements and continually improve the effectiveness of the HV quality system.

The HV quality policy supports HV's Business Mission Statement:

The HV Business Mission Statement is three-fold:

- To be the leading manufacturer of custom metal stampings, assemblies and value added services to a variety of industries.
- To exceed our customers'requirements and expectations in quality, service and delivery.
- To provide our employees with a high quality work environment that emphasizes safety and personal growth.

To meet HV's commitment, HV must focus on the following quality related requirements:

- Foster a team approach and continuous improvement environment
- Emphasize appropriate training for all employees
- Recognize each employee's responsibility for quality
- Empower employees to question processes, which appear to produce discrepancies
- Acknowledge employee's self-improvements and contributions to the company
- Use only selected, approved, preferred or certified suppliers
- Accept only conforming products and services from suppliers
- Keep the Quality Department independent of, but as a partner with Manufacturing
- Reduce waste and inefficiency wherever found
- Seek out technologies for assuring error-free work
- Continue to implement statistical approaches to reduce variation
- Strive for complete understanding of our customers' application requirements
- Earn customer recognition of our quality progress
- Practice good housekeeping and never compromise safety
- Review and renew this Quality Policy on a regular basis

HV's strategies as defined in HV's Strategic Plan help define our quality commitment and goals:

- Be proactive, not reactive. Demonstrate a sense of urgency at all levels
- Take action, implement ideas instead of just discussing
- Continue to implement continuous improvement concepts and practices across our processes, products and services
- Develop consistent methods, processes and procedures to avoid reinventing the wheel
- Communicate appropriate information to all levels of the company
- Provide employees with needed training to provide high quality products and services
- Initiate partnerships with customers and suppliers
- Regularly measure customer service for primary products and services
- Identify high risk products and develop methods to monitor their performance
- Expand incentive and recognitiion systems to reinforce appropriate customer service behavior
- Develop practices to understand our costs better
- Be committed to all regulatory requirements and continually improve the effectiveness of the HV quality system.

1.2 Quality Objectives

1. To implement, monitor, analyze, review and ultimately achieve the HV performance objectives as outlined in the HV annual strategic plan.

2. To implement, monitor, analyze, review and ultimately achieve the HV business and quality objectives as outlined in the HV annual strategic plan. The President and the Director of Quality will monitor this.

3. To implement, monitor, analyze, review and ultimately achieve the departmental goals as outlined in the appendix of the HV annual strategic plan.

4. To continually improve product quality with standard and systematic methods through strong quality control.

1.3 Permissable Exclusions

The manual as written addresses the requirements of ISO 9001 except for the following exclusions:

- Harvey Vogel does not perform product design. As a result, element 7.3 – Design and Development is excluded in the HV Quality Manual.

- Harvey Vogel does not perform post delivery activities such as servicing and installation. As a result, that portion of clause 7.2.1.a is excluded in the HV Quality Manual.

The manual also serves to direct the user from the policy statements to the procedures required to implement the policy.

2 About the HV Quality Manual

2.1 Purpose

The purpose of this quality manual is to outline and state the general policies governing the Harvey Vogel Manufacturing Co. quality assurance system. It is designed to demonstrate our capability to consistently provide conforming products and services to our customers.

Note 1: Wherever within HVMC's documented Quality System it states ISO 9001:2000 it now means ISO 9001 (dropping the revision date year).

2.2 Normative References

Harvey Vogel Manufacturing Co.'s quality system is based on the ISO 9001 quality management system.

2.3 Related Documents

Documents related to this quality manual include:

- HV Quality Procedure Manual that includes all procedures with the prefix "Q"
- HV Work Instruction Manual
- All other procedures referenced in this manual
- All work instructions that directly or indirectly have impact on product or processes
- All forms used in conjunction with this manual and the procedures and work instructions described in all above.

2.4 Distribution

The President and Director of Quality have hard copy QMS manuals in their possession. The Director of Quality is responsible for maintaining the QMS documents to ensure that only current revisions are available for use.

The HV Quality Manual, HV Quality Procedure Manual and the HV Work Instruction Manual are available on-line in read only format to all employees.

Department Managers and Supervisors are responsible for assuring that accesses to all manuals are available to company personnel.

2.5 Revisions

Anyone can submit suggestions for revision to these policies to their Manager, Supervisor or directly to the Director of Quality. The Director of Quality and President are responsible for reviewing suggestions and must approve any revisions to these policies. A revision history page is in the front of the manual. This page contains the history of all revisions to this manual. All changes to policies and procedures must be reviewed to ensure that there are no conflicts with the policies stated in any other quality related policies or procedures.

3 Terms and Definitions

As stated in the ISO-9001 Quality Management System - Fundamentals and Vocabulary:

Terms/Abbreviations	Definitions
QM	Quality Manual
QPM	Quality Procedure Manual
HVMC	Harvey Vogel Manufacturing Co. (the company)
HV	Harvey Vogel Manufacturing Co. (the company)
Harvey Vogel	Harvey Vogel Manufacturing Co. (the company)

4 Quality Management System

4.1 General Requirements

4.1.1 General

The Quality System consists of the following Four Tier System:

Tier One: This Quality Manual
Tier Two: Quality Procedures Manual
Tier Three: Work Instruction Manual
Tier Four: Forms and other related documents

The Quality System ensures that all product meets customer requirements. This manual is designed to reflect the format of the ISO 9001 standard. The procedures are organized in a manner useful to Harvey Vogel Manufacturing Co..

Procedure Q4.1.1 - HV Process Based Quality Management System, depicts the order and interaction of Harvey Vogel Manufacturing Co.'s quality management system general processes. The order and interaction of specific quality management system processes can be found on process sheets or flow charts associated with them. The criteria and methods for effective control of processes are found in internal audit procedures, inspection instructions and work instructions.

Processes interact on a daily basis at the appropriate level. The main processes and strength of correlation to organizational unit is listed below:

Process Identification	Organizational Units												
Key Processes	Management	Quality Assurance	Sales and Marketing	Materials Mgmt.	Purchasing	Engineering/Product Dev./Design	Process Engineering	Production/Manufacturing	Human Resources/Safety	Tool Room	Shipping	Finance and Accounting	Information Systems
4.1 Leadership	5*	5	3	1	1	1	1	1	5	1	1	3	1
4.2 Sales and Marketing	5	3	5*	1	3	3	3	1	1	1	1	1	3
4.3Product Development	1	3	3	3	3	5*	5	1	1	1	1	1	1
4.4 Purchasing	1	3	1	5	5*	3	3	3	1	3	3	1	1
4.5 Scheduling	1	1	1	5*	3	1	1	3	1	3	3	1	1
4.6 Production	1	3	1	5	3	3	3	5*	1	5*	5*	1	3
4.7 Inspection and Testing	1	5*	1	3	1	1	1	1	1	1	1	1	1
4.8 Customer Service	5	3	5*	5	1	1	1	1	1	1	1	1	1
4.9 Continuous Improvement	3	5*	3	3	3	3	3	3	3	3	3	1	3
4.10 Finance	3	1	1	1	1	1	1	1	1	1	1	5*	1
4.11 Accounting	3	1	1	1	1	1	1	1	1	1	1	5*	1
4.12 Human Relations	5	3	3	3	3	3	3	3	3	3	3	3	3

Legend:

5 – strong correlation;
3 – medium correlation
1 - weak correlation
* - process owner
Empty - no correlation

4.1.2 Responsibility and Authority

Officers, Directors, Managers, Supervisors and Employees are obligated to work in accordance with the specific requirements of the documented quality system.

4.1.3 Quality System

All quality related activities are governed by processes, procedures and written instructions and coordinated in a system for continual improvement of the quality management system. This is further defined in Procedures Q4.1.2 - Basis for Quality Management System and Q4.1.3 – Basis for Qualtiy Control Planning. Within the quality system, emphasis is placed upon the following:

- Prevention versus detection
- Selection, monitoring and control of suppliers and outsourced processes
- Procedures assuring the safe handling, package storage and delivery of products to customers
- Establishment of appropriate acceptability standards at specified process points
- Procedures to establish, monitor, measure and analyze process capability and ensure that both the operation and control of these processes are effective
- Regular internal audit and review
- Effective corrective action procedures for dealing with customer complaints and other instances of nonconformance
- Effective management of measuring and test equipment
- Use of appropriate statistical techniques
- Maintenance of appropriate certifications, records and documents both internal and external
- Ensure the availability of resources and information necessary to support the operation and monitor processes effectively
- Ability to implement actions necessary to achieve planned results and continual improvement of the processes
- To enhance customer satisfaction through the effective application of the quality system.

4.1.4 Related Documentation

- Q4.1.1- HV Process Based Quality Management System
- Q4.1.2- Basis for Quality Management System
- Q4.1.3- Basis for Quality Control Planning

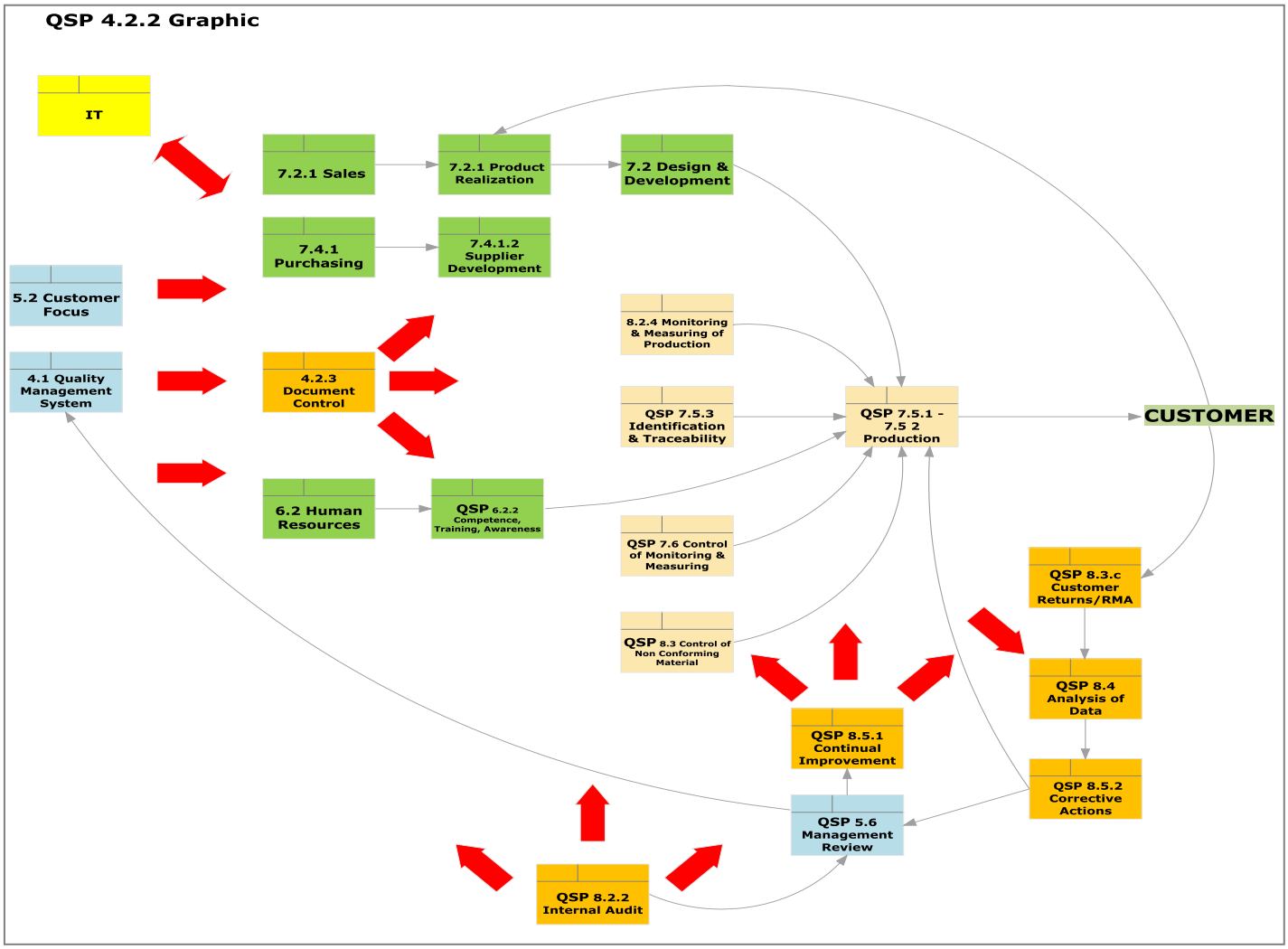
4.2 Documentation Requirements

4.2.1 General

The HV quality system is an integrated effort that encompasses management policies, quality objectives, organization, documentation, and records. It is not just a system of inspection and testing, but rather a company-wide program. It includes such areas as product development, component and/or supplier selection, documentation, testing and inspection procedures and equipment, production and/or process development, reviews and validation, and employee training.

4.2.2 Quality Manual

This HV Quality Manual contains Harvey Vogel Manufacturing Co.'s quality policies, defines our organizational structure, authorities, and responsibilities. It also references applicable quality management system processes and procedures and the HV Process Based Quality Management System flowchart that provides a description of the interaction of processes within the quality management system. In addition, it has a scope with exclusion statements.



4.2.3 Control of Documents

The Quality Manual, Quality Procedures Manual, and the HV Work Instruction Manual are controlled documents. Specific job instructions and other work aids are controlled by individual departments according to documented guidelines.

Document and Data Control will be applied to both internal documents and external documents such as standards and customer drawings. Documents may be in the form of hard copy or electronic media. Documents will be legible and readily identifiable. Blueprints, specifications and databases are controlled according to Procedure Q4.3.1 - Contract and Document Review and Control Specification and Procedure Q4.5.1 - Drawing and Change Control.

Authorized personnel approve documents and data prior to issue. Controls ensure that appropriate documents are available for use, invalid/obsolete documents are removed from use or otherwise assured against use. Documents are controlled to procedure Q4.2.3 – Document Control.

A master forms list identifying the correct revision level of each document will be maintained by the Director of Quality. The master list shall be available to departmental personnel to ensure use of the correct document.

Note: HVMC maintains the latest form revision in procedures. As procedures are revised any forms within the procedure will be removed. The form number will remain referenced in the procedure.

Control of documentation including approval, issuance, and changes will be maintained to ensure the integrity of the quality system. The proper revision of the document will be available at the work location to ensure use of the proper document. Obsolete documents will be removed from the work location except for documents retained for legal or knowledge preservation. The documents retained for legal and knowledge preservation purposes shall be identified for this use. Responsibility and authority for these functions will be as follows unless noted otherwise in that specific documentation.

- **Tier I (Quality Manual) –** President and Manager of Quality
- **Tier II (Quality Procedure Manual) -** President and Manager of Quality Assurance & Continous Improvement
- **Tier III (HV Work Instructions) –** Departmental Managers
- **Tier IV (Forms & Other Documents) -** As applicable in conjunction with the above authority levels.

Quality procedures will be revised and updated to Procedure Q4.2.1- Revising and Updating Controlled Quality Manuals and formatted to Procedure Q4.2.2 – Procedure Documentation and Format.

4.2.4 Quality Records

All quality records that are used directly or relative to Harvey Vogel's quality assurance system will be maintained per Procedure Q4.5.2 – Control of Quality Records. Records may be in the form of hard copy or electronic media. Quality records are to be retained in an orderly fashion and for the time periods that comply with legal and regulatory requirements and as needed for general operation requirements as identified in the implementing procedure. These records provide evidence of conformity and the effective operation of the Quality Management System.

The Quality Records will be stored in identified locations after the product is complete. The Quality Records will be identified and legible. The records will be stored in a manner that they are readily retrievable and in an area to prevent deterioration from poor environmental conditions. The record retention times and methods are also designed to prevent loss of records. Disposition of records is an element of this control.

When required, due to contract requirements, Quality Records will be made available to the customer, or an authorized representative of the customer, for review.

HV will require that sub-contractor's keep written records as stated in Procedure Q4.16.1 – Determination and Implementation of Recorded Characteristics.

4.2.5 Related Documentation

- Q4.2.1- Revising and Updating Controlled Quality Manuals
- Q4.2.2 – Procedure Documentation and Format
- Q4.3.1 - Contract and Document Review and Control Specification
- Q4.5.1 - Drawing and Change Control
- Q4.5.2 – Control of Quality Records
- Q4.16.1 – Determination and Implementation of Recorded Characteristics

5 Management Responsibility

5.1 Management Commitment

5.1.1 General

The following are expressions of Harvey Vogel's management commitment to develop, implement and improve the effectiveness of the quality management system:

- Communication about the importance of fulfilling customer legal and regulatory requirements occurs throughout the company. That communication happens through the use of:
    - General and product specific training
    - Retraining when and where shortfalls appear
    - Displays and postings in high traffic areas of the facilities
    - Periodic communication meetings
    - Specific emphasis in provided documentation
- The quality policy (see Quality Policy stated in section 1.1)
- The quality objectives (see Quality Objectives stated in section 1.2)
- The management review records
- Few, if any, incidents of resource shortfalls as root causes of occurring nonconformities

Management's commitment and communication of the quality management system is further defined in Procedure Q4.1.2 – Basis for Quality Management System.

5.1.2 Related Documentation

- Q4.1.2 – Basis for Quality Management System

5.2 Customer Focus

5.2.1 General

Harvey Vogel Manufacturing Co. will continually focus on customer satisfaction as our primary goal. Top management assures that all customer requirements will be uncovered through the processes described in section 7.2 later in this quality manual. Through all of the policies, objectives and processes described in this quality manual and other controlled quality documents, top management assures the needed environment to consistently fulfill customer requirements. By routinely assessing customer satisfaction, top management optimizes the likelihood of moving toward complete customer satisfaction. Procedures Q4.3.1 – Contract and Document Review, Control Specification, Q4.1.1- HV Process Based Quality Management System, Q4.1.6 – Tool Approval and Q4.21.1 -Customer Satisfaction serves this purpose.

5.2.2 Related Documentation

- Q4.1.1- HV Process Based Quality Management System
- Q4.3.1 – Contract and Document Review, Control Specification
- Q4.21.1 - Customer Satisfaction

5.3 Quality Policy

5.3.1 General

Harvey Vogel Manufacturing Co.'s quality policy is listed in Section 1.1. The quality policy is:

- Appropriate to the purpose of the organization as identified in HV's Mission Statement
- Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system
- Provides a framework for establishing and reviewing quality objectives as stated in Procedure Q4.1.2 – Basis for Quality Management System.

The quality policy is prominently displayed at many strategic locations throughout HV. After communication of the quality policy to the employee population, employees at any level of the organization are expected to fulfill the requirements of this policy in their work related efforts and decisions.

Lastly, the quality policy is reviewed at least annually for suitability. Its distribution is controlled because of the possibility that it might change.

5.3.2 Related Documentation

- Q4.1.2 – Basis for Quality Management System

5.4 Quality Planning

5.4.1 Quality Objectives

Harvey Vogel Manufacturing top management has established clear quality objectives that are consistent with our quality policy. The high-level quality objectives are listed in Section 1.2. These objectives are rolled down to managers at subsequent levels who in turn covert them into objectives at their level. These objectives address product requirements along with Quality Management System requirements. Company performance business objectives and quality objectives are outlined in the HV Strategic Plan. Business objectives are analyzed and tracked in the Strategic Plan Project List that is maintained by the President. Performance objectives are tracked and reviewed by the President, discussed with the Key Group and posted throughout the company. Quality objectives are followed up in Management Review meetings and tracked by the Director of Quality. Each quality objective uses a 3-Tier project management approach to ensure project implementation and success. Departmental quality objectives are submitted and reviewed for progress and acceptability throughout the year using Departmental Objective Submission Forms as outlined in Procedure Q4.1.2 – Basis for Quality Management System.

5.4.2 Quality Management System Planning

Harvey Vogel Manufacturing shall prepare, implement, review and maintain at all times a system for the assurance of quality. The documentation of this system will be achieved through this quality manual, quality records, and through the establishment of written operating policies, procedures and work instructions. The Quality Manual shall reference in each section the implementing procedures or work instructions for the specific section. The basis for quality control planning is described in procedure Q4.1.3 - Basis for Quality Control Planning.

If there are special requirements for specific contracts, a Quality Plan will be developed and implemented for the specific project addressing the following items:

- The identification and acquisition of any controls, processes, equipment, fixture, resources, and skills that may be needed to achieve the required quality
- Ensure the compatibility of the design, the production process, installation, inspection and test procedures, and the applicable documentation
- The updating, as necessary of quality control, inspection and testing techniques, including the development of new instrumentation
- The identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed
- The identification of suitable verification of product
- The clarification of standards of acceptability for all features and requirements, including those which contain a subjective element
- The identification and preparation of Quality Records.

These Quality Plans will be in conjunction with projects as identified by management and listed in Procedure Q4.1.7 – Project Management.

Procedure Q4.1.5 - Dealing With Change is employed to ensure integrity and compatibility of the quality management system when significant changes occur in categories such as the organization, the facilities or business strategy.

5.4.3 Quality Objectives Deployment

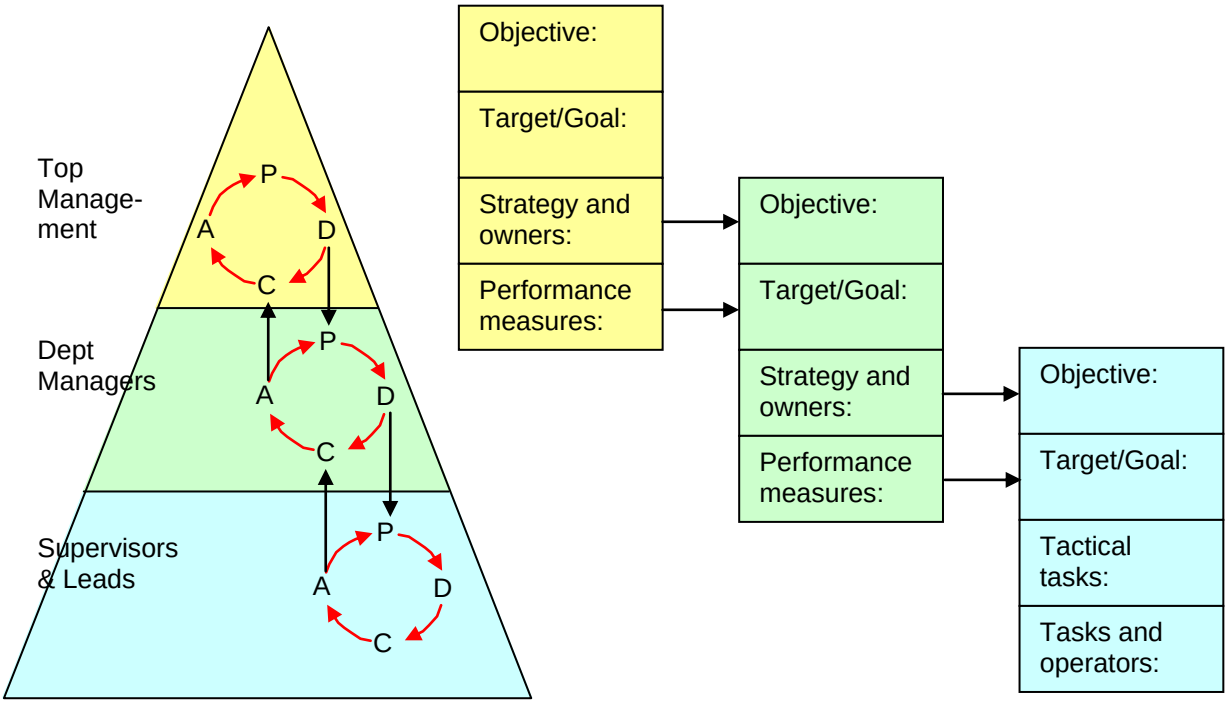


Figure 5.4.3.1. Preparation and deployment of management plan

5.4.4 Related Documentation

- Q4.1.2 – Basis for Quality Management System
- Q4.1.3 - Basis for Quality Control Planning
- Q4.1.5 - Dealing With Change
- Q4.1.7 – Project Management

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

Procedure Q4.1.1 - HV Process Based Quality Management System illustrates functions, their interrelations, responsibilities and authorities relevant to the quality management system. More specific quality management system responsibilities and authorities can be found on job descriptions, process sheets, flow charts, work instructions, etc. associated with machines utilized, products manufactured and services provided. Appropriate distribution of these documents and associated training assures clear communication of this information.

5.5.2 Management Representative

The Director of Quality has been appointed by the President to serve as management representative. The assigned duties include:

- Overseeing the implementation and maintenance of the quality management system in accordance with ISO 9001/14001 requirements.
- Reporting on the performance of the quality management system to the highest level of management
- Reporting on the need for improvement of the quality management system to the highest level of management
- Encouraging and assisting in extending the understanding of customer requirements to the degree necessary throughout the organization.

5.5.3 Internal Communication

The highest level of management shares data, indicating the performance of the quality management system, throughout Harvey Vogel Manufacturing Co. in the following ways:

- Daily MRB meeting minutes posted throughout the company
- Monthly updated postings of performance data in each department
- Real-time data on the computer network
- Monthly and weekly departmental meetings
- Monthly Leadership/Strategic Team Meetings
- Bi-Annual Strategic Planning
- Quarterly Company Meetings
- Accessibility of corrective and preventive action status to all who inquire.

This is further defined in Procedure Q4.1.2 – Basis for Quality Management System.

5.5.4 Related Documentation

- Q4.1.1 - HV Process Based Quality Management System
- Q4.1.2 – Basis for Quality Management System

5.6 Management Review

5.6.1 General

In order to assure the continuing suitability, adequacy and effectiveness, the highest level of management will conduct periodic reviews of the quality management system. The reviews can address the quality management system entirely or in parts, as long as the entire quality management system is reviewed at least semi-annually. Management Review Forms as described in Procedure Q4.1.2 – Basis for Quality Management System are provided for that purpose. An expected outcome of that review is the determination of the need for any changes or to reveal opportunities for improvement to the quality management system, including adjustments to the quality policy and quality objectives. Management review records are maintained in accordance with Procedure Q4.2.3 – Document Control.

These management reviews will be coordinated with Quality Management System Audits (internal audits) as depicted in Procedure Q4.17.1 – Quality Management System Audits. In addition, top management will conduct quarterly Quality Preventive Action meetings as described in Procedure Q4.14.2 – Preventive Action. This is all in conjunction with Procedure Q4.22.1 – Continual Improvement.

5.6.2 Review Input

Quarterly performance and opportunities for improvement are determined by reviewing the following type of information, where applicable:

- Audit results:
    - Internal quality management system audits
    - 3rd party quality management system audits
    - Customer audits
    - Regulatory audits
- Customer feedback:
    - Customer surveys
    - Customer complaints
    - Customer feedback
- Process performance and product conformity:
    - C_{pk}
    - PPM
    - Returns and Allowances
    - Cost of Quality
    - Trend analysis, pareto charting

- Preventive and corrective action status:
    - Number Open
    - Aging
    - Effectiveness
- Follow up actions from previous management reviews
- Quality management system related changes
- Recommendations for improvement

5.6.3 Review Output

Actions associated with the following are included in the output from management review:

- Improvement of effectiveness of the processes of the quality management system
- Overall improvement of the quality management system effectiveness
- Improvements upon product associated with customer requirements
- Improvements upon service associated with customer requirements
- Maintenance of appropriate resources

Management review records are maintained per Procedure Q4.2.3 – Document Control.

5.6.4 Related Documentation

- Q4.1.2 – Basis for Quality Management System
- Q4.2.3 – Document Control
- Q4.14.2 – Preventive Action
- Q4.17.1 – Quality Management System Audits
- Q4.22.1 – Continual Improvement.

6 Resource Management

6.1 Provision of Resources

6.1.1 General

Top management determines needed resources and provides resources to implement and maintain the quality management system and continually improve its effectiveness and to enhance customer satisfaction by meeting customer requirements.

6.1.2 Related Documentation

- Q4.1.2 – Basis for Quality Management System

6.2 Human Resources

6.2.1 General

Anyone at Harvey Vogel Manufacturing Co. having an assignment that can affect product quality, must be competent through education, skills, training and experience as necessary. Requirements for education, skills, training and experience can be found in the job descriptions, job training needs, and union contract maintained by the Human Resource department. Competency is determined by pre-testing where possible and by temporary assignments. Apprenticeships are also used to develop competency. All personnel performing an operation will be considered trained in accordance with Procedure Q4.9.2 – Control of Manufacturing Processes and Generic Quality Standards.

6.2.2 Competence, Awareness and Training

Managers and supervisors are jointly responsible for the determination of competence needed as new quality management system processes evolve and existing ones change. When training is required to aid achievement of the required competence, one or more of the following may occur:

- Classroom training (internal or external) will be scheduled and coordinated by the Human Resource department
- On-the-job training will be coordinated by department managers/supervisors
- Apprenticeships will be jointly arranged and coordinated by the Human Resource department and the supervisor of the department where the apprenticeship will take place.

When and where it is necessary, actions other than training will be used to achieve the needed competence and appropriate measures of effectiveness applied.

One or more of the following will evaluate effectiveness of the training and other actions taken:

- Testing on the material presented in the classroom
- Operator certification
- Certificates of completion for externally provided training
- Measuring process outcomes before and after training
- Performance monitoring and reviews on new hires.

Managers will be responsible for ensuring that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

The Human Resource department is responsible for keeping records of education, training, skills and experience per Procedure Q4.18.1 – Training.

6.2.3 Related Documentation

- Q4.9.2 – Control of Manufacturing Processes and Generic Quality Standards
- Q4.18.1 – Training
- Q4.18.2 – Qualification of Inspection Personnel

6.3 Infrastructure

6.3.1 General

Harvey Vogel Manufacturing Co. has established and will maintain the infrastructure necessary to achieve conformity to customer product and service requirements. This will include:

- Workspace and associated facilities
- Equipment, hardware, and software
- Suitable maintenance
- Supporting services.

6.4 Work Environment

6.4.1 General

Harvey Vogel Manufacturing Co. has established and will maintain a suitable work environment for personnel safety and product realization while meeting customer product and customer service requirements. This will include:

- Health and safety conditions
- Work methods
- Work ethics
- Ambient working conditions.

7 Product Realization

7.1 Planning of Product Realization

7.1.1 General

Harvey Vogel Manufacturing Co. will plan for appropriate processes that lead to realization of deliverable products that conform to defined requirements.

Any complaints or operation questions regarding the performance, safety, reliability or quality of the company's products or services will be subject to management review and/or investigation and will result in prompt response and corrective action when indicated.

The procedures to be specifically followed for implementation of this policy are Procedures Q4.1.3 – Basis for Quality Planning, Q4.1.4 – Control Plans (PPAPs and FMEAs), Q4.3.1 – Contract and Document Review, Control Specification, Q.4.3.2 - Contract and Document Review, Control Specification for Government or Nuclear Specification, Q4.5.1 - Drawing and Change Control, Q4.20.1 - Statistical Process Control Training/Selection and Q4.21.1 - Customer Satisfaction.

7.1.2 Related Documents

- Q4.1.3 – Basis for Quality Planning
- Q4.1.4 – Control Plans (PPAPs and FMEAs)
- Q4.3.1 – Contract and Document Review, Control Specification
- Q.4.3.2 - Contract and Document Review, Control Specification for Government or Nuclear Specification
- Q4.5.1 - Drawing and Change Control
- Q4.20.1 - Statistical Process Control Training/Selection
- Q4.21.1 - Customer Satisfaction

7.2 Customer Related Processes

7.2.1 Determination of Requirements Relating to the Product

Harvey Vogel Manufacturing Co. will review all requests for proposals, contracts and sales orders to determine customer requirements. This review will include:

- Completeness of the customer’s product and/or service requirements
- Customer’s product and/or service requirements not specified by the customer, but necessary for fitness for purpose
- Obligations related to product and/or service, including regulatory and legal requirements
- Customer’s requirements for availability, delivery and support of product and/or service.

7.2.2 Review of Requirements Relating to the Product

All requests for proposals, contracts and sales orders will be reviewed per Procedures Q4.3.1 – Contract and Document Review, Control Specification and Q.4.3.2 - Contract and Document Review, Control Specification for Government or Nuclear Specification. Any changes to the contract, specification, or customer purchase order are described in Procedure Q4.5.1 - Drawing and Change Control.

Before accepting an order, Harvey Vogel Manufacturing reviews the customer's requirements and evaluates Harvey Vogel's capabilities to meet the customer's needs and requirements. Requests for quotations for which Harvey Vogel does not have the capabilities and/or cannot find an appropriate supplier to provide subcontract services are returned to the customer as "no quotes".

Authorized personnel approve documents and data prior to use. Controls ensure that appropriate documents are available for use; invalid/obsolete documents are removed from use or otherwise assured against use.

Procedures Q4.10.4.1 – First Article Inspection and Q4.10.4.2 – Sample Approval describe customer approval processes to product run the first time at Harvey Vogel.

Procedure Q4.9.5 – Obsolescence of Tooling and Parts ensures that Harvey Vogel will not use obsolete tools or parts.

7.2.3 Customer Communication

Harvey Vogel Manufacturing Co. will implement arrangements to communicate with customers with the aim to meet customer requirements. This communication will include:

- Product and/or service information
- Inquiry and order handling, including amendments
- Customer complaints and actions relating to non-conforming product and/or service
- Customer responses relating to performance of products and/or service.

7.2.4 Related Documents

- Q4.3.1 – Contract and Document Review, Control Specification
- Q.4.3.2 - Contract and Document Review, Control Specification for Government or Nuclear Specification
- Q4.5.1 - Drawing and Change Control
- Q4.9.5 – Obsolescence of Tooling and Parts
- Q4.10.4.1 – First Article Inspection
- Q4.10.4.2 – Sample Approval

7.4 Purchasing

7.4.1 Purchasing Process

To ensure that purchased products and materials conform to specified requirements, Harvey Vogel Manufacturing shall assess all vendors' capabilities and performance according to our quality requirements. This includes, selection, evaluation, and re-evaluation as necessary of Vendor performance and applicable records including actions taken. Approved vendors will be maintained on an "Approved Vendor List" and all purchasing of components and materials must be made from an approved vendor on this list unless otherwise specified per Procedure Q4.6.1 – Control of Subcontracted Suppliers. Approved vendors will be reviewed periodically or if placed on conditional status to assure satisfactory performance and quality.

7.4.2 Purchasing Information

Further, all purchasing documents will clearly and adequately define the components or materials to be purchased in sufficient detail as to describe the following whenever applicable:

- Precise identification of product or service ordered
- Positively identified specifications, drawings, pertinent standards or other technical documents required to establish full acceptability
- Specialized equipment
- Uniquely qualified personnel
- Quality management system requirements

Purchasing information will be reviewed by personnel and approved by the purchasing manager prior to issuance of orders.

Procedure Q4.6.1 – Control of Subcontracted Suppliers, and supporting work instructions detail the purchase order procedures and requirements.

Harvey Vogel's intentions to place source inspectors at a subcontractor's premises will be noted on the purchase order, along with verification arrangements. Procedures Q4.6.1 – Control of Subcontracted Suppliers and Q4.6.2 – Supplier Verification at Subcontractor Premises details this.

7.4.3 Verification of Purchased Product

All parts, components and materials utilized in production of products will be received in an organized manner, inspected and tested for conformance in accordance with written work instructions. This includes provision for Customer verification at the supplier's premise, where applicable. HV utilizes a FIFO (First In/First Out) System whenever possible.

Receiving personnel or Quality personnel will inspect all incoming products before use per Procedure Q4.10.3.1 – Final and Receiving Inspection. Product that is not inspected due to urgent need will be marked and controlled in accordance with work instructions.

Any items or shipments rejected for nonconformance will be properly tagged and segregated. No further processing of the item will occur until the nonconformance is disposition, corrected and approved by the quality department.

Quality Records of receiving, in-process, and final inspection and test shall be identified and maintained in accordance with Procedure Q4.5.2 – Control of Quality Records.

Purchase material will be controlled per Procedure Q4.10.5 – Raw Material Verification. Government or nuclear material will be controlled per Procedure Q4.9.1 – Material Control System, Government or Nuclear.
Customer supplied tools, components and materials will be inspected per Procedure Q4.7.1 – Customer Supplied Tooling, Components and Material Control.

7.4.4 Related Documents

- Q4.5.2 – Control of Quality Records
- Q4.6.1 – Control of Subcontracted Suppliers
- Q4.6.2 – Supplier Verification at Subcontractor Premises
- Q4.7.1 – Customer Supplied Tooling, Components and Material Control
- Q4.9.1 – Material Control System, Government or Nuclear
- Q4.10.3.1 – Final and Receiving Inspection.
- Q4.10.5 – Raw Material Verification

7.5 Product and Service Operation

7.5.1 Product and Service Operation Control

Harvey Vogel does not provide installation or servicing. Control of production is based on detailed planning of all phases of the production process. This detailed planning will be documented for each product in the form of work instructions depicted on process sheets. Production is planned using Harvey Vogel's computer network software. Production is performed according to appropriate procedures. These procedures describe the conditions that all production at HV takes place. Work instructions, that outline daily activities, are utilized throughout the production area. Operations that require additional skill or attention are provided on the process sheets listing the requirements of that particular job.

Any processes that cannot be fully verified in subsequent tests and/or inspections will be continuously monitored and provided with work instructions describing in detail how the special situation is to be handled.

The requirements for qualified processes including personnel and equipment is documented in procedures and work instructions. Procedure Q4.9.2- Control of Manufacturing Processes and Generic Quality Standards outlines these production controls. Work Instructions also describes process control methods.

Work Instructions describe a preventative maintenance plan that ensures the continuing process capability of equipment.

Controlled conditions include the following:

- Use of suitable equipment and suitable working environment
- Compliance with applicable standards/codes, quality plans, working instructions
- Monitoring and control of suitable process parameters and product characteristics
- Approval of processes and equipment as appropriate

- Workmanship criteria
- Suitable maintenance of equipment to ensure continuing process capability

Quality Records will be identified and maintained for qualified processes, equipment, and personnel.

Other procedures that relate to process control include Q4.9.3 – Dump System, Q4.9.4 – Process Change and Q4.9.5 – Obsolescence of Tooling and Parts.

7.5.2 Validation of Processes for Production and Service Provision

Processes within Harvey Vogel whose outcomes are not verifiable at reasonable cost, must be validated to assure that requirements will be met. Procedures Q4.9.2- Control of Manufacturing Processes and Generic Quality Standards, Q4.10.1 – In Process Inspection, Q4.10.2 – Rerun Inspection, Q.4.1.3 – Basis for Quality Planning, Q4.1.4 – Control Plans (PPAPs and FMEAs), Q4.10.4.1 – First Article Inspection and Q4.12.1 – Quality Status and Inspection Control validate processes for production. These procedures provide the following:

- Define criteria for review and approval of processes
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records (see Procedure Q4.5.2 – Control of Qualtiy Records
- Revailidation.

7.5.3 Identification and Traceability

In order to prevent the misuse or misapplication and to maintain identity and inspection status of purchased material, work-in-process, or completed product, Harvey Vogel utilizes product identification Procedure Q4.8.1 – Product Identification and Traceability.

Procedure Q4.10.5 – Raw Material Verification details identification and traceability of raw material at HV.

Procedure Q4.8.2 – Lot, Dot and Tag Procedure details identification and traceability of work in process at HV.

7.5.4 Customer Property

Customer property is treated the same as purchased material. It is identified and controlled per Procedure Q4.7.1 – Customer Supplied Tooling, Components and Material Control and verified per product quality plans. This includes the identification, verification, and protection of Customer Supplied property and notifcation and records to the Customer of any lost, damaged, or otherwise unsuitable condition.

Lost, damaged, or non-conforming customer supplied material is subject to Procedure Q4.13.1 – Control of In-House Non-Conforming Product and Procedure Q4.13.2 – Control of Non-Conforming Customer Returns.

7.5.5 Handling, Storage, Packaging, Preservation, and Delivery

Product handling including sub-assembly, components, or product characteristics will be in accordance with each specific part as defined on process sheets or in general handling procedures. Care will be implemented by all personnel in order that product is not damaged and meets all quality requirements.

Storage of the items will be in accordance with part characteristics. All parts will be properly marked and identified in accordance with work instructions. Storage of products will be controlled to prevent inadvertent damage and deterioration.

Product packaging will be designed and constructed to protect the product from alteration or damage during the customary conditions of processing, storage and handling. The part identification and other necessary items will be identified on the packaging. Procedure Q4.15.1 – Packaging Control details this further.

Preservation methods will be implemented as necessary to assure that the item will not deteriorate to a nonsatisfactory status when controlled by Harvey Vogel Manufacturing.

Shipping containers and shipping methods will be used that ensure the protection and maintenance of quality during shipping and through delivery to destination. Special shipping requirements will be identified and implemented in accordance with the contract requirements.

7.5.6 Related Documents

- Q.4.1.3 – Basis for Quality Planning
- Q4.1.4 – Control Plans (PPAPs and FMEAs)
- Q4.7.1 – Customer Supplied Tooling, Components and Material Control
- Q4.8.1 – Product Identification and Traceability
- Q4.8.2 – Lot, Dot and Tag Procedure
- Q4.9.2- Control of Manufacturing Processes and Generic Quality Standards
- Q4.9.3 – Dump System
- Q4.9.4 – Process Change
- Q4.9.5 – Obsolescence of Tooling and Parts
- Q4.10.1 – In Process Inspection
- Q4.10.2 – Rerun Inspection
- Q4.10.4.1 – First Article Inspection
- Q4.12.1 – Quality Status and Inspection Control
- Q4.13.1 – Control of In-House Non-Conforming Product
- Q4.13.2 – Control of Non-Conforming Customer Returns
- Q4.15.1 – Packaging Control

7.6 Control of Inspection, Measuring, and Test Equipment

7.6.1 General

Inspection, measuring, and test equipment used in production or testing for acceptance or rejection of product, will be properly maintained, controlled, and calibrated. This includes equipment provided by suppliers, sub-contractors, and/or employees. In accordance with the product plan or the specific use of the inspection or test equipment, the equipment will meet the following requirements:

- Capable of meeting the required accuracy and precision
- Periodically calibrated against nationally recognized standards or other valid documented standards determined appropriate due to the nature of the piece of equipment
- Have a defined process used for calibration including details of equipment type, unique identification, location of use, calibration frequency, calibration method, acceptance/rejection criteria
- Properly identified in such a manner to indicate its calibration status
- Procedure to indicate what action is taken when the equipment is out of calibration including reviewing and determining the effect on previous inspection and test results
- Procedure to ensure that proper environmental conditions exist for the use and calibration
- Will be stored, handled, and maintained as appropriate to assure continued measurements of accuracy giving consideration to environmental and other relevant factors
- Procedure to identify and maintain Quality Records of activities identified above.

This is further documented in Procedure Q4.11.1 – Calibration.

7.6.2 Related Documents

- Q4.11.1 – Calibration

8 Measurement, Analysis and Improvement

8.1 General

8.1.1 General

Harvey Vogel Manufacturing will plan for appropriate processes that lead to realization of deliverable products that conform to defined requirements and ensure conformity of the Quality Management System to the ISO 9001 standard.

Statistical needs are identified in the implementing procedures. Appropriate statistical techniques including statistical sampling are used to effectively establish, control, and verify process capability and to verify product characteristics.

The procedures to be specifically followed for implementation of this policy are Q4.10.1 – In Process Inspection, Q4.10.2 – Rerun Inspection and Q4.20.1 – Statistical Process Control Training/Selection.

The process for improvement is found in Procedure Q4.22.1 – Continual Improvement.

8.1.2 Related Documents

- Q4.10.1 – In Process Inspection
- Q4.10.2 – Rerun Inspection
- Q4.20.1 – Statistical Process Control Training/Selection
- Q4.22.1 – Continual Improvement

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Customer surveys and satisfaction are conducted in accordance with Procedure Q4.21.1 – Customer Satisfaction.

8.2.2 Internal Audit

Internal audits of the quality management system are conducted in accordance with Procedure Q4.17.1 – Quality Management System Audits. Frequency of audits of specific areas and/or specific requirements will vary with need. That variation will be reflected in the required audit plans along with the scope, the methods and the assigned auditors. The audits are seeking conformance with the requirements of ISO 9001:2000, and the requirements of this quality system and plans as indicated in Section 7.1.

The criteria for auditor independence and clarification of auditor responsibilities are found in Q4.17.1 – Quality Management System Audits . The results are recorded to enable management and others to take timely corrective action and to allow for proper verification of effectiveness.

8.2.3 Monitoring and Measurement of Processes

Quality management system processes are monitored and measured when required in accordance with specific product plans as described in Section 7.1 in order to demonstrate the ability of the processes to achieve planned results. When departures from planned results occur, process specific reaction plans listed in procedures Q4.13.1 – Control of In-House Non-Conforming Product, Q.4.13.2 – Control of Non-Conforming Customer Returns and Q4.14.1 – Corrective Action enable corrective action where appropriate.

HV uses various root cause/problem-solving methods such as the “5 Whys” or “8D” to help resolve quality issues.

8.2.4 Monitoring and Measurement of Product

Parts, components and materials utilized in production of products will be received in an organized manner, inspected and tested for conformance in accordance with written work instructions.

Receiving personnel or Quality personnel will inspect incoming products before use per Procedure Q4.10.3.1 – Final and Receiving Inspection.

In-process inspection and testing will be conducted in accordance with steps identified on process sheets and per Procedure Q4.10.1 – In Process Inspection and Q4.10.2 – Rerun Job Inspection.

Final inspection and testing will also be conducted in accordance with steps listed on each process sheet and per Procedure Q4.10.3.1 – Final and Receiving Inspection. Stock parts will

be inspected per Procedure Q4.10.3.2 – Final Inspection of Stock Parts. The final inspection sequence on the process sheet will assure that all inspection and tests as required were conducted and documented.

Any items or shipments rejected for nonconformance will be properly tagged and segregated. No further processing of the item can occur until the nonconformance is dispositioned and corrected.

Quality records will be identified and maintained including the name of the person authorizing release of product in accordance with Procedure Q4.5.2 – Control of Quality Records.

8.2.5 Related Documents

- Q4.5.2 – Control of Quality Records
- Q4.10.1 – In Process Inspection
- Q4.10.2 – Rerun Job Inspection
- Q4.10.3.1 – Final and Receiving Inspection
- Q4.10.3.2 – Final Inspection of Stock Parts
- Q4.13.1 – Control of In-House Non-Conforming
- Q.4.13.2 – Control of Non-Conforming Customer Returns
- Q4.14.1 – Corrective Action
- Q4.17.1 – Quality Management System Audits
- Q4.21.1 – Customer Satisfaction
- Q4.22.1 – Continual Improvement

8.3 Control of Non-Conforming Product

8.3.1 General

All product, assemblies or components rejected or found to be in nonconformance to specified requirements will be identified, segregated, and documented to prevent their inadvertent shipment or continued use in production operations. Procedures Q4.13.1 – Control of In-House Non-Conforming Product and Q4.13.2 – Control of Non-Conforming Customer Returns details this policy. All non-conforming items will be evaluated and reviewed by the Quality Department and for disposition of the items as follows:

- Reworked to meet specified requirements
- Accepted with or without repair by concession
- Rejected or scrapped.

Any repaired or reworked items shall be inspected again using appropriate procedures. Nonconforming product that is detected after delivery is also controlled with this system and includes determinination of impact on associated lots.

Quality records will be identified and maintained in accordance with Procedure Q4.5.2 – Control of Quality Records.

8.3.2 Related Documents

- Q4.5.2 – Control of Quality Records
- Q4.13.1 – Control of In-House Non-Conforming Product
- Q4.13.2 – Control of Non-Conforming Customer Returns

8.4 Analysis of Data

8.4.1 General

At Harvey Vogel, quality management system related data is recorded as indicated in Procedure Q4.5.2 – Control of Quality Records and analyzed with the objectives below in mind to determine the suitability, effectiveness and opportunities for improvement of the quality management system. The data analysis objectives for Harvey Vogel are:

- To assess customer satisfaction levels
- To determine success rates in fulfilling customer requirements
- To gather knowledge on trends associated with products and processes in order to initiate appropriate preventive action
- To maintain awareness of the performance of suppliers and request them to take action to correct or improve the performance.

8.4.1 Related Documents

- Q4.5.2 – Control of Quality Records

8.5 Improvement

8.5.1 Continual Improvement

The process for continual improvement is described within Procedure Q4.22.1 – Continual Improvement. Continual improvement is:

- A part of the quality policy
- Reflected in the quality objectives
- A part of the actions taken upon audit results
- Driven by opportunities surfacing from data analysis
- A result of corrective action when the action taken corrects a new problem
- Always a result of preventive action
- A required output from management review.

8.5.2 Corrective Action

In order to avoid the recurrence of problems, appropriate corrective actions are taken. Harvey Vogel procedure Q4.14.1 – Corrective Action provides a systematic approach to corrective action problems that includes:

- Reviewing nonconformities including customer complaints
- The determination of causes of nonconformities using various quality methods such as “5 Whys” or “8D”
- Assessing the need for actions to avoid reoccurrence
- The determination of corrective actions needed
- The implementation of determined corrective actions
- Making records of the outcomes from actions taken
- Verifying the effectiveness of corrective actions taken

8.5.3 Preventive Action

In order to avoid the occurrence of potential problems, appropriate preventive actions are taken. Procedure Q4.14.2 – Preventive Action provides a systematic approach to preventive action problems that includes:

- The determination of potential nonconformities
- The determination of causes of potential nonconformities
- The determination of preventive actions needed
- The implementation of determined preventive actions
- Making records of the outcomes from actions taken
- Reviewing preventive actions taken.

8.5.4 Related Documents

- Q4.14.1 – Corrective Action
- Q4.14.2 – Preventive Action
- Q4.22.1 – Continual Improvement.