
	Document ID: POL-001	Title: Quality and Environmental Management System Manual	Revision: J
	Standard: ISO 9001 / ISO 14001 / AS9100	Approved By: 	Date Approved: 08/15/2022



HARVEY VOGEL manufacturing CO.

Custom Metal Stampings and Assemblies

425 Weir Drive • Woodbury, MN 55125-1200

Phone: 651-739-7373 • Fax: 651-739-8666



Quality and Environmental Management System Manual

ISO 9001 / ISO 14001 / AS9100



LEADERSHIP ENDORSEMENT

The contents within this Quality and Environmental Management System (Q&EMS) manual demonstrate our high-level of commitment to quality and environmental performance and continual improvement of the products and services we provide to meet or exceed the expectations of our customers, and other relevant internal and external interested parties.

This manual is available for review on our company website @ www.harveyvogel.com




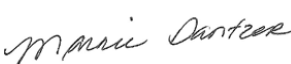






Name	Approval	Date
Robert Verhey President and CEO		08/09/2022
Dave Daley Vice President of Finance		08/02/2022
Matthew Mountain Vice President of Sales & Marketing		08/03/2022
Marnie Dantzer Vice President of Operations		08/04/2022
Jennifer Rehder Vice President of Manufacturing & Engineering		08/03/2022
Darren Dershem Vice President of Quality & Continuous Improvement		08/03/2022
Kent Stepan Director of Engineering & Facilities		08/03/2022
Jay Case Director of Manufacturing, Woodbury		08/04/2022
John Nosbusch Director of Manufacturing, HV West		08/03/2022
Donna Winter Director of Human Resources		08/15/2022

Table of Contents

Leadership Endorsement	2
1. WELCOME.....	5
2. NORMATIVE REFERENCE	5
3. TERMS AND DEFINITIONS.....	5
3.1. General Terminology	5
4. CONTEXT OF THE ORGANIZATION	6
4.1. Understanding the Organization and Its Context.....	6
4.2. Understanding the Needs and Expectations of Interested Parties	6
4.3. Determining the Scope of the Q&EMS.....	6
4.4. Q&EMS and Its Processes	6
5. LEADERSHIP	8
5.1. Leadership & Commitment	8
5.1.1. General.....	8
5.1.2. Customer Focus	8
5.2. Policy.....	9
5.3. Organizational Roles Responsibilities and Authorities	9
6. PLANNING.....	12
6.1. Actions to Address Risks and Opportunities	12
6.2. Company Objectives and Planning to Achieve Them	12
6.3. Planning of Changes	12
7. SUPPORT.....	12
7.1. Resources	12
7.1.1. General.....	12
7.1.2. People	12
7.1.3. Infrastructure.....	13
7.1.4. Environment for the Operation of Processes	13
7.1.5. Monitoring and Measuring Resources	13
7.1.6. Organizational Knowledge	13
7.2. Competence	14
7.3. Employee Awareness.....	14
7.4. Communication	15
7.4.1. Internal Communication	15
7.4.2. External Communication.....	15
7.5. Documented Information	16
8. OPERATION.....	16
8.1. Operational Planning and Control.....	16
8.1.1. Operational Risk Management.....	16
8.1.2. Configuration Management.....	17
8.1.3. Product Safety	17
8.1.4. Prevention of Counterfeit Parts	17
8.1.5. Emergency Preparedness & Response	17
8.2. Requirements for Products and Services.....	17
8.2.1. Customer Communication.....	17
8.2.2. Determining the Requirements Related to Products and Services.....	17
8.2.3. Review of Requirements Related to Products and Services	18
8.2.4. Changes to Requirements for Products and Services	18
8.3. Design and Development of Products and Services	18
8.4. Control of Externally Provided Processes, Products and Services.....	18
8.4.1. General.....	18

8.4.2.	Type and Extent of Control.....	19
8.4.3.	Information for External Providers	19
8.5.	Production and Service Provision	19
8.5.1.	Control of Production and Service Provision	19
8.5.2.	Identification and Traceability	19
8.5.3.	Property Belonging to Customers or External Providers	20
8.5.4.	Preservation	20
8.5.5.	Post-Delivery Activities	20
8.5.6.	Control of Changes	20
8.6.	Release of Products and Services.....	20
8.7.	Control of Nonconforming Outputs	20
9.	PERFORMANCE EVALUATION	21
9.1.	Monitoring, Measurement, Analysis, and Evaluation.....	21
9.2.	Internal Audit	21
9.3.	Management Review	21
9.3.1.	General.....	21
9.3.2.	Review Input.....	21
9.3.3.	Review Output	22
10.	IMPROVEMENT	22
10.1.	General	22
10.2.	Nonconformity and Corrective Action.....	22
10.3.	Continual Improvement.....	22

1. WELCOME

With over 75 years of excellence in manufacturing, Harvey Vogel Manufacturing Company's team of 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 Manufacturing Company a metal stamping resource that holds your interests first.

Harvey Vogel Manufacturing Company (HVMC) has 2 facilities; its corporate headquarters in Woodbury, Minnesota with 132,000 square feet and its HV West facility in Eagan, Minnesota 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 machining capabilities, HVMC can meet the closest, most exacting tolerances in fabrications from one millimeter to 36" x 72", using almost any metal material.

HVMC also provides many other value added services such as complete tool room and engineering services, plating, water jet cutting, anodizing, painting, welding, leveling, tapping, reaming, pem setting, assembly, and more.

HVMC 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.

HVMC is certified to the AS9100, ISO 9001 and ISO 14001 standards. HVMC complies with all required regulatory requirements. Customers determine the specifications to which HVMC 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. HVMC also complies with all local, state, and federal environmental and safety guidelines in accordance with Occupational Safety and Health Administration (OSHA) and the Minnesota Environmental Protection Agency (EPA).

2. NORMATIVE REFERENCE

HVMC's Quality and Environmental Management System (Q&EMS) is based on the AS9100, ISO 9001 Quality Management System and the ISO 14001 Environmental Management System fundamentals and vocabulary.

3. TERMS AND DEFINITIONS

HVMC adopts the following terms and definitions within its Integrated Management System. Where no definition is provided, the company typically adopts the definitions provided in *ISO 9000: Quality Management – Fundamentals and Vocabulary*.

3.1. General Terminology

CIT	Continuous Improvement Team
Document	Written information used to describe how an activity is done
HVMC	Harvey Vogel Manufacturing Company
KI	Key Initiative
NCR	Nonconforming Material Report
Record	Captured evidence of an activity having been done

4. CONTEXT OF THE ORGANIZATION

4.1. Understanding the Organization and Its Context

Relevant external and internal issues are determined and monitored in accordance with PRO4010 Context of the Organization.

4.2. Understanding the Needs and Expectations of Interested Parties

HVMC's interested parties and requirements are determined and monitored in accordance with PRO4010 Context of the Organization.

4.3. Determining the Scope of the Q&EMS

HVMC has determined the scope of the Q&EMS as: *Manufacturer of custom metal stampings, fabrications and assemblies.*

The Q&EMS applies to all processes, activities, and employees at the following locations:

Corporate Headquarters 425 Weir Drive Woodbury, MN 55125 651-739-7373	HV West 2861 Eagandale Blvd. Eagan, MN 55121 651-739-7373
--	--

The following clause of AS9100/ISO 9001 cannot be applied as HVMC does not perform design or validation activities, therefore the clause is not applicable:

- 8.3 (8.3.1 through 8.3.6) *Design and development of products and services – HVMC manufactures to customer design specifications.*

4.4. Q&EMS and Its Processes

HVMC has identified the processes needed to comply with the requirements of ISO 9001, ISO 14001, AS9100, and customer, statutory, and regulatory requirements. Figure 1 identifies the sequence and interaction of processes, including support processes required for HVMC's Q&EMS to be effective and efficient.

HVMC Process Sequence and Interactions

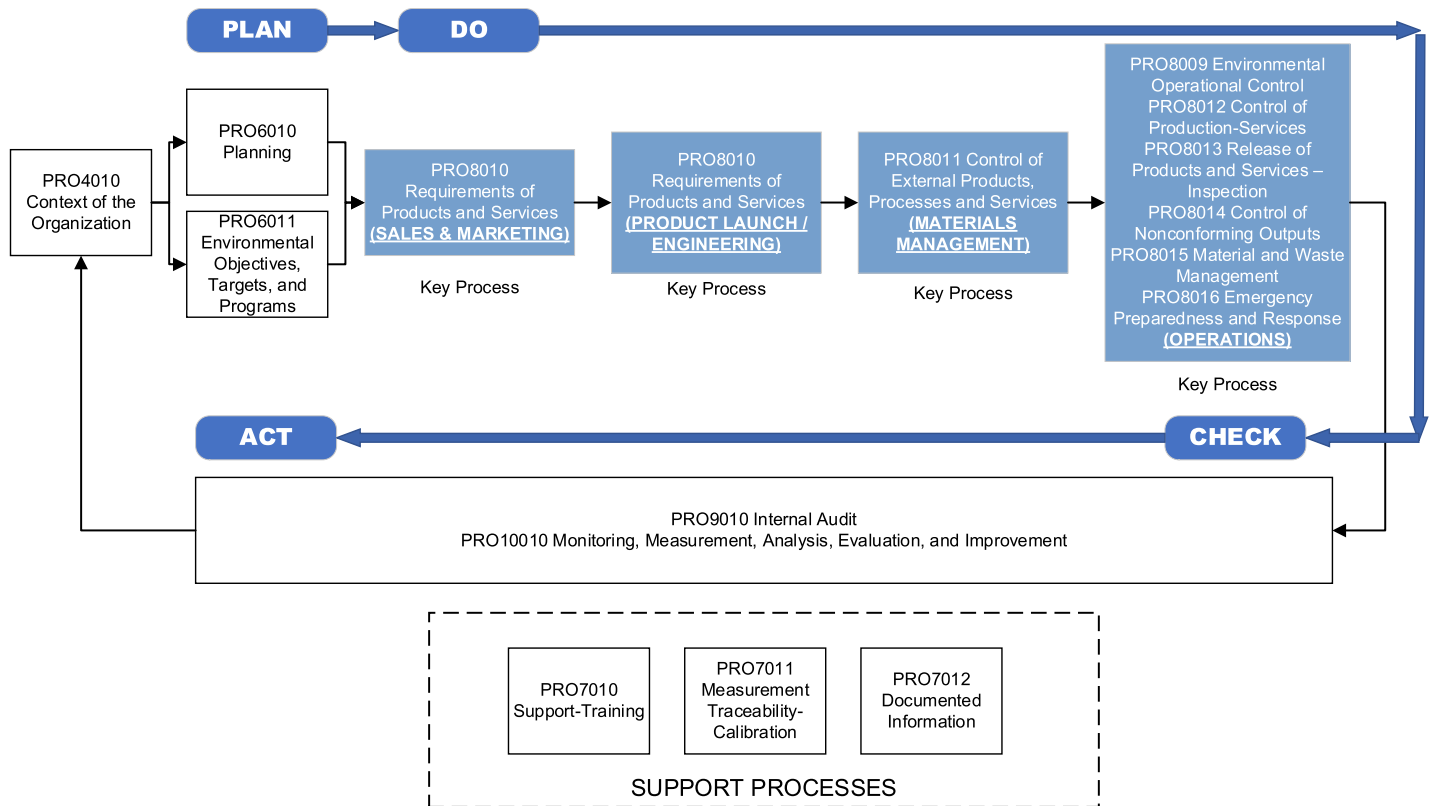


Figure 1 Process Sequence and Interactions

HVMC's Process Matrix (ref. F4010.1.4) defines the following for HVMC's Key Processes:

- Process Owner(s)
- Inputs
- Criteria and Methods
- Resources
- Outputs
- Risks
- Performance Indicators

Performance Indicators are identified in the HVMC Process Matrix, ref. F4010.1.4, and may be added to the Risk and Opportunity Log, ref. F4010.1.3 where they would be reassessed as a yearly metric during quarterly Management Review Meetings (MRM). When a process is in jeopardy of not meeting a goal or it is determined to be unrecoverable, a decision is made to take action toward research and resolution of the issue(s). This may include modifying the goal as an output from an MRM or taking appropriate action per Planning, ref. PRO6010. Actions taken to mitigate risk are recorded in the HVMC Action Log, ref. F6010.1.4. If a Performance Indicator is not recoverable it must be added to the Action Log for disposition.

5. LEADERSHIP

5.1. Leadership & Commitment

5.1.1. General

The Leadership Team of HVMC provides evidence of its leadership and commitment to the development and implementation of the Q&EMS and continually improving its effectiveness by:

- a) actively participating in and supporting the quarterly Management Review Meetings (MRM) to ensure the Q&EMS remains effective and achieves its intended results;
- b) establishing and maintaining a Q&EMS policy and company objectives that are consistent with the strategic direction and the context of HVMC. Includes communicating the Q&EMS policy and driving understanding and application of it;
- c) ensuring the integration of the management system requirements into the organization's other business processes through rigorous review of Q&EMS proposed changes;
- d) promoting awareness of the process approach in day-to-day interactions and via routine meetings, along with review and approval of Q&EMS updates, written to demonstrate HVMC's process approach;
- e) providing adequate resources needed for the management system. Includes providing periodic checks of the system through Internal Audit processes;
- f) communicating the importance of effective quality and environmental management and of conforming to the management system requirements via communication at periodic company meetings and other all-company events as well as in day-to-day interactions;
- g) engaging, directing and supporting staff in contributions to the effectiveness of the management system;
- h) promoting continual improvement through the support of HVMC's key initiatives and Continuous Improvement Teams (CIT) and informal continuous improvement projects and events;
- i) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2. Customer Focus

The Leadership Team of HVMC is committed to assuring that:

- 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;
- d) Product and service conformity and on-time delivery performance are measured and action taken if planned results are not achieved.

These commitments are demonstrated through continuous improvement initiatives, the Product Launch process, cross-functional project team activities, Material Review Board (MRB) meetings, and Foundation customer spot check meetings.

5.2. Policy

The Leadership Team has established and implemented a Q&EMS Policy that is appropriate to the purpose and context of our organization, including the nature, scale, and environmental impact of our activities, products and services; supports strategic direction and; provides a framework for setting company objectives.

The Q&EMS Policy is released as a standalone document as well, and is communicated and implemented throughout the organization. The Q&EMS Policy of HVMC Manufacturing Company is as follows:

To produce custom metal stampings and value-add assemblies that go into products that in turn make people's quality of life better!

We will commit to:

- maintaining a workplace that respects and values all employees and their contributions that in turn makes our business success possible;
- consistently provide products and services that meet or exceed our customers' designs and expectations in quality, service, and delivery;
- understanding the needs and expectations of interested parties that are relevant to our quality management system and take action as appropriate;
- utilizing our strategic goals as the framework to establish our quality objectives and continual improvement of our business management system;
- the prevention of pollution and compliance to environmental requirements while maintaining a safe and healthy workplace.

The Q&EMS Policy is communicated to all employees. Interested parties may review HVMC's Q&EMS Manual and Policy at any time. The Q&EMS Policy is controlled as POL-002.

5.3. Organizational Roles Responsibilities and Authorities

The Vice President of Quality acts as the Management Representative at HVMC. This individual accepts responsibility for ensuring that the management system conforms to the ISO 9001, ISO 14001, and AS9100 standards and for ensuring that the integrity of the management system is maintained when changes are planned and implemented. The Management Representative is also responsible for reporting on the performance of the Q&EMS and on opportunities for improvement related to the Q&EMS (via MRM).

Individual process owners are responsible for ensuring that the processes they own are delivering their intended outputs and for identifying and reporting opportunities for improvement, related to the those processes, to the Strategic Team (as defined in Figure 2).

The Strategic Team at HVMC has the responsibility and authority to promote customer focus throughout the organization.

Assigned responsibilities and authorities for relevant roles within HVMC are defined and communicated via:

- Office job descriptions;
- Job Training Needs (JTN);
- Plant personnel job descriptions (including physical demands);
- Team Member Guideline;
- Organizational charts (see Figure 2).

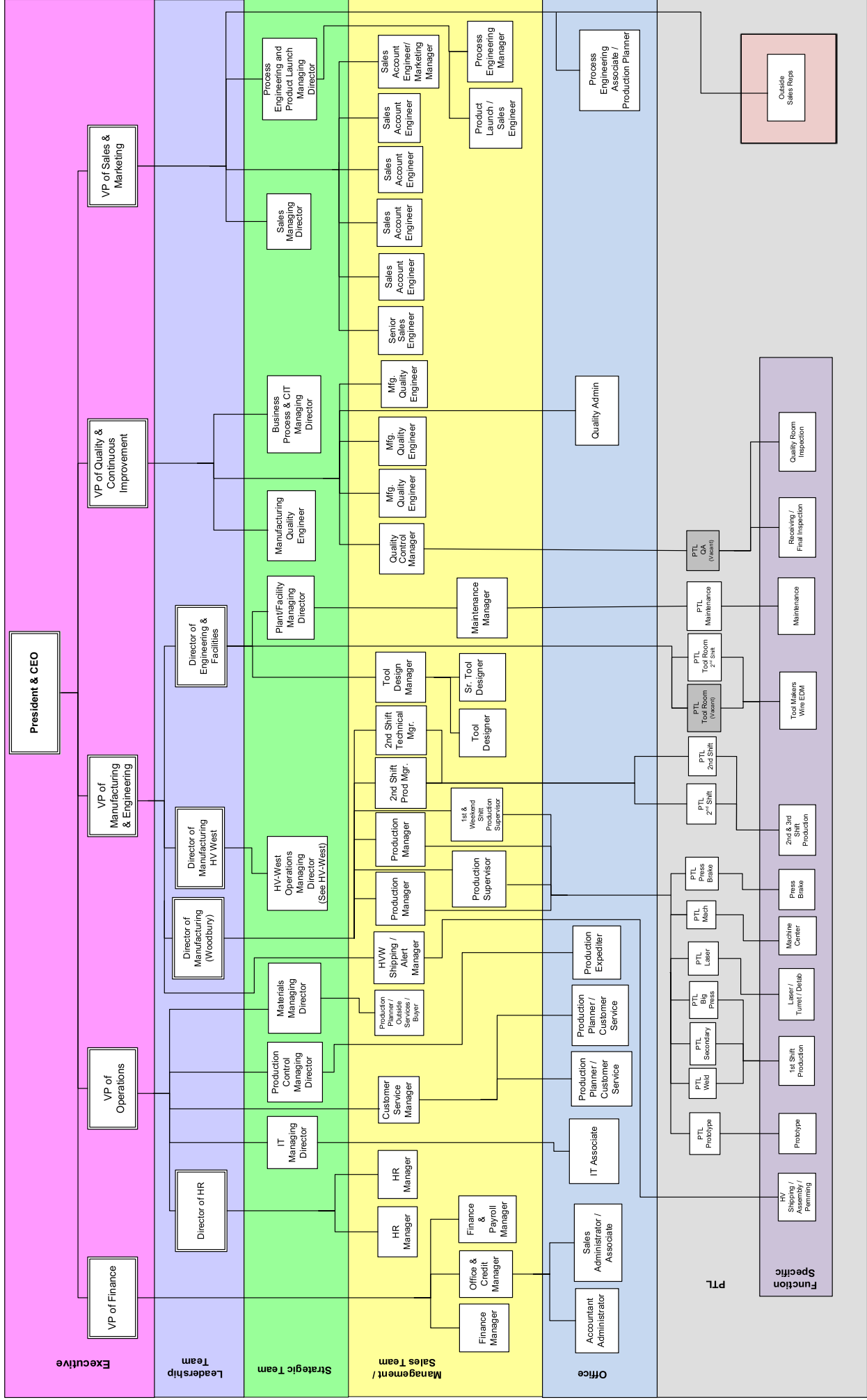


Figure 2 -A Organizational Charts

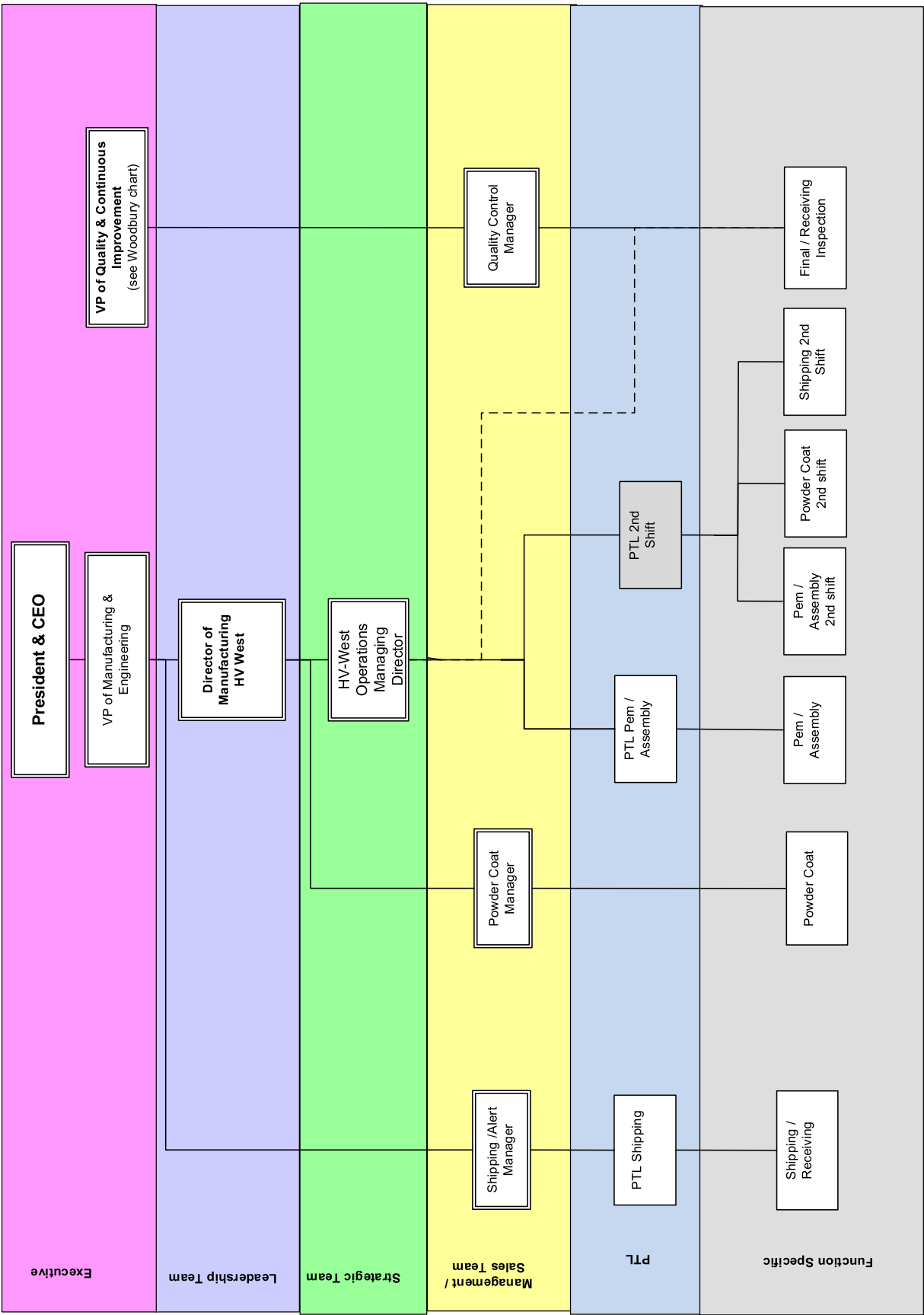


Figure 2 -B Organizational Charts

6. PLANNING

6.1. Actions to Address Risks and Opportunities

The process of identifying and handling risks and opportunities is described in Planning, ref. PRO6010.

6.2. Company Objectives and Planning to Achieve Them

HVMC identifies company objectives at the strategic level (long term needs for growth and development) and at the tactical level (core processes and operational efficiency).

These objectives have been developed in consideration that they:

- a) be consistent with the Q&EMS policy;
- b) be measurable;
- c) take into account applicable requirements;
- d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

Company objectives are identified as part of a twice annual Strategic Planning meeting and documented in HVMC's Objective Tracker, F6010.1.3. The Objective Tracker includes information on what will be done, the resources required, who is responsible, when the objective will be completed, and how the results will be evaluated. The tracker also includes environmental-related objectives (ref. PRO6011, Environmental Objectives, Targets, and Programs).

When an objective is in jeopardy of not meeting a goal, a decision is made by the Vice President of Quality or the strategic team as part of the quarterly Management Review Meetings (MRM) to create an entry in the Risk and Opportunity Log, ref. F4010.1.3. This will allow for continual monitoring and reassessment to determine the need for initiating actions for mitigating risk per Planning, ref. PRO6010. Actions are recorded in the HVMC Action Log, ref. F6010.1.4. Documented risks and associated actions may be long standing based on the determined scope of the initiative. If a goal is not recoverable it must be added to the Action Log for disposition.

6.3. Planning of Changes

Changes to the Q&EMS and its processes are carried out in a planned manner, ref. PRO6010, Planning.

7. SUPPORT

7.1. Resources

7.1.1. General

HVMC provides resource allocation with consideration of:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

Resources and resource allocation are assessed during key initiative meetings and management review meetings.

7.1.2. People

The Leadership Team determines and provides sufficient staffing for the effective operation of the Q&EMS as well its identified processes.

7.1.3. Infrastructure

HVMC 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 technology.

HVMC has a comprehensive contingency plan for the purpose of safeguarding and recovering from disaster related “incidents” (*ref. POL-005, Disaster Recovery Plan*). This plan discusses potential threats to sustaining business operations.

HVMC has a Cyber Security Plan to define existing cyber security–related activities and controls within the organization (*ref. POL-006, Cyber Security Plan*). This plan encompasses security relating to the HVMC network and infrastructure, incident response, and file backup/restoration.

7.1.4. Environment for the Operation of Processes

HVMC utilizes 5S practices, safety audits, and periodic maintenance checks throughout the organization to ensure a safe and healthy workplace is maintained to achieve conformity to product while striving for improvement in the prevention of pollution and compliance to environmental requirements.

7.1.5. Monitoring and Measuring Resources

Equipment used for monitoring and measurement to provide evidence of conformity of product to determined requirements must be identified and controlled per PRO7011 Measurement Traceability-Calibration.

Other measurement devices are subject to calibration based on its intended use and these decisions are based on the importance of a measurement, and considerations of risk.

7.1.6. Organizational Knowledge

HVMC 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 feedback from employees, administrative tests, the results of improvements in processes, products, and services, and lessons learned during post production reviews;
- b) external sources may include gathering knowledge from customers or suppliers, and regulatory agencies.

Knowledge may be maintained in training materials, updated procedures, work instructions, part master files, and is made available to the extent necessary. When addressing changing needs and trends, a determination is made whether or not additional knowledge is required and where to acquire or access it.

Examples of knowledge necessary for operating HVMC's business and for achieving conformity of products and services include:

- Knowledge of customer requirements and specifications;
- Knowledge of business management practices;
- Knowledge of metal stamping techniques and equipment;
- Knowledge of quality assurance and quality control standards and practices;
- Knowledge of environmental requirements and expectations.

Specific organizational knowledge is defined, maintained, and made available through the documentation depicted in the HVMC Process Sequence and Interactions diagram of this document (reference Figure 1). Knowledge transfer is achieved via update of the aforementioned documentation as well as through internal and external training sessions.

7.2. Competence

Employees performing work affecting product quality and environmental performance are competent on the basis of appropriate education, training, skills, and experience. The documented procedure *PRO7010 Support-Training* defines these activities in detail.

7.3. Employee Awareness

Training and subsequent communication is enacted to ensure that employees are aware of:

- a) the Q&EMS policy;
- b) relevant company objectives;
- c) their contribution to the effectiveness of the Q&EMS, including the benefits of improved performance;
- d) the significant environmental aspects and related actual or potential impacts associated with their work;
- e) the implications of not conforming with the Q&EMS requirements, including not fulfilling the organization's compliance obligations;
- f) relevant Q&EMS documented information and changes thereto;
- g) their contribution to product or service conformity, and to product safety;
- h) the importance of ethical behavior.

HVMC uses the following communication and training methods, amongst others, to promote employee awareness:

- a) New hire orientation training;
- b) A Quality Awareness bulletin board;
- c) Communication boards unique to each work center;
- d) Large bright signs hung from the walls and ceiling;
- e) Discussions with production personnel during routine production meetings;
- f) Distribution of revised documents to affected employees upon the release of a change.

In addition, *POL-004 Hazard Communication-Right to Know*, is available to all employees.

7.4. Communication

7.4.1. Internal Communication

The Leadership Team of HVMC ensures internal communication takes place regarding the effectiveness of the management system, see the following table:

Table 1 Internal Communication

WHAT	WHEN	WHO TO	HOW	WHO FROM
Status of Objectives	Quarterly	All employees	In person, State of the Company meeting	Company President
Continuous Improvement Projects	Monthly	CIT Project Members	In person, CIT meetings	CIT Leads
Significant Environmental Aspects	Quarterly	All employees	In person, Mgmt. Review, Bulletin Boards	Vice President of Quality
Audit Results	Quarterly	Strategic Team	In person, Management Review	Vice President of Quality
Customer Satisfaction	Monthly	Foundation Customer Teams	Email Distribution	Customer Service
Customer Satisfaction	Quarterly	Strategic Team	In person, Management Review	Materials Managing Director
Company Strategy	Twice Annually	Strategic Team	Strategic Planning Session	Company President
Leadership Topics	Monthly	Leadership Team	In person	Company President

7.4.2. External Communication

The Q&EMS Steering Committee is responsible for all external communications from interested parties pertaining to HVMCs Environmental Management System.

Upon notification from an External Interested Party concerned with the environmental performance of our organization, the Director of Human Resources will enter the concern in the External Communication Log, F001-01.

The Director of Human Resources reviews the concerns and determines the course of action to be taken and responsible party.

The Director of Human Resources monitors the log to ensure timely closure and response to External Interested Parties.

The External Communication Log, F001-01, is reviewed by the Q&EMS Steering Committee quarterly during Management Review.

HVMC does not communicate externally about its significant environmental aspects, except where regulations require it.

Table 2 External Communication

WHAT	WHEN	WHO TO	HOW	WHO FROM
Regulatory and Compliance Information	Upon Notification	Regulators	External Communication Log*	Director of Human Resources

7.5. Documented Information

Documents required for the Q&EMS are controlled in accordance with procedure PRO7012 Documented Information to assure employees have access to the latest, approved information, and to restrict the use of obsolete information.

Documented records are controlled per procedure PRO7012 Documented Information which defines the controls needed for the identification, storage, retrieval, protection, retention time, and disposition. This procedure also defines the methods for controlling documented information that are retained by suppliers. These controls provide evidence of conformance to contractual requirements, procedural requirements, or statutory/regulatory compliance and provide evidence of the effective operation of the Q&EMS.

8. OPERATION

8.1. Operational Planning and Control

HVMC plans and develops the processes needed for realization of the products and services it provides. Such planning is accomplished through the Product Launch process (ref. Requirements for Products and Services, PRO8010) and the Product Launch form, F8010.1.1 which includes:

- a) determining the requirements for the product and services;
- b) establishing criteria for the processes and the acceptance of the product;
- c) determining the resources needed to achieve conformity to the product requirements;
- d) implementing control of the processes in accordance with the criteria;
- e) maintaining documented information to the extent necessary to have evidence that the processes have been carried out as planned and to demonstrate the conformity of the product to its requirements;
- f) determining the processes and controls needed to manage critical items;
- g) engaging representatives of affected functions for operational planning and control;
- h) determining the process and resources to support the use and maintenance of the products and services;
- i) determining the products and services to be obtained from external providers.

Controls used to prevent the delivery of nonconforming products to the customer are described in PRO8014, Control of Nonconforming Outputs.

Environmental Operational Control, PRO8009, is used for operations and activities associated with significant environmental aspects.

Changes to operational processes are controlled per procedure PRO8012 Control of Production/Services.

Outsourced processes are controlled per procedure PRO8011 Control of External Processes/Products/Services.

8.1.1. Operational Risk Management

Operational risks are typically identified as part of the Strategic Planning Process as referenced in procedure PRO4010, Context of the Organization. They can also be identified as part of the Product Launch process, ref. PRO8010, Requirements for Products and Services, but may be identified at any point in the product realization process. Operational risks are documented in HVMC's Risk / Opportunity Log, ref. F4010.1.3, in accordance with PRO6010, Planning.

8.1.2. Configuration Management

The configuration management process involves how changes to both documentation and product and processes are made, and as such, is covered in PRO7012, Documented Information, and PRO8012, Control of Production and Services, respectively.

8.1.3. Product Safety

HVMC has implemented processes needed to assure product safety during the entire product lifecycle. Product safety hazards are assessed and managed as part of the Product Launch process, ref. PRO8011, Requirements for Products and Services, including the management of safety critical items. Upon notification from a customer of an occurred event affecting safety, the issue is analysed as part of HVMC's customer complaint process, ref. PRO8014, Control of Nonconforming Outputs, or as directed by the customer. In the event of a report from a customer, employees would be made aware of the event and undergo additional training, where appropriate or directed.

8.1.4. Prevention of Counterfeit Parts

HVMC's counterfeit part prevention program includes preventive controls applied to the procurement process, PRO8011, Control of External Processes, Products, and Services as well as an inspection component, described in PRO8013, Release of Products and Services-Inspection.

8.1.5. Emergency Preparedness & Response

PRO8016, Emergency Preparedness and Response and the associated POL-003 Emergency Action Plan describe the company's approach to emergency preparedness and response.

8.2. Requirements for Products and Services

8.2.1. Customer Communication

HVMC has implemented effective communication with customers in relation to:

- a) providing information relating to products and services;
- b) handling inquiries, 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.

8.2.2. Determining the Requirements Related to Products and Services

When determining the requirements for products and services offered to the customer, HVMC will ensure that:

- a) requirements for the products and services are defined, including:
 - 1. any applicable statutory and regulatory requirements;
 - 2. those considered necessary by HVMC.
- b) that HVMC can meet the claims for the products and services it offers;
- c) special requirements of the products and services are determined;
- d) operational risks are identified

These activities are defined in greater detail in the procedure PRO8010 Requirements for Products/Services.

8.2.3. Review of Requirements Related to Products and Services

HVMC reviews the requirements for products and services prior to its commitment to the customer. This review ensures that HVMC has the capability and capacity to:

- a) meet all requirements specified by the customer, including requirements for delivery activities and any applicable post-delivery activities;
- b) meet any requirements not stated by the customer, but which HVMC deems necessary;
- c) meet all related statutory and regulatory requirements;
- d) meet any contract or order requirements differing from those previously expressed.

These activities are defined in greater detail in the procedure *PRO8010 Requirements for Products/Services*.

8.2.4. Changes to Requirements for Products and Services

HVMC updates all relevant requirements and documents when the requirements are changed, and ensures that all relevant parties are notified; see the documented procedure *PRO8010 Requirements for Products/Services*.

8.3. Design and Development of Products and Services

HVMC manufactures products to meet customer print specifications and does not design nor develop its own products for sale. Design and development activities are owned by the customer, thus this clause does not apply to products and services provided by HVMC.

8.4. Control of Externally Provided Processes, Products and Services

8.4.1. General

HVMC evaluates and selects suppliers based on their ability to provide processes, products, and services in accordance with the specified requirements; see documented procedure *PRO8011 Control of External Processes/Products/Services*.

The type and extent of controls applied to externally provided processes, products, and services are determined when:

- a) products and services from external providers are incorporated into the products and services provided by HVMC;
- b) products and services are provided directly to the customer(s) by external providers on behalf of HVMC and/or requested by our customer(s);
- c) a process or part of a process is provided as a result of a decision by HVMC or our customer(s).

Supplier performance is monitored and quarterly reports are sent to the Top Tier suppliers. Corrective actions may be issued for specific non-conforming processes, products, and services, or when systemic trends are identified or the overall performance evaluation scores have unacceptable ratings.

8.4.2. Type and Extent of Control

HVMC ensures that external providers do not adversely affect our ability to consistently deliver conforming products and services to our customers by:

- a) ensuring that external provided processes remain within the control of our Q&EMS;
- b) defining the controls that apply to the external provider and the controls that apply to the resulting output;
- c) taking into consideration:
 - 1. the potential impact of the externally provided processes, products, and services and HVMC's ability to consistently meet customer and applicable regulatory requirements;
 - 2. the effectiveness of the controls applied by the external provider;
 - 3. the results of the periodic review of external provider performance.
- d) determining the verification, or other activities to ensure externally provided processes, products, or services meet requirements.

8.4.3. Information for External Providers

HVMC will ensure that the requirements for products, processes, and services adequately describe the requirements prior to communicating them to the external provider(s).

Requirements are communicated to suppliers via an HVMC Purchase Order and through the HVMC Supplier Guide, ref. POL-007.

8.5. Production and Service Provision

8.5.1. Control of Production and Service Provision

PRO8012, Control of Production/Services, describes the methods used by HVMC to control production activities. The document includes discussion of methods in place to control equipment, tools, and software programs, and the validation and control of special processes.

Production process verification methods (i.e. First Article Inspection) are described in PRO8013, Release of Products and Services – Inspection, ref. PRO8011, Requirements for Products and Services

8.5.2. Identification and Traceability

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

If unique traceability is required by contract, regulatory, or other established requirement, HVMC controls and records the unique identification of the product. PRO8012 Control of Production/Services defines these methods in detail.

HVMC's procedures for managing material and waste products (including identification, storage, handling, and disposal) are detailed in PRO8015 Material and Waste Management.

8.5.3. Property Belonging to Customers or External Providers

Property belonging to customers or external provider's property is identified and controlled while under the control of or being used by HVMC. Upon receipt, the 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 external provider 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.

This activity is defined in greater detail in procedure PRO8012 Control of Production/Services.

8.5.4. Preservation

HVMC preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection as described in Procedure PRO8012 Control of Production/Services.

8.5.5. Post-Delivery Activities

HVMC's post-delivery activities are limited to the provision of customer support, when requested within a reasonable timeframe, resulting from:

- a) the detection of a nonconformance to customer requirements, at HVMC or at a customer;
- b) inquiries with regards to HVMC performance to customer expectations, e.g. delivery, quality, service performance.

8.5.6. Control of Changes

HVMC 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 procedure PRO8012 Control of Production/Services. Documents are changed in accordance with procedure PRO7012 Documented Information.

8.6. Release of Products and Services

Acceptance criteria for products are defined in customer specifications, control plans, and work instructions. Reviews, inspections, and tests are conducted at appropriate stages to verify that the requirements have been met. This is done before products are released.

Each process utilizes different methods for measuring and releasing products and services. These methods are defined in procedure PRO8013 Control of Release of Products/Services-Inspection.

8.7. Control of Nonconforming Outputs

HVMC ensures that process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. It is the responsibility of every HV employee to identify and prevent the flow of non-conforming product.

The controls for such nonconformance, including the disposition process, are defined in PRO8014, Control of Nonconforming Outputs.

9. PERFORMANCE EVALUATION

9.1. Monitoring, Measurement, Analysis, and Evaluation

HVMC has determined which aspects of its Q&EMS must be monitored, measured, analyzed, and evaluated, as well as the methods to utilize and records to maintain within this Q&EMS Manual and subordinate documentation. This topic is discussed in detail in PRO10010, Monitoring, Measurement, Analysis, Evaluation, and Improvement.

Results from these analyses may identify new risks, opportunities, and improvement projects.

9.2. Internal Audit

HVMC conducts internal process audits at planned intervals to determine whether the Q&EMS:

- a) conforms to:
 - 1. its own requirements for its Q&EMS;
 - 2. the requirements of the ISO 9001, ISO 14001, and AS9100 International Standards.
- b) is effectively implemented and maintained.

The Internal audit plan takes into consideration:

- a) the importance of the processes within the audit scope, results of previous audits, and any changes that may be affecting the business climate;
- b) defines the audit criteria and scope for each audit;
- c) assigns auditors to ensure objectivity and impartiality of the audit process;
- d) ensures the audit results are reported to relevant management;
- e) that correction and corrective actions occur without undue delay;
- f) That the audit is documented and records retained.

Internal audits are further discussed in PRO9010, Internal Audit.

9.3. Management Review

9.3.1. General

The Strategic Team, as defined in Figure 2, reviews the Q&EMS on a quarterly basis to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of HVMC. At least one representative from each division shall be in attendance for this review.

9.3.2. Review Input

The Management Review includes discussion of the following:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the Q&EMS;
- c) changes in the needs and expectations of interested parties, including compliance obligations;
- d) changes in significant environmental aspects;
- e) changes in risks and opportunities;
- f) information on the performance and effectiveness of the business Q&EMS, including:
 - 1. customer satisfaction and feedback;
 - 2. the extent to which company objectives have been met;
 - 3. process performance and conformity of products and services;
 - 4. nonconformities and corrective actions;

- 5. monitoring and measurement results;
- 6. fulfillment of compliance obligations;
- 7. audit results;
- 8. the performance of external providers
- 9. on-time delivery performance
- g) the adequacy of resources;
- h) relevant communications from interested parties, including complaints;
- i) the effectiveness of actions taken to address risks and opportunities;
- j) opportunities for improvement.

9.3.3. Review Output

Output from the Management Review includes conclusions on the continuing suitability, adequacy, and effectiveness of the Q&EMS.

Decisions and actions related to the following are recorded as meeting minutes:

- a) Opportunities for improvement;
- b) Need for changes to the Q&EMS;
- c) Resource needs;
- d) Actions, if needed, when objectives have not been achieved;
- e) Opportunities to improve integration of the environmental management system with other business processes, if needed;
- f) Any implications for the strategic direction of the organization;
- g) Risks identified

Records from management reviews are maintained by the Vice President of Quality.

10. IMPROVEMENT

10.1. General

HVMC identifies improvement opportunities based on process performance results and any necessary actions to meet customer requirements and enhancements to customer satisfaction. Improvement is discussed in detail in PRO10010, Monitoring, Measurement, Analysis, Evaluation, and Improvement.

10.2. Nonconformity and Corrective Action

HVMC takes corrective action when nonconformity occurs, including those arising from complaints, to eliminate the cause of nonconformity in order to prevent recurrence.

The corrective action taken is appropriate to the effects of the nonconformities encountered. These activities are defined in procedure PRO8014 Control of Nonconforming Outputs.

10.3. Continual Improvement

HVMC works to continually improve the suitability, adequacy, and effectiveness of the Q&EMS through strategic planning, SWOT analysis, continuous improvement teams, key initiatives, key projects, and the needs of internal and external interested parties.

The results of analysis, evaluation, and outputs from management review determine if there are new issues or opportunities to be addressed as part of continual improvement.

Revision History

<i>Rev</i>	<i>Date</i>	<i>Description of Change</i>	<i>Author</i>
D	04-23-2019	Updated Org Charts and signatories; Added AS9100 references; Added reference to POL-002, POL-005, and POL-006, and PRO9010; Added detail to leadership; Removed quality memo from Employee Awareness; Document structuring cleanup.	Darren Dershem; Daniel Kramlinger
E	12-13-2019	Updated Org charts and signatory page for inclusion of new executive Vice President and Director of Process Engineering roles; Updated internal communication table.	Daniel Kramlinger
F	07-21-2020	Updated Org Charts and corresponding title changes throughout policy; Removed union reference; Added maintenance checks as a measure to ensure safety; Added Strategic Planning as a source to identify Operational Risks; Added detail to analysis of performance indicators.	Darren Dershem; Daniel Kramlinger
G	08-10-2020	Updated the Woodbury Org Chart to encompass recent organizational changes that took place on August 10 th 2020.	Daniel Kramlinger
H	03-16-2021	Updated both Org Charts and updated leadership endorsement table accordingly; Clarified the employee responsibility to identify non-conforming product.	Daniel Kramlinger
I	08-09-2021	Updated both Org Charts; Updated leadership endorsement table for Director of Materials Management & Customer Service.	Daniel Kramlinger
J	08-02-2022	Updated leadership endorsement table and Org Chart; Added MRM attendance requirements; Further defined the process for risks and actions taken against Performance Indicators and Company Objectives.	Daniel Kramlinger