**HFI FLUID POWER PRODUCTS**

**A Division of Hydraulic Fittings, Inc.**

# QUALITY MANUAL

ISO 9001:2015

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## ABOUT HFI FLUID POWER PRODUCTS

HFI Fluid Power Products is a manufacturer, fabricator and distributor of hydraulic and pneumatic components. HFI manufactures both a standard line of connectors as well as customs that adhere to the specifications of JIC, SAE and ISO. Hydraulic tube and hose assemblies are fabricated at our facilities with modern processes and inspection criteria in place.

The entirety of HFI's campus is included in the scope of registration. Locations are:

1210 – 1232 Washington Avenue, Racine, Wisconsin
1230 Racine Street, Racine, Wisconsin

This manual defines the company's policies in relation to the ISO standards. The Company Management endorses the policies contained in this manual and certifies that this manual correctly describes the company's quality system.

## ABOUT THIS QUALITY MANUAL

HFI Fluid Power Products has developed and implemented a Quality Management System to document the company's business practice and better satisfy the requirements and expectations of its customers and improve the overall management of the company. Our Quality Management System (QMS) meets the requirements of the international standard for ISO 9001. This system addresses the processes involved in the manufacture of the company's products.

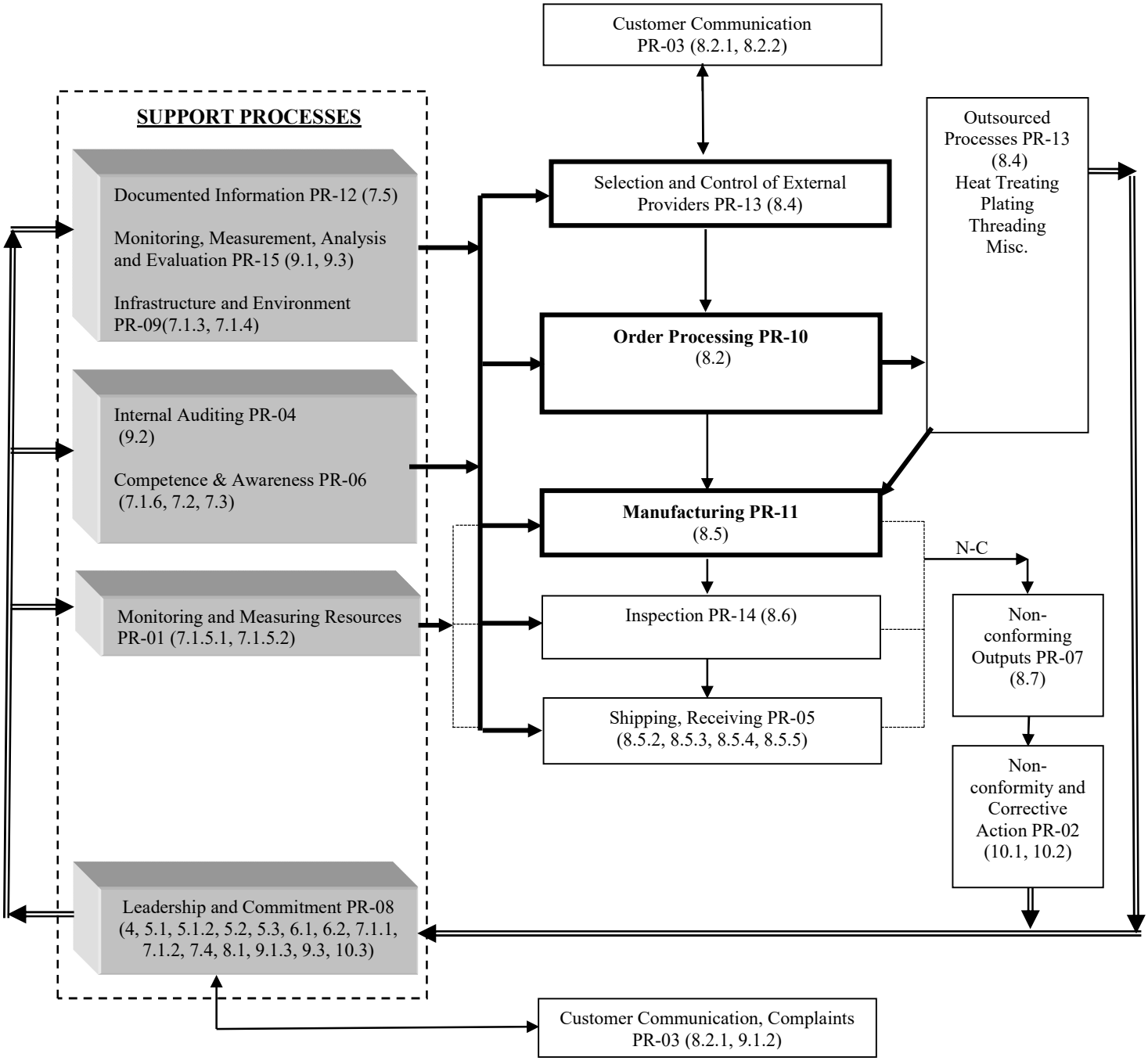
The requirements of the International Standard are included in this quality manual. Each clause is summarized in a section under it called "Our Interpretation", wherein the standard is explained in conversational terms that may be easier for non-ISO readers to better understand. Under each interpretation is a list of the processes that the clause addresses. And lastly, "Supporting Evidence" cites at least one place where evidence can be found that the 'shall' statements are being addressed.

The numbering and the nomenclature of the 2015 standard have been adopted in this manual.

# QUALITY POLICY

# INTERACTION BETWEEN THE PROCESSES

Key processes in **Bold** font
ISO Clauses within parenthesis, e.g. (9.9.9)
'P' designates a documented procedure



# REVISION HISTORY

| REVISION | DATE | CHANGES | Page | ISO Clause |
|---|---|---|---|---|
| 1 | 8/10/2018 | Revised 2008 quality manual to meet 2015 requirements | All | All |
| 2 | 8/20/18 | Minor changes to verbiage | 6 | IOP |
| 3 | 8/21/18 | Changed HFI Fluid Power Products from Wisconsin Industries, MRM to MRC. | 4, all | IOP |
| 4 | 10/2/19 | Added processes to Interaction Between Processes | 6 | IOP |
| 5 | 8/19/21 | Updated Quality Policy | 5 | IOP |
| 6 | 4-3-22 | Corrected 9001:2015 Page 9. | 9 | IOP |
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# QUALITY SYSTEM MANAGEMENT—REQUIREMENTS

## 1 Scope

This Quality Manual outlines the policies of our Quality Management System (QMS) as they relate to the requirements of ISO 9001:2015 (herein referred to as "9001" or "ISO").

The International Standard specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements. The applicable statutory requirements are displayed in the chart below.

| Legal Requirement | Method of Monitoring | Specific to a Customer |
|---|---|---|
| ANSI Regulations | Send out applicable tools for certification, review new and updated standards as they are made available | NO |
| OSHA Regulations | Dir of Fabrication and Mgr. of Facilities and Safety keep up to date | NO |
| MSDS/SDS | Vendors whose products are effected keep us up to date with current MSDS sheets for their products. | NO |
| Country of Origin | Project by Project review of applicable rules and regulations | NO |
| Conflict of Minerals | Certifications from external suppliers | NO |

All the requirements of the International Standard are applicable to HFI Fluid Power Products (in this QMS referred to as 'HFI' and the products and services we provide with the exception to those listed below in 4.3.

## 2 Normative references

ISO 9000:2015, Quality Management Systems – Fundamentals and Vocabulary, is referenced. See 3 below for explanation.

## 3 Terms and definitions

The terms and definitions given in ISO 9001:2015 apply to this quality manual and to all other QMS documents. Because re-writing every document that may contain a term that has been revised is a daunting task, and because there is no requirement to use the 2015 terms, we have chosen to continue to use the vernacular for most of our QMS. "Retained documented information" and "maintained documented information," as examples, that appear in the 2015 standard, may be referred to as "records" and "documents" in many documents in this QMS. And other common terms used prior to publication of the 2015 standard, such as "external provider", may still be seen as "supplier," and so forth. The nomenclature may be found together within a document.

## 4 Context of HFI

### 4.1 Understanding HFI and its context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

**Our Interpretation:** This QMS advocates and employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle, and risk-based thinking (RBT).

- The process approach enables HFI to plan its processes and their interactions.

- The PDCA cycle enables HFI to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.
- Risk-based thinking enables HFI to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise.

HFI has determined external and internal issues that are relevant to its purpose and its strategic direction, and that affect its ability to achieve the intended results of its QMS. We monitor and review information about these external and internal issues and understands that issues can include positive and negative factors or conditions for consideration. Additionally, understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local, and understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of HFI.

**Process(es):** Documented Information

**Supporting Evidence:** The chart below listing information about internal and external issues.

| **Internal Issues** | **Method of Monitoring** | **Method of Reviewing** |
|---|---|---|
| Availability of qualified people | Research by HR Mgr., discussions with employment agencies, local colleges, etc. | Comparing |
| Keeping up with training required. | Training Matrix | Training Records |
| Meeting Quality Objectives | Measuring Key Processes via KPIs | AR's, MRC meeting minutes. |
| Employee Morale | Discussions with employees | Compensation reviews, benefit planning |
| **External Issues** | **Method of Monitoring** | **Method of Reviewing** |
| Competitive environment, e.g. lead time | Sales people discuss lead time with potential and current customers | Checking surveys, customer complaints or negative comments about lead times |
| Price of materials | Requesting quotes from suppliers | Regular pricing updates from suppliers and market updates |
| Customer Satisfaction | Customer Reviews | Customer feedback, requirements, repeat orders, complaints, etc. |

## 4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:
a) the interested parties that are relevant to the quality management system;
b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

**Our Interpretation:** Due to their effect or potential effect on our ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, HFI has determined the interested parties—and their requirements—that may be relevant to the QMS.

It is for an organization to decide if a particular requirement of a relevant interested party is relevant to its QMS, and HFI has created a general listing of interested—or potentially interested—parties identified in the chart below.

We will monitor and review information about these interested parties and their relevant requirements as appropriate, as dictated by external context prevalent at any given time.

**Process(es):** Leadership and Commitment

**Supporting Evidence:** This Quality Manual, Management Review Minutes

| Interested Party | Reason for Interest | Monitoring Method |
|---|---|---|
| Owners, including any stockholders | The profit motive; ROI. | Meetings, email, web site, financial statements, audit report. |
| Potential buyers of HFI | Same as above. | Meetings, business documents as required. |
| Employees of HFI and their families | The continuity of HFI ensures a living for them. | Providing a forum for and listening to employees. |
| Customers | They rely on the products and services of the company to deliver products to enhance their opportunity for success. | Customer feedback in any manner. General business news outlets, e.g. magazines. |
| External providers | Selling their products and/or services to HFI helps keep them in business. | Feedback from them in any manner. General business news outlets, e.g. magazines. |
| Creditors | They want and need HFI to pay their bills. | Monthly statements |
| Debtors | The desire for a debt to be repaid. | Monthly statements. One on one meetings. |
| External auditors | Auditing the QMS | Determines the effectiveness of our QMS and may see and report relevant issues. |
| Registrars | We are their customer and they register us to ISO 9001 | Notify us of educational opportunities, e.g. webinars, newsletters. |
| Emergency responders | Public Safety | Yearly facility tour |

## 4.3 The scope of HFI's QMS

The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;
b) the requirements of relevant interested parties referred to in 4.2;
c) the products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

**Our Interpretation:** We should—and have—determined the boundaries and applicability of its QMS in order to establish its scope.

Leadership has considered the external and internal issues referred to in 4.1, the requirements of relevant interested parties referred to in 4.2 and our products and services.

All the requirements of the International Standard are applicable within the determined scope of its quality management system except 8.3, Design and Development, because HFI does not design products.

This Quality Manual outlines the policies of our QMS as they relate to the requirements of ISO.

Briefly described, the scope of our QMS encompasses the **manufacture, fabrication, and distribution of hydraulic and pneumatic components.**

**Process(es):** Leadership and Commitment

**Supporting Evidence:** MRC minutes, this Quality Manual.

## 4.4 Quality management system and its processes

**4.4.1** The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

a) determine the inputs required and the outputs expected from these processes;
b) determine the sequence and interaction of these processes;
c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
d) determine the resources needed for these processes and ensure their availability;
e) assign the responsibilities and authorities for these processes;
f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
h) improve the processes and the quality management system.

**Our Interpretation:** HFI must adhere to the documentation requirements of the International Standard—and its own requirements—and be able to demonstrate compliance.

**Process(es):** Leadership and Commitment, Internal Audit, Documented Information

**Supporting Evidence:** This Quality Manual, MRC minutes, Audit results, Documented Information

**4.4.2** As necessary, HFI:

a) maintains documented information to support the operation of its processes; and

b) retains documented information to have confidence that the processes are being carried out as planned.

**Our Interpretation:** HFI must adhere to the documentation requirements of the International Standard—and its own requirements—and be able to demonstrate compliance that the processes are being carried out as planned.

**Process(es):** Commitment, Documented Information

**Supporting Evidence:** This Quality Manual, MRC minutes

# 5 Leadership

## 5.1 Leadership and commitment

### 5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system;
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
c) ensuring the integration of the quality management system requirements into the organization's business processes;
d) promoting the use of the process approach and risk-based thinking;
e) ensuring that the resources needed for the quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
g) ensuring that the quality management system achieves its intended results;
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

**Our Interpretation:** Management should take an active role in the QMS to drive these issues.

**Process(es):** Leadership and Commitment

**Supporting Evidence:** MRC minutes

### 5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring 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.

**Our Interpretation:** When possible, we will have knowledge of the application of our product and any regulations surrounding that use. The associated risks inherent in a project will be determined and acted upon. Management will focus on customer satisfaction.

**Process(es**): Customer Communication; Order Processing, Leadership and Commitment

**Supporting Evidence:** MRC minutes

## 5.2 Policy

### 5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:
a) is appropriate to the purpose and context of the organization and supports its strategic direction;
b) provides a framework for setting quality objectives;
c) includes a commitment to satisfy applicable requirements;
d) includes a commitment to continual improvement of the quality management system.

**Our Interpretation:** Top management initiates the quality policy that gives direction to our employees and sets expectations of customers, external providers and any other interested parties.

**Process(es):** Leadership and Commitment, Documented Information

**Supporting Evidence:** This Quality Manual, MRC Minutes, W-010 Quality Policy and Responsibilities Poster

### 5.2.2 Communicating the quality policy

The quality policy shall:
a) be available and be maintained as documented information;
b) be communicated, understood and applied within the organization;
c) be available to relevant interested parties, as appropriate.

**Our Interpretation:** The Quality Policy is shared with all interested parties and should be reviewed periodically and upgraded as necessary to maintain its relevance. All employees need to understand its relevance and apply it in daily activities.

**Process(es):** Leadership and Commitment, Documented Information

**Supporting Evidence:** HFI web site, this Quality Manual, MRC Minutes

## 5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.
Top management shall assign the responsibility and authority for:
a) ensuring that the quality management system conforms to the requirements of this International Standard;
b) ensuring that the processes are delivering their intended outputs;
c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
d) ensuring the promotion of customer focus throughout the organization;
e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

**Our Interpretation:** A person should be appointed to a position designed to administer inputs to the QMS, be the focal point for communications about the QMS, ensure the QMS is effective and conforming to ISO; and to our quality system, ensure promotion of a customer focus within HFI and that reports to Leadership relative to all of this. The title of this position at HFI will be 'Management Representative' (MR) and will report to top management on these issues regardless of any other responsibilities that person has. The Vice President has provided information specifying what each function is responsible for, and to whom each person reports. The responsible people will ensure the processes are performing correctly and will report on the integrity of the processes for which they are responsible, with all activity being focused on the ultimate satisfaction of the customer.

**Process(es):** Leadership and Commitment, Competence & Awareness, Monitoring, Measurement, Analysis and Evaluation

**Supporting Evidence:** Organization Chart(s), Job Descriptions, MRM Minutes, Quality Objectives, various metrics, Internal Audit.

# 6 Planning

## 6.1 Actions to address risks and opportunities

**6.1.1** When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:
a) give assurance that the quality management system can achieve its intended result(s);
b) enhance desirable effects;
c) prevent, or reduce, undesired effects;
d) achieve improvement.

**Our Interpretation:** Leadership should be periodically monitoring internal and external issues for relevancy and the needs and expectations of interested parties, and the opportunities that may need to be addressed based upon the associated risk.

**Process(es):** Leadership and Commitment, Customer Communication

**Supporting Evidence:** MRC minutes, Process Risk Matrix, Risk Management Log, Risk Assessment and Management Procedure, customer feedback

**6.1.2** The organization shall plan:
a) actions to address these risks and opportunities;
b) how to:
    1) integrate and implement the actions into its quality management system processes (see 4.4);
    2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

**Our Interpretation:** Where appropriate, the issues resulting from the analysis in the above clause should be used as input to determine 1) the actions required to address any risks or opportunities, 2) a plan to implement the change and 3) a method of evaluating the actions.

**Process(es):** Leadership and Commitment

**Supporting Evidence:** MRC minutes

## 6.2 Quality objectives and planning to achieve them

**6.2.1** The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.
The quality objectives shall:
a) be consistent with the quality 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.
The organization shall maintain documented information on the quality objectives.

**Our Interpretation:** We should understand what our processes are and establish measureable objectives on the most critical to the overall success of HFI. The other processes need not be measured, but need to be assessed

periodically to understand they are still effective. This is done via observations on a routine basis and during internal audits.

**Process(es):** Leadership and Commitment, Internal Audit, Competence and Awareness

**Supporting Evidence:** Charted results of the measurements, documented information from internal audits.

**6.2.2** When planning how to achieve its quality objectives, the organization shall determine:
a) what will be done;
b) what resources will be required;
c) who will be responsible;
d) when it will be completed;
e) how the results will be evaluated.

**Our Interpretation:** HFI should document the process of retrieving, specific data, assign a function to ensure it is retrieved in a timely manner and how and when to analyze the data in order to understand trends.

**Process(es):** Leadership and Commitment.

**Supporting Evidence:** charted results of the measurements.

### 6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).
The organization shall consider:

a) the purpose of the changes and their potential consequences;
b) the integrity of the quality management system;
c) the availability of resources;
d) the allocation or reallocation of responsibilities and authorities.

**Our Interpretation:** Leadership should be cognizant of changes that may be required within HFI via analysis of the Quality Objectives, measurements e.g., customer input, and make plans to initiate those changes in a manner that will maintain the integrity of the QMS.

**Process(es):** Leadership and Commitment

**Supporting Evidence:** HFI metrics, Risk Analysis, MRC minutes

## 7 Support

### 7.1 Resources

#### 7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.
The organization shall consider:
a) the capabilities of, and constraints on, existing internal resources;
b) what needs to be obtained from external providers.

**Our Interpretation:** HFI believes this to mean we need to understand our short, medium and long-term requirements relative to our capacity—and to some extent, that of our external providers—in terms of skill sets and resource availability, and ensure we are able to budget appropriately in order to meet the demands.

**Process(es):** Customer Requirements, Selection and Control of External Suppliers

**Supporting Evidence:** List of Approved External Providers

### 7.1.2 People
The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

**Our Interpretation:** HFI will supply adequate staffing for each process, to the best of its ability, giving consideration to local labor limitations.

**Process(es):** Leadership and Commitment

**Supporting Evidence:** MRC minutes

### 7.1.3 Infrastructure
The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

NOTE Infrastructure can include:
a) buildings and associated utilities;
b) equipment, including hardware and software;
c) transportation resources;
d) information and communication technology.

**Our Interpretation:** HFI will supply adequate utility for each process, to the best of its ability, giving consideration to limitations on leased and associated items, and other items that are outsourced and outside of our immediate influence.

**Process(es):** Selection and Control of External Providers, Infrastructure and Environment

**Supporting Evidence:** MRC minutes, maintenance records / contracts for support of infrastructure.

### 7.1.4 Environment for the operation of processes
The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:
a) social (e.g. non-discriminatory, calm, non-confrontational);
b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);
c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).
These factors can differ substantially depending on the products and services provided.

**Our Interpretation:** "Suitable environment" applies to anyplace and any time work is performed or discussed.

**Process(es):** Infrastructure and Environment, Commitment

**Supporting Evidence:** MRC minutes

### 7.1.5 Monitoring and measuring resources

### 7.1.5.1 General
The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.
The organization shall ensure that the resources provided:
a) are suitable for the specific type of monitoring and measurement activities being undertaken;
b) are maintained to ensure their continuing fitness for their purpose.
The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

**Our Interpretation:** All equipment used for monitoring or measuring should have the capability to measure with the same or greater resolution of the dimension being measured, that the equipment is in good working order and that calibration records are retained.

**Process(es):** Monitoring and Measuring Resources

**Supporting Evidence:** Retained documentation information for Calibration equipment, P-110 Calibration System

### 7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
b) identified in order to determine their status;
c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

**Our Interpretation:** All equipment needs to be calibrated by a qualified person on a schedule commensurate with the frequency of use and harshness of its environment, or verified prior to each use. If a device is not calibrated to a standard then the method and rationale of the calibration must be recorded and the information retained. All measuring equipment must be identified so that its calibration status can be determined and it must be stored and handled so as to prevent it from becoming damaged or compromised as to its condition.

**Process(es):** Monitoring and Measuring Resources, Competence and Awareness, Documented Information.

**Supporting Evidence:** Retained documentation information for Calibration equipment, training records of people performing calibration, certificates of calibration.

### 7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.
This knowledge shall be maintained and be made available to the extent necessary.
When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

**Our Interpretation:** Consideration should be given to information learned by doing the job, e.g. 'tribal knowledge' as to whether it needs to be formally documented in the QMS or retained in a different way, or retained at all. Information considered necessary to the viability of HFI must be documented so as to not lose it. The scope and depth of this knowledge may change over time and should be continually updated with current, relevant knowledge.

**Process(es):** Competence and Awareness

**Supporting Evidence:** Job descriptions, training records, Documented Information.

## 7.2 Competence

The organization shall:
a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
b) ensure that these persons are competent on the basis of appropriate education, training, or experience;
c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
d) retain appropriate documented information as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

**Our Interpretation:** People must have had training or education in some form on the tasks and/or duties they need to perform. The final proof is being able to demonstrate they can adequately perform a task. All new employees or employees taking a new position after that date must have competence documentation.

**Process(es):** Competence and Awareness

**Supporting Evidence:** Training Matrix, Training records, Job Descriptions, P-180 Training System

## 7.3 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:
a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
d) the implications of not conforming with the quality management system requirements.

**Our Interpretation:** All employees should have specific training about the Quality Policy, the Quality Objectives, how they contribute to the Quality Objectives and what happens when a process is not meeting the requirements of the QMS.

**Process(es):** Competence and Awareness

**Supporting Evidence:** Training record for items mentioned in this clause, "You and ISO" illustration

## 7.4 Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:
a) on what it will communicate;
b) when to communicate;
c) with whom to communicate;
d) how to communicate;
e) who communicates.

**Our Interpretation:** Most communication channels are set up and used by each function on an 'as needed' basis, e.g. we talk with customers when there is current business between us. There are some specifics in 9001 as to what must be communicated, e.g. communications to external providers regarding what is required. Other information that is understood, such as the timing of Management Review Meetings, is documented in this quality manual or in other ISO documentation.

**Process(es):** All processes

**Supporting Evidence:** This Quality Manual, Meeting Matrix

## 7.5 Documented information

### 7.5.1 General

The organization's quality management system shall include:
a) documented information required by this International Standard;
b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:
— the size of organization and its type of activities, processes, products and services;
— the complexity of processes and their interactions;
— the competence of persons.

**Our Interpretation:** HFI needs to have the documentation required by the International Standard and the documentation required by this QMS. If a process can be achieved without documentation and there is no evidence that we are not meeting requirements as a result of not having documented information, it is not necessary to have documentation.

**Process(es):** Documented Information, this Quality Manual.

**Supporting Evidence:** Performance metrics such as KPIs, customer feedback, the general accuracy of outputs, Documented Information

### 7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:
a) identification and description (e.g. a title, date, author, or reference number);
b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
c) review and approval for suitability and adequacy.

**Our Interpretation:** The Management Representative must approve any new or revised maintained documented information and update the QMS accordingly.

**Process(es):** Documented Information

**Supporting Evidence:** Documented Information

### 7.5.3 Control of documented information

**7.5.3.1** Documented information required by the quality management system and by this International Standard shall be controlled to ensure:
a) it is available and suitable for use, where and when it is needed;
b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

**Our Interpretation:** Documentation must be controlled and not be amended without proper authority, be kept safe and be made available when and where needed.

**Process(es):** Documented Information

**Supporting Evidence:** Documented Information, P-050 Document and Data Control, ref - F-000 Forms, Master List, P-000 Procedure Master List, P-000 Procedure Master List, W-000 Work Instruction Master List, S-000 Standards Master List, P-050 Document and Data Control, P-160 Quality Records

**7.5.3.2** For the control of documented information, the organization shall address the following activities, as applicable:
a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;
c) control of changes (e.g. version control);
d) retention and disposition.
Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.
Documented information retained as evidence of conformity shall be protected from unintended alterations.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

**Our Interpretation:** There must be only one point that users can go to get documented information and documents. The Management Representative controls all maintained information as to the changes made, how it is stored, the distribution and how it is disposed of—both electronically and hard copy. This ensures the latest revision is being used.

**Process(es):** Documented Information

**Supporting Evidence**: Documented Information

# 8 Operation

## 8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:
a) determining the requirements for the products and services;
b) establishing criteria for:
    1) the processes;
    2) the acceptance of products and services;
c) determining the resources needed to achieve conformity to the product and service requirements;
d) implementing control of the processes in accordance with the criteria;
e) determining, maintaining and retaining documented information to the extent necessary:
    1) to have confidence that the processes have been carried out as planned;
    2) to demonstrate the conformity of products and services to their requirements.
The output of this planning shall be suitable for the organization's operations.
The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.
The organization shall ensure that outsourced processes are controlled (see 8.4).

**Our Interpretation:** Employees must be trained or have written instructions or both, that will guide the work to be done, in the same way, at all times, by anyone performing it. Adequate inspection of the product must be performed, and the product must be identified that the work has been completed and it has passed inspection. Parts acquired from external providers are not exempt from acceptance criteria and those suppliers must control their processes and provide evidence of that control when required.

**Process(es):** All processes

**Supporting Evidence:** This Quality Manual—specifically the Interaction of Processes, Inspection reports, management system documents related to meeting the requirements for the provision of products and services.

## 8.2 Requirements for products and services

### 8.2.1 Customer communication

Communication with customers shall include:
a) providing information relating to products and services;
b) handling enquiries, contracts or orders, including changes;
c) obtaining customer feedback relating to products and services, including customer complaints;
d) handling or controlling customer property;

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

**Our Interpretation:** HFI employees need to be knowledgeable enough to either answer general questions customers may have about products and how we conduct business, or to know how to direct any inquiry or complaint. If we use customer property in any way, the employee who made the arrangements to use it must let pertinent HFI employees know to ensure compliance with this clause.

**Process(es):** Order Processing, Customer Communication, Selection and Control of External Suppliers

**Supporting Evidence:** Sales contracts or agreements

### 8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) the requirements for the products and services are defined, including:
    1) any applicable statutory and regulatory requirements;
    2) those considered necessary by the organization;
b) the organization can meet the claims for the products and services it offers.

**Our Interpretation:** We must ensure that the requirements for product are known and understood, including when there are legal implications regarding a product. HFI claims about its products are able to be substantiated.

**Process(es):** Order Processing, Selection and Control of External Providers.

**Supporting Evidence:** Sales Orders, Order Processing, P-030 Contract Review

### 8.2.3 Review of the requirements for products and services

**8.2.3.1** The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
c) requirements specified by the organization;
d) statutory and regulatory requirements applicable to the products and services;
e) contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

**Our Interpretation:** We will confirm the details of an order before agreeing to it and entering it into the system. If the order cannot be made to meet customer requirements, it will not be taken. All customer, HFI, and legal requirements are considered doable before an order is taken. If details differ between the original understanding and the order review, they will be discussed and clarified before the order is accepted.

**Process(es):** Customer Communication, Order Processing

**Supporting Evidence:** Documentation of communicating with customers, Order Processing, design changes

**8.2.3.2** The organization shall retain documented information, as applicable:

a) on the results of the review;
b) on any new requirements for the products and services.

**Our Interpretation:** Records of the order review plus any new requirements will be retained

**Process(es):** Order Processing

**Supporting Evidence:** Records of the results of the review

### 8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

**Our Interpretation:** Requirements may be changed and when they are, relevant persons will be informed.

**Process(es):** Order Processing, Production

**Supporting Evidence:** Amended information and evidence of notification.

## 8.3 Design and development of products and services

This clause is not applicable because HFI Fluid Power Products does not design products.

## 8.4 Control of externally provided processes, products and services

### 8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.
The organization shall determine the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization's own products and services;
b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;
c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

**Our Interpretation:** HFI will evaluate all, and re-evaluate specified (based on documented criteria) external providers that might in some way adversely affect our ability to deliver conforming products to ensure they can supply material, products, people or services that meet requirements, and we will provide specifications and information to external providers that is adequate for the provider to understand what is needed and to supply them. Any new provider will need to be evaluated.

**Process(es):** Inspection, Non-Conformity and Corrective action, Selection and Control of External Providers

**Supporting Evidence:** External Provider evaluations and re-evaluations, Certificates of Conformance, Inspection Records, Laboratory Test Results or other such documents that indicate that appropriate processes were followed for the item, P-060 Purchasing

### 8.4.2 Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The organization shall:

a) ensure that externally provided processes remain within the control of its quality management system;
b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
c) take into consideration:

1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
2) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

**Our Interpretation:** HFI will notify our external providers that we measure supplier performance in terms of delivery timeliness as well as quality so that we, in turn, can meet our customers' requirements. As appropriate, we will require documentation from external providers that product meets regulatory requirements and that effective controls are in place.

**Process(es):** Selection and Control of External Providers, Outsourced Processes, Inspection: In-Process / Finished

**Supporting Evidence:** Records of rejected material/product, Corrective Actions to providers

### 8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.
The organization shall communicate to external providers its requirements for:
a) the processes, products and services to be provided;
b) the approval of:
1) products and services;
2) methods, processes and equipment;
3) the release of products and services;
c) competence, including any required qualification of persons;
d) the external providers' interactions with the organization;
e) control and monitoring of the external providers' performance to be applied by the organization;
f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

**Our Interpretation:** HFI will know the requirements for its materials and products, and transmit that information to the external provider to the extent that the external provider will understand the requirement. We will inform the external provider if special expertise, certification, etc. is required on their part. We typically do not have a need to perform verification or validation at the provider's premises, but will make appropriate arrangements if required.

**Process(es):** Selection and Control of External Providers, Outsourced Processes, Selection and Control of External Providers

**Supporting Evidence:** Information obtained from customers about their order, Quotes, Purchase Orders.

## 8.5 Production and service provision

### 8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions.
Controlled conditions shall include, as applicable:
a) the availability of documented information that defines:
1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
2) the results to be achieved;
b) the availability and use of suitable monitoring and measuring resources;
c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
d) the use of suitable infrastructure and environment for the operation of processes;
e) the appointment of competent persons, including any required qualification;
f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;
h) the implementation of release, delivery and post-delivery activities.

**Our Interpretation:** There needs to be enough information provided to anyone performing work on a customer order to complete the operation and meet the customer's requirement. Appropriate controls must be in place to ensure that the product meets the requirements defect free in all respects.

**Process(es):** Production

**Supporting Evidence:** Paperwork associated with production, P-011 PQMC, P-020 Quality Planning, P-090 Process Control, P-200 Statistical Techniques

### 8.5.2 Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.
The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.
The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

**Our Interpretation:** All product will be identified at all times as to its status and/or condition. Each item will have unique identification. If customer's request, HFI can supply information as to a product's origin.

**Process(es):** Selection and Control of External Suppliers

**Supporting Evidence:** Contractual information about traceability, a review of product in its various states.

### 8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.
The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.
When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

**Our Interpretation:** Any material, product, equipment, information belonging to either an external supplier or a customer must be treated in the same safe manner as is HFI's material, etc. If anything owned by a supplier or customer is deemed unusable, a report to the owner must be made and the information retained by us.

**Process(es):** Inspection, Shipping and Receiving, Non-conformity and Corrective Action.

**Supporting Evidence:** Inspection Reports, Non-conforming reports, Scrap reports

### 8.5.4 Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

**Our Interpretation:** We will ensure that everything that will ship to a customer is kept in a condition that will meet requirements and customer expectations.

**Process(es):** Shipping, Receiving; Selection and Control of External Providers

**Supporting Evidence:** Contracts, a review of products in its various stages, P-150 Handling, Storage, Packaging, Preservation, and Delivery

### 8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.
In determining the extent of post-delivery activities that are required, the organization shall consider:
a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products and services;
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

**Our Interpretation:** Post-delivery includes 'feedback' which typically involves every customer in some way.

**Process(es):** Production, Order Processing

**Supporting Evidence:**

### 8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.
The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

**Our Interpretation:** Changes to products are reviewed and documented.

**Process(es):** Customer

**Supporting Evidence:** Change requests from customers or suppliers.

## 8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.
The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.
The organization shall retain documented information on the release of products and services. The documented information shall include:
a) evidence of conformity with the acceptance criteria;
b) traceability to the person(s) authorizing the release.

**Our Interpretation:** Product that is ready to be moved downstream in the process, or to another location, or shipped to finished goods or a customer, must be identified such that it is evident the product meets requirements and is OK to be moved.

**Process(es):** Shipping, Receiving

**Supporting Evidence:** Inspection reports, P-100 Inspection and test, P-120 Inspection and Test Status

## 8.7 Control of nonconforming outputs

**8.7.1** The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.
The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.
The organization shall deal with nonconforming outputs in one or more of the following ways:
a) correction;
b) segregation, containment, return or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under concession.
Conformity to the requirements shall be verified when nonconforming outputs are corrected.

**Our Interpretation:** Products that do not meet specification should never be sent to a customer unless the customer has given sufficient written authorization to ship that product to them. Any product that does not conform must be made good (changed to make conforming) or scrapped.

**Process(es):** Nonconformity and Corrective Action,

**Supporting Evidence:** Inspection reports, Nonconforming Reports, Scrap tags

**8.7.2** The organization shall retain documented information that:
a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action in respect of the nonconformity.

**Our Interpretation:** When nonconformities happen, detailed information regarding what happened, what action was taken, what concessions were granted and from whom, and who authorized the ultimate action must be documented in the QMS.

**Process(es):** Nonconformity and Corrective Action

**Supporting Evidence:** Corrective Action Reports

# 9 Performance evaluation

## 9.1 Monitoring, measurement, analysis and evaluation

### 9.1.1 General

The organization shall determine:
a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
c) when the monitoring and measuring shall be performed;
d) when the results from monitoring and measurement shall be analyzed and evaluated.
The organization shall evaluate the performance and the effectiveness of the quality management system.
The organization shall retain appropriate documented information as evidence of the results.

**Our Interpretation:** We must determine what things need to be monitored and/or measured in order to understand how effective the QMS is in meeting customer, HFI, applicable legal and ISO requirements. Documented information about this activity must be retained.

**Process(es):** Internal Audit, Monitoring, measurement, analysis and evaluation

**Supporting Evidence:** Retained information, e.g. Quality Objectives, regarding the above processes, P-010 Management review, P-011 PQMC, P-020 Quality planning and evaluation

### 9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

**Our Interpretation:** We must understand how customers view our products and services.

**Process(es):** Customer

**Supporting Evidence:** Notes from conversations with customers, report cards from customers, reports from outside sales people, P-030 Contract Review

### 9.1.3 Analysis and evaluation

The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement.
The results of analysis shall be used to evaluate:
a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.

NOTE Methods to analyze data can include statistical techniques.

**Our Interpretation:** In addition to gathering information, HFI must have a basis for determining if the measurement indicates expected results relative to whether our products conform to customers' requirements, the level of satisfaction with our customers overall, the performance of our QMS and whether it needs to be changed to make it better for us, how well we are addressing risk and handling opportunities,

**Process(es):** Monitoring and Measuring Resources

**Supporting Evidence:** Leadership and Commitment, P-011 PQMC

## 9.2 Internal audit

**9.2.1** The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:
a) conforms to:
    1) the organization's own requirements for its quality management system;
    2) the requirements of this International Standard;
b) is effectively implemented and maintained.

**Our Interpretation:** An internal audit must be conducted that checks to understand if the QMS meets the requirements of ISO and of HFI's QMS, and that both are implemented effectively.

**Process(es**): Internal audit

**Supporting Evidence:** Audit working documents or other audit outputs, P-170 Internal Quality Audits

**9.2.2** The organization shall:
a) plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) define the audit criteria and scope for each audit;
c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
d) ensure that the results of the audits are reported to relevant management;
e) take appropriate correction and corrective actions without undue delay;
f) retain documented information as evidence of the implementation of the audit program and the audit results.

NOTE See ISO 19011 for guidance.

**Our Interpretation:** The audit program has to identify how the audit will be handled in terms of direction and control, when and how often it will be conducted, and ensure that auditors are sufficiently trained in 9001 and ISO 19011.

**Process(es):** Internal audit

**Supporting Evidence:** Audit working documents and/or other audit outputs

## 9.3 Management review

### 9.3.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

**Our Interpretation:** All agenda items for the review, as outlined in 9.3.1 above and both 9.3.2 and 9.3.3 below must be included in a MRC at least one time per year. There must be at least one Management Review Committee Meeting, however, we can change both the number of meetings and the agenda items as dictated by business levels and other issues.

**Process(es):** Leadership and Commitment

**Supporting Evidence:** MRC agenda, MRC minutes, P-010 Management Review

### 9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:
a) the status of actions from previous management reviews;
b) changes in external and internal issues that are relevant to the quality management system;
c) information on the performance and effectiveness of the quality management system, including trends in:
    1) customer satisfaction and feedback from relevant interested parties;
    2) the extent to which quality objectives have been met;
    3) process performance and conformity of products and services;
    4) nonconformities and corrective actions;
    5) monitoring and measurement results;
    6) audit results;
    7) the performance of external providers;
d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
f) opportunities for improvement.

**Our Interpretation:** Management Review Meetings will cover—at a minimum—the subjects listed in this clause over the course of a year.

**Process(es):** Leadership and Commitment

**Supporting Evidence:** MRC agenda and minutes

### 9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;
b) any need for changes to the quality management system;
c) resource needs.
The organization shall retain documented information as evidence of the results of management reviews.

**Our Interpretation:** MRC meetings will produce—at a minimum—output regarding the subjects listed in this clause.

**Process(es):** Leadership and Commitment

**Supporting Evidence:** MRC agenda and minutes

# 10 Improvement

## 10.1 General

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.
These shall include:
a) improving products and services to meet requirements as well as to address future needs and expectations;
b) correcting, preventing or reducing undesired effects;
c) improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

**Our Interpretation:** Products and services may be improved by HFI if identified by either HFI or a customer, or other. Methods of producing products and tools—including systemic concepts—may also be improved by us to make our QMS more effective.

**Process(es):** All processes are considered in this endeavor.

**Supporting Evidence:** Corrective actions, internal audits, customer input, performance data

## 10.2 Nonconformity and corrective action

**10.2.1** When a nonconformity occurs, including any arising from complaints, the organization shall:
a) react to the nonconformity and, as applicable:
    1) take action to control and correct it;
    2) deal with the consequences;
b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
    1) reviewing and analyzing the nonconformity;
    2) determining the causes of the nonconformity;
    3) determining if similar nonconformities exist, or could potentially occur;
c) implement any action needed;
d) review the effectiveness of any corrective action taken;
e) update risks and opportunities determined during planning, if necessary;
f) make changes to the quality management system, if necessary.
Corrective actions shall be appropriate to the effects of the nonconformities encountered.

**Our Interpretation:** When an issue is discovered by HFI personnel or comes to us from the outside, the issue is analyzed to determine its severity and risk. Correction to low risk issues may be handled via the Corrective action process; high risk issues must use the Nonconforming and Corrective Action procedure.

**Process(es):** Nonconformity and Corrective Action

**Supporting Evidence:** Nonconformity and Corrective Action, emails, P-140 Corrective and preventive action, P-130 Control of Non-Conforming Product

**10.2.2** The organization shall retain documented information as evidence of:
a) the nature of the nonconformities and any subsequent actions taken;
b) the results of any corrective action.

**Our Interpretation:** The source and results of corrective actions will be retained.

**Process(es):** Nonconformity and Corrective Action

**Supporting Evidence:** Nonconformity and corrective actions.

## 10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.
The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

**Our Interpretation:** The backbone of ISO is continual improvement, and HFI continually analyzes results of operations, customer input and other sources of ideas to make our QMS better and more effective. Suggestions for improvements are discussed at MRC and other meetings.

**Process(es):** All

**Supporting Evidence:** MRC minutes, customer complaints, employee suggestions, P-010 Management review,

P-011 PQMC, P-020 Quality planning and evaluation, P-140 Corrective and Preventive Action