Harmony Castings LLC	Quality Manual Section:	Page 1 of 29
	Issue Date: 10/10/12	
Aluminum V-Process Castings	Revision Date: 2/14/17	Revision 02
Approval Signature: Andy Renkey, President		
Mark Fallen, Plant Manager	Approval Date:	
Gary Dindinger, Quality Manager		
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- **1.0. Scope**. **Harmony Castings LLC's** quality management system in the manufacture of and supply of aluminum V-Process castings. **Harmony Castings LLC**'s quality system is based on AS9100 Rev D.
  - 1.1 This standard includes ISO 9001:2015 quality management system requirements and specifies additional aviation, space, and defense industry requirements, definitions, and notes.
  - 1.2 It is emphasized that the requirements specified in this standard are complementary (not alternative) to customer and applicable statutory regulatory requirements.
  - 1.3 If there is a conflict between the requirements of this standard and customer or applicable statutory or regulatory requirements then the latter shall take precedence.
  - 1.4 Harmony Castings LLC excludes AS9100 Rev D section 8.3 Design and Development of Products and Services from its quality management system. Harmony Castings LLC is a job shop, which produces castings to order per customer-supplied designs, drawings and specifications. Harmony Castings LLC does not perform any design and development activities or services. Harmony Castings LLC assumes no responsibility for the design of parts produced for customers.

#### 2.0 Normative References

2.1 ISO 9001:2015 Quality management systems Requirements.

## 3.0 Terms and Definitions

- 3.1 Counterfeit Part
  - 3.1.1 An unauthorized copy, imitation, substitute, or modified (e.g., material, part, component), which is knowingly misrepresented as a specific genuine part of an original or authorized manufacturer.
    - 3.1.1.1 Examples of a counterfeit part can include, but not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

#### 3.2 Critical Items.

3.2.1 Those items(e.g., functions, parts, software, characteristics, processes) having significant effect on the provision and the use of the products and services; including safety, performance, form, fit function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed.

NOTE: Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

# 3.3 Key Characteristics

3.3.1 An attribute or feature whose variation has a significant effect on product fit, function, form, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

Harmony Castings LLC	Quality Manual Section:	Page 2 of 29
	Issue Date: 10/10/12	
Aluminum V-Process Castings	Revision Date: 2/14/17	Revision 02
Approval Signature: Andy Renkey, President		
Mark Fallen, Plant Manager	Approval Date:	
Gary Dindinger, Quality Manager		
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# 3.4 Product safety

3.4.1 The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

# 3.5 Special Requirements

- 3.5.1 Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, pat experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.
  - 3.5.1.1 Special requirements (3.5) and critical times (3.2), along with key characteristics (3.3) are interrelated. Special requirements are identified when determining and reviewing requirements related to the product (see 8.2.2 and 8.2.3). Special requirements can require the identification of critical items. Design output (see 8.3.5) can include identification of critical items that require specific actions to ensure they are adequately managed. Some critical items will be further classified as key characteristics because their variation needs to controlled.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 3 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

## **Quality Policy Statement**

# **QUALITY POLICY**

It is the policy of Harmony Castings LLC to provide products conforming in all respects to the functional quality requirements specified by our customers, to include all applicable specifications, procedures, standards, and codes. Conformance to this standard of quality must be built into each casting in order to achieve optimum cost and insure scheduling integrity.

Aiding in the achievement of company objectives, **Harmony Castings LLC**, established and maintains a comprehensive Quality Management System based on AS9100 Rev. D while acknowledging customers' specific requirements. Harmony Castings LLC realizes and emphasizes the importance of continual process improvement of our Quality Management System.

The Quality Management System shall;

Establish procedures that standardize processes and minimize variation; Engineer solutions that eliminate the potential for defects Drive employee accountability for process and product produced.

The established program for the assurance of quality at Harmony Castings LLC has been recorded in the company Quality Assurance Manual. No deviation from the scope of this manual is permitted.

Quality will be the cornerstone of our reputation, our productivity, and our continued growth in a highly competitive marketplace.

Andy Renkey	
General Manager	

Harmony Castings LLC.	Quality Manual Section:	Page 4 of 29
Aluminum V-Process Castings	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

#### 4.0 QUALITY MANAGEMENT SYSTEM

# **4.1 Understanding the Organization and its Context**

**Harmony Castings LLC** 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 result(s) of it quality management system.

**Harmony Castings LLC** has established, documented, implemented, maintained a quality management system and continually improves its effectiveness including the process needed and their interactions, in accordance with the requirements of AS9100 Rev D.

**Harmony Casting LLC's** quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

# **Harmony Castings LLC:**

- a) Determined the processes needed for the quality management system and their application throughout the organization,
- b) Determined the sequence and interaction of these processes,
- c) Determined criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) Understands issues can be positive or negative factors or conditions for consideration.
- e) Understands 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.
- f) Understands the internal context can be facilitated by considering issues related to values, culture, knowledge, and performance of the organization.

# 4.2 Understanding the Needs and Expectations of Interested Parties.

Due to their effect or potential effect on the organizations ability to consistently provide products and services that meet the customer and applicable statutory and regulatory requirements **Harmony Castings LLC** shall;

- a) Determine the interested parties that are relevant to the quality management system;
- b) Determine the requirements of these interested parties that are relevant to the quality management system.

**Harmony Castings LLC** shall monitor and review information about these interested parties and their relevant requirements.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 5 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

## 4.3 Determining the Scope of the Quality Management System

**Harmony Castings LLC** shall determine the boundaries and applicability of the quality management system to establish its scope.

While determining this scope, Harmony Castings LLC shall:

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

**Harmony Castings LLC** shall apply all the requirements of AS9100 Rev D if they are applicable within the determined scope of the quality management system.

The scope of **Harmony Castings LLC** quality management system shall be available and documentation shall include:

- a) Documented statements of a quality policy and quality objectives,
- b) A quality manual,
- c) Documented procedures and records required by AS9100 Rev D,
- d) Documents, including records, determined by **Harmony Castings LLC** to be necessary to ensure the effective planning, operation and control of its processes
- e) The types of products and services covered and provide justification for any requirement of the AS9100 Rev D that we determine is not applicable to the scope of the quality management system.
- f) The documentation may be in any form or type of medium.

**Harmony Castings LLC** shall ensure that personnel have access to, and are aware of, relevant quality management system documentation and changes.

Conformity to the AS9100 Rev D standard may only be claimed if the requirements determined as not being applicable do not affect **Harmony Castings LLC's** ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

#### 4.4 Quality Management System and its Processes

**4.4.1 Harmony Castings LLC** has established and maintains a quality management system that shall address customer and applicable statutory and regulatory quality management system requirements.

Harmony Castings LLC shall determine the processes needed for the quality management system and the applications throughout the organization and shall;

- a) Determine the inputs and outputs expected from these processes;
- b) Determine the sequences and the interactions of these processes;
- Determine and apply the criteria and methods (including monitoring, measurements and related performances 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 responsibility and authorities for these processes;

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 6 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

- f) Address the risk and opportunities as determined in accordance with the requirements of 6.1;
- g) Evaluate these processes and implement any changes needed to ensure these processes achieve their intended results;
- h) Improve the processes and the quality management system;

# **4.4.2** To the extent necessary **Harmony Castings LLC** shall:

- a) Maintain documented information to support the operation of its processes;
- b) Retain documented information to have confidence that the processes are being carried out as planned;

## Harmony Castings LLC shall maintain a Quality Manual that;

- a) Includes a general description of relevant interested Parties (4.2.a);
- b) The scope of the quality management system, including boundaries and applicability (see 4.3)
- c) A description of the process needed for the quality management system and their application throughout the organization
- d) The sequences and interaction of these processes
- e) Assignment of responsibility for these processes.

## **5.0 LEADERSHIP**

#### 5.1 Leadership and commitment

- **5.1.1** Top management of Harmony Castings LLC 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 the 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 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 person 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.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 7 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

- **5.1.2** Top management of Harmony Castings LLC 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;
  - d) Product and service conformity and on-time delivery performance are measured and appropriate action taken if planned results are not, or will not be, achieved.
- **5.2** Top management of Harmony Castings LLC 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 commitment to satisfy applicable requirements;
  - d) Includes a commitment to continual improvement of the quality management system;
  - e) Be available and maintained as documented information;
  - f) Be communicated, understood, and applied within the organization;
  - g) Be available to relevant interested parties, as appropriate
- 5.3 Top Management of Harmony Castings LLC shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization.
- **5.3.1 Harmony Castings LLC** shall assign the responsibility and authority for;
  - a) Ensuring that the quality management system conforms to the requirements of the AS9100 Rev D 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 (see10.1) 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;
- 5.3.2 Top management of Harmony Castings LLC shall appoint a specific member of the organization's management, identified as the management representative, who shall have the responsibility and authority for oversight of the above requirements.
- 5.3.3 The management representative shall have the organizational freedom and unrestricted access to top management to resolve quality management issues.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 8 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

#### **6.0 PLANNING**

# 6.1 Actions to Address Risks and Opportunities

- **6.1.1** When planning for the quality management system, Harmony Castings LLC 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.
- **6.1.2 Harmony Castings LLC** shall plan actions to address these risks and opportunities and how to;
  - a) Integrate and implement the actions into its quality management system processes (see 4.4)
  - b) 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.

## 6.2 Quality Objectives and Planning to Achieve Them

- **6.2.1 Harmony Castings LLC** 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.
  - h) Maintain documented information on the quality objectives.

# 6.3 Planning of Changes

- **6.3.1** When **Harmony Castings LLC** determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4). The following considerations will be addressed;
  - 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.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 9 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

# 7.0 SUPPORT

#### 7.1 Resources

- **7.1.1 General Harmony Castings LLC** shall determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system. Along with the consideration of:
  - a) The capabilities of, and constraints on, existing internal resources;
  - b) What needs to be obtained from external providers?

## 7.1.2 People

**7.1.2.1 Harmony Castings LLC** 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.

#### 7.1.3 Infrastructure

**7.1.3.1 Harmony Castings LLC** shall determine, provide, and maintain the infrastructure necessary for its operation of its processes and to achieve conformity of products and services. This can include buildings and associated utilities, equipment, including hardware and software, transportation resources, & information and communication technology.

# 7.1.4 Environment for Operations of Processes

- **7.1.4.1 Harmony Castings LLC** shall determine, provide, and maintain the environment necessary for the operation of its processes and to achieve the conformity of products and services. This 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, emotional protective);
  - c) Physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise).

#### 7.1.5 Monitoring and Measuring Resources

## 7.1.5.1 General

**Harmony Castings LLC** 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. We 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.
- c) Retain appropriate documented information as evidence of fitness for purpose of monitoring and measurement resources.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 10 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

## 7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or considered by **Harmony Castings LLC** 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 specific 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.
- d) Establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.
- e) Maintain a register of the monitoring and measuring equipment which shall include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.
- f) Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions (see 7.1.4).
  - Monitoring and measuring equipment can include, but not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product or service conformity.

**Harmony Castings LLC** 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.

## 7.1.6 Organization Knowledge

- **7.1.6.1 Harmony Castings LLC** 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.
- 7.1.6.2 When addressing changing needs and trends, Harmony Castings LLC shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.
- 7.1.6.3 Organizational knowledge is knowledge specific to Harmony Castings LLC; it is generally gained by experience. It is information that is used and shared to achieve our objectives. This 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).

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 11 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

## 7.2 Competence

# 7.2.1 Harmony Castings LLC 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;
- 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 with consideration given to periodic review of competency.
- e) Applicable actions can include, for example, the provision of training to, the mentoring of, or in the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

#### 7.3 Awareness

# **7.3.1 Harmony Castings LLC** shall ensure that persons doing the work under our 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;
- e) Relevant quality management system documentation information and changes thereto;
- f) Their contribution to product or service conformity;
- g) Their contribution to product safety;
- h) The importance of ethical behavior.

## 7.4 Communication

# **7.4.1 Harmony Castings LLC** shall determine the internal and external communications relevant to the quality management system, including:

- a) On what to communicate:
- b) When to communicate;
- c) With whom to communicate;
- d) How to communicate;
- e) Who communicates;
- f) Communication shall include internal and external feedback relevant to the quality management system;

#### 7.5 Documented Information

## 7.5.1 General

#### **7.5.1.1 Harmony Castings LLC's** quality management system shall include:

a) Documented information by the AS9100 Rev D standard;

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 12 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

- b) Documented information determined to by harmony as being necessary for the effectiveness of the quality management system.
- c) The extent of the documented information for a quality management system can differ from other such organizations depending on size, type of activities, processes, products, and services.

# 7.5.2 Creating and Updating

- **7.5.2.1** When creating or updating documented information **Harmony Castings LLC** 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 of suitability and adequacy, (Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by this company.

#### 7.5.3 Control of Documented Information

- **7.5.3.1** Documented information required by the quality management system and by the AS9100 Rev D 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.
- 7.5.3.2 For the control of documented information, **Harmony Castings LLC** 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:
  - e) The prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.
  - f) When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized change, unintended alteration, corruption, physical damage).

Documented information of external origin determined by Harmony Castings LLC to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 13 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

#### 8. OPERATION

# 8.1 Operational Planning and Control

**Harmony Castings LLC** 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;

Determination of requirements for the products and services should include consideration of:

- a) Personal and product safety;
- b) Producibility and inspectability;
- c) Reliability, availability, and maintainability;
- d) Suitability of parts and materials used in the product;
- e) Selection and development of embedded software;
- f) Product obsolescence;
- g) Prevention, detection, and removal of foreign objects;
- h) Handling, packaging, and prevention;
- i) Recycling or final disposal of the product at the end of its life;

# Establishing criteria for:

- a) The processes;
- b) The acceptance of products and services;

According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:

- 1) Design verification (e.g., reliability, maintainability, product safety);
- 2) Process control such as:

Selection and verification of key characteristics

Process capability measurements:

Statistical process control;

Design experiments;

- Determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of product and services;
- 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;
- f) Determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;
- g) Engaging representatives of affected organization functions for operational planning and control
- h) Determining the process and resources to support the use and maintenance of the product and services;
- i) Determining the products and services to be obtained from external providers;
- j) Establishing the controls needed to prevent the delivery of nonconforming product and services to the customer:

<b>Harmony Castings LLC.</b>	Quality Manual Section:	Page 14 of 29
Aluminum V-Process Castings	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

As appropriate to the organization, customer requirements, and products and services, **Harmony Castings LLC** shall plan and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints. (May be referred to as Project Management, project planning or program management).

The output of this planning shall be suitable for Harmony Castings' operations. As an output of this planning, documented information specifying the processes of the quality management system and the resources to be applied to a specific product, service project, or contract can be referred to a quality plan.

**Harmony Castings LLC** shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

**Harmony Castings LLC** shall ensure that outsourced processed are controlled (see 8.4).

**Harmony Castings LLC** shall establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process shall ensure that work transfer impacts and risks are managed.

a) For the control of work transfer from the Harmony Castings LLC to an external provider, or from an external provider to another external provider, see 8.4. For the control of work transfer from one organization facility to another or from an external provider to Harmony Castings LLC, see 8.5

# 8.1.1 Operational Risk Management

**Harmony Castings LLC** shall plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to Harmony Castings and the product and services:

- a) Assignment of responsibilities for operational risk management;
- b) Definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);
- c) Identification, assessment, and communication of risks throughout operations
- d) Identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;
- e) Acceptance of risks remaining after implementation of mitigating actions.

# 8.1.2 Configuration Management

**Harmony Castings LLC** shall plan, implement and control a process for configuration management as appropriate to the our organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the products lifecycle. This process shall:

- a) Control product identity and traceability to requirements, including the implementation of identified changes;
- b) Ensure that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 15 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

## 8.1.3 Product Safety

**Harmony Castings LLC** shall plan, implement and control the processes needed to assure product safety during the entire product life cycle as appropriate to the organization and the product.

Examples of these include:

- a) Assessment of hazards and management of associated risks (see 8.1.1);
- b) Management of safety critical items;
- c) Analysis and reporting of occurred events affecting safety;
- d) Communication of these events and training of persons.

#### 8.1.4 Prevention of Counterfeit Parts

**Harmony Castings LLC** shall plan, implement and control processes, appropriate to the organization and the product for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

Counterfeit part prevention processes should consider:

- a) Training of appropriate persons in the awareness and prevention of counterfeit parts;
- b) Application of a part obsolescence monitoring program
- c) Controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;
- d) Requirements for assuring traceability of parts and components to their original authorized manufacturers
- e) Verification and test methodologies to detect counterfeit parts;
- f) Monitoring of counterfeit parts reporting from external sources
- g) Quarantine and reporting of suspect or detected counterfeit parts.

## 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.

## 8.2.2 Determining the Requirements for Products and Services

When determining the requirements for the products and services to be offered to customers, **Harmony Castings LLC** shall ensure that:

- a) The requirements for the product and services are defined, including:
  - 1) Any applicable statutory and regulatory requirements
  - 2) Those considered necessary by the organization:

Harmony Castings LLC.	Quality Manual Section:	Page 16 of 29
Aluminum V-Process Castings	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

- b) Harmony Castings can meet the claims for the products and services it offers;
- c) Special requirements of products and services are determined;
- d) Operational risks (e.g., new technology, ability and capability to provide, short delivery time frame) have been identified.

# 8.2.3 Review of Requirements of Products and Services

- **8.2.3.1 Harmony Castings LLC** 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 the 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 Review shall be coordinated with the applicable functions of our organization. If upon review **Harmony Castings LLC** determines that some customer requirements cannot be met or can only be partially met, Harmony Castings shall negotiate a mutually acceptable requirement with our customer.

**Harmony Castings LLC** shall ensure that contract or order requirements differing from those previously defined are resolved. The customer requirements shall be confirmed by Harmony Castings before acceptance, when the customer does not provide a documented statement of their requirements. 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.

## 8.2.3.2 Harmony Castings LLC shall retain documented information as applicable:

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

# 8.2.4 Changes to Requirements for Products and Services

**Harmony Castings LLC** 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.

# 8.3 Design and Development of Products and services (Exclusion)

## 8.4 Control of Externally Provided Processes, Products, and Services

#### 8.4.1 General

**Harmony Castings LLC** shall ensure that externally provided processes, products, and services conform to requirement.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 17 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

**Harmony Castings LLC** shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

**Harmony Castings LLC** shall ensure when required, that customer-designated or approved external providers, including process sources (e.g., special processes) are used.

**Harmony Castings LLC** shall identify and manage the risks associated with the external provision of the processes, products, and services, as well as the selection and use of external providers.

**Harmony Castings LLC** shall require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

**Harmony Castings LLC** 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 our own products and services;
- b) Products and services are provided directly to the customer(s) by external providers on behalf of the Harmony Castings LLC;
- c) A process, or part of a process, is provided by an external provider as a result of a decision by harmony Castings LLC.

Harmony Castings LLC shall determine and apply criteria for the evaluation, selection, monitoring of performances and reevaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Harmony Castings LLC shall retain documented information of these activities and any necessary actions arising from the evaluation.

# 8.4.1.1 Harmony Castings LLC shall;

- Define process, responsibility, and authority for the approval status decision, changes to the approval status, and condition for a controlled use of external providers depending on their approval status
- b) Maintain a register of external providers that includes approval status, (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family):
- c) Periodically review external provider performance including process, product and service conformity, and on-time delivery performance;
- d) Define the necessary actions to take when dealing with external providers that do not meet requirements;
- e) Define the requirements for controlling documented information created by and /or retained by external providers.

## 8.4.2 Type and Extent of Control

**Harmony Castings LLC** shall ensure that externally provided processes, products, and services do not adversely affect our ability to consistently deliver conforming products and services to our customers. We shall:

 Ensure that externally provided processes remain within the control of its quality management system;

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 18 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

- b) Define both the controls that it intends to apply to an external provider and those we intend to apply to the resulting output.
- c) Take into consideration:
  - The potential impact of the externally provided processes, products, and services on our ability to consistently meet customer and applicable statutory and regulatory requirements;
  - 2) The effectiveness of the controls applied by the external provider;
  - 3) The results of periodic review of external provider performance (see 8.4.1.1c)
- d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements;

Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by Harmony castings LLC. These shall include inspection or periodic testing, as applicable, when there is a high risk of nonconformities including counterfeit parts.

When externally provided product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements

When **Harmony Castings LLC** delegates verification activities to the external provider, the scope and the requirements for delegation shall be defined and a register of delegations shall be maintained. We shall periodically monitor the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, **Harmony Castings LLC** shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), we shall implement a process to validate the accuracy of test reports.

## 8.4.3 Information for External Providers

**Harmony Castings LLC** shall ensure the adequacy of requirements prior to their communication to the external provider. We shall do so by communicating to external providers its requirements for:

- The process, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);
- 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' interaction with the organization;
- e) Control and monitoring of the external providers' performance to be applied by the **Harmony Castings LLC**;
- f) Verification or validation activities that Harmony Castings LLC or its customer, intends to perform at the external providers' premises;

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 19 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

- g) Design and development control;
- h) Special requirements, critical items, or key characteristics;
- i) Test, inspection, and verification (including production process verification);
- j) The use of statistical techniques for product acceptance and related instructions for acceptance by **Harmony Castings LLC**.

# k) The need to:

- 1) Implement a quality management system
- 2) Use customer-designated or approved external providers, including process sources (e.g., special processes);
- 3) Notify **Harmony Castings LLC** of nonconforming processes, products, and services and obtain approval for their disposition;
- 4) Prevent the use of counterfeit parts (see 8.1.4);
- Notify Harmony Castings LLC of changes to processes, products, or services, including changes to their external providers or location of manufacture, and obtain Harmony's approval;
- 6) Flow down to external providers applicable requirements including customer requirements;
- Provide test specimens for design approval, inspection/verification, investigation, or auditing:
- 8) Retain documented information, including retention periods and disposition requirements;
- The right to access by harmony Castings LLC, our customer, and regulatory authorities to applicable areas of the facilities and to applicable documented information, at any level of the supply chain;
- m) Ensuring that persons are aware of:
  - 1) Their contribution to product or service conformity;
  - 2) Their contribution to product safety;
  - 3) The importance of ethical behavior.

## 8.5 Production and Service Provision

#### 8.5.1 Control of Production and Service Provision

**Harmony Castings LLC** 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 product to be produced, the services to be provided, or the activities to be performed;
  - 2) The results to be achieved, (e.g., digit definition data, drawings, parts lists, materials, process specifications, process flow charts, control plans, production documents and verification documents).
- b) The availability and use of suitable monitoring and measuring resources;
- The implementation of monitoring and measuring activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
  - 1) Ensuring the documented information for monitoring and measurement activity for product acceptance includes:
    - Criteria for acceptance and rejection;

Harmony Castings LLC.	Quality Manual Section:	Page 20 of 29
Aluminum V-Process Castings	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

- Where in the sequence verification operations are to be performed;
- Measurement results to be retained (at a minimum an indication of acceptance or rejection)
- Any specific monitoring or measurement equipment required and instructions associated with their use:
- 2) Ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (e.g., matching the sampling plan to the criticality of the product and to the process capability).
- d) The use of suitable infrastructure and environment for the operation of processes; (infrastructure can include product specific tools such as jigs, fixtures, molds and software programs.)
- 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; (These can be referred to as special processes, see 8.5.1.2)
- g) The implementation of actions to prevent human error;
- h) The implementation of releases, delivery, and post-delivery activities;
- i) The establishment of criteria for workmanship (e.g., written standards, representative sample, illustrations);
- j) The accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
- k) The control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
- The determination of methods to measure variable data(e.g., tooling, on-machine probing, inspection equipment);
- m) The identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
- n) The availability of evidence that all production and inspection/verification operations have been completed as planned or as otherwise documented and authorized;
- o) The provision for the prevention, detection, and removal of foreign objects:
- p) The control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirement (see 7.1.3)
- q) The identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later to be found that the product does not meet requirements.

# 8.5.1.1 Control of Equipment, Tools, and Software Programs

Equipment tools, and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release of production and shall be maintained.

Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 21 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

## 8.5.1.2 Validation and Control of Special Processes

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, **Harmony Castings LLC** shall establish arrangements for these processes including, as applicable;

- a) Definition of criteria for the review and approval of the processes;
- b) Determination of conditions to maintain the approval;
- c) Approval of facilities and equipment;
- d) Qualification of persons:
- e) Use of specific methods and procedures for implementation and monitoring the processes;
- f) Requirements for documented information to be retained.

#### 8.5.1.3 Product Process Verification

**Harmony Castings LLC** shall implement production process verification activities to ensure the production process is able to produce products that meet requirements. These activities can include risk assessments, capacity studies, and control plans.

**Harmony Castings LLC** shall use a representative item from the first production of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements. This activity shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes. This can be referred to as a FAI).

**Harmony Castings LLC** shall retain documented information on the results of production process verification.

## 8.5.2 Identification and Traceability

**Harmony Castings LLC** shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

**Harmony Castings LLC** shall maintain the identification and the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

**Harmony Castings LLC** shall identify the status of outputs with respect to monitoring and measurement requirements throughout the production and service provision.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), **Harmony Castings LLC** shall establish controls for the media.

Harmony Castings LLC shall control the unique identification of outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability. (This can include the identification to be maintained throughout the product life, the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 22 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

batch, to the destination, for assembly, the ability to trace its components to assembly and then to the next higher assembly, for a product, sequential record of production to be retrievable.)

## 8.5.3 Property Belonging to Customers or External Providers.

**Harmony Castings LLC** shall exercise care with the property belonging to customers or external providers while it is under our control or being used by the organization.

**Harmony Castings LLC** shall identify, verify, protect and safeguard customers or external provider's property 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, we shall report this to the customer or external provider and retain documented information on what has occurred. This may include such things as materials, components, tools and equipment, premises, intellectual property, and personal data.

#### 8.5.4 Preservation

**Harmony Castings LLC** shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. Preservation can include things such as identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation of outputs shall also include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for;

- a) Cleaning;
- b) Prevention, detection, and removal of foreign objects;
- c) Special handling and storage of sensitive products;
- d) Marking and labeling, including safety warnings and cautions;
- e) Shelf life control and stock rotation;
- f) Special handling and storage for hazardous materials.

#### 8.5.5 Post-Delivery Activities

**Harmony Castings LLC** 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;
- f) Collection and analysis of in-service data (e.g., performance, reliability, lessons learned):
- g) Control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 23 of 29
	Issue Date: 10/10/12	
	Revision Date: 2/14/17	Revision 02
Approval Signature on page 1	Approval Date: 2/14/17	
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.	

- h) Controls required for work undertaken external to the organization 9e.g., off-site work);
- i) Product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence);

While problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.

## 8.5.6 Control of Changes

**Harmony Castings LLC** shall review and control changes for production or services provision, to the extent necessary to ensure continuing conformity with requirements. Persons authorized to approve production or service changes shall be identified. Production and service changes can include the changes affecting processes, production, equipment, tools, or software programs.

**Harmony Castings LLC** 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.

#### 8.6 Release of Products and Services

**Harmony Castings LLC** 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.

**Harmony Castings LLC** 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.

When required to demonstrate product qualification, **Harmony Castings LLC** shall ensure that the retained documented information provides evidence that the products and services meet the defined requirements.

**Harmony Castings LLC** shall ensure that all documented information required to accompany the product and services are present at delivery.

## 8.7 Control of Nonconforming Outputs

**8.7.1 Harmony Castings LLC** shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 24 of 29			
	Issue Date: 10/10/12				
	Revision Date: 2/14/17	Revision 02			
Approval Signature on page 1	Approval Date: 2/14/17				
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.				

**Harmony Castings LLC** 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.

**Harmony Castings LLC's** nonconformity control process shall be maintained as documented information including the provision for;

- Defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions:
- Taking actions necessary to contain the effect of nonconformity on other processes, products, or services;
- c) Timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
- d) Defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2)
- e) Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.

Harmony Castings LLC 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 by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance on nonconforming products shall only be implemented;

- a) After approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;
- b) After authorization by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.

Conformity to the requirements shall be verified when nonconforming outputs are correct.

#### 8.7.2 Harmony Castings LLC shall retain documented information that;

- a) Describes the nonconformity;
- b) Describes the actions taken;
- c) Describes the concessions obtained:
- d) Identifies the authority deciding the action in respect of the nonconformity.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 25 of 29			
	Issue Date: 10/10/12				
	Revision Date: 2/14/17	Revision 02			
Approval Signature on page 1	Approval Date: 2/14/17				
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.				

#### 9. PERFORMANCE EVALUATION

# 9.1 Monitoring, Measurement, Analysis, and Evaluation

#### 9.1.1 General

Harmony Castings LLC shall determine;

- a) What needs to be monitored and measured;
- b) The methods for monitoring, measuring, 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:

**Harmony Castings LLC** shall evaluate the performance and the effectiveness of the quality management system and retain appropriate documented information as evidence of the results.

#### 9.1.2 Customer Satisfaction

**Harmony Castings LLC** shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled as well as the methods for obtaining, monitoring, and reviewing this information.

Examples of monitoring customer perceptions can but not limited to include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims, and dealer reports.

Information to be monitored and used for the evaluation of customer satisfaction shall include, but not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective actions requests. **Harmony Castings LLC** shall develop and implement plans for customer satisfaction improvements that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

# 9.1.3 Analysis and Evaluation

**Harmony Castings LLC** shall analyze and evaluate appropriate data and information arising from monitoring and measurement. (This can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisors).

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 managements 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; (Methods to analyze data can include statistical techniques).

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 26 of 29			
	Issue Date: 10/10/12				
	Revision Date: 2/14/17	Revision 02			
Approval Signature on page 1	Approval Date: 2/14/17				
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.				

#### 9.2 Internal Audit

- **9.2.1 Harmony Castings LLC** shall conduct internal audits at planned intervals to provide information on whether the quality management system;
  - a) Conforms to:
    - 1) **Harmony Castings LLC** own requirements for its quality management system which should include customer and applicable statutory and regulatory quality management system requirements.
    - 2) The requirements of AS9100 Rev D;
  - b) Is effectively implemented and maintained.
  - c) Audits will take into consideration performance indicators to determine if the quality management system is effectively implemented and maintained.

## 9.2.2 Harmony Castings LLC 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 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 implementation of the audit program and the audit results

#### 9.3 Management Review

#### 9.3.1 General

Top management of **Harmony Castings LLC** shall review our quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization.

#### 9.3.2 Management Review Inputs

The management review shall be planned and carried out taking into consideration;

- The status of actions from previous management reviews;
- b) Changes in external and internal issues that are relevant to the quality management system;
- 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:
  - The performance of external providers;
  - 8) On-Time delivery performance:
- d) The adequacy of resources
- e) The effectiveness of actions taken to address risks and opportunities (see 6.1);
- f) Opportunities for improvement.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 27 of 29			
	Issue Date: 10/10/12				
	Revision Date: 2/14/17	Revision 02			
Approval Signature on page 1	Approval Date: 2/14/17				
A controlled copy will be stored in Harmony Castings' computer network.	All printed copies of the manual are considered uncontrolled.				

#### 9.3.3 Management Review Outputs

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

- a) Opportunities for improvement;
- b) Any need for changes to the quality management system;
- c) Resources needs;
- d) Risks identified.

**Harmony Castings LLC** shall retain documented information as evidence of the results of the management reviews.

#### 10. IMPROVEMENT

#### 10.1 General

**Harmony Castings LLC** 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:
  - 1) Improvements can include correction, corrective action, continual improvement, breakthrough change, innovation, and re-organization.

## 10.2 Nonconformity and Corrective Action

**10.2.1** When a nonconformity occurs, including any arising from complaints, **Harmony Castings LLC** shall:

- a) React to the nonconformity and as acceptable:
  - 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;
  - Determining the causes of the nonconformity, including, as applicable, those related to human factors;
  - 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 the planning, if necessary;
- f) Make changes to the quality management system, if necessary:
- g) Flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity.
- h) Take specific actions when timely and effective corrective actions are not achieved.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 28 of 29			
	Issue Date: 10/10/12				
	Revision Date: 2/14/17	Revision 02			
Approval Signature on page 1	Approval Date: 2/14/17				
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**Harmony Castings LLC** shall maintain documented information that defines the nonconformity and corrective action management processes.

- 10.2.2 Harmony Castings LLC shall retain documented information as evidence of;
  - a) The nature of the nonconformities and any subsequent actions taken;
  - b) The results of the corrective action;

# **10.3 Continual Improvement**

**Harmony Castings LLC** shall continually improve the suitability, adequacy, and effectiveness of the quality management system.

**Harmony Castings LLC** shall consider the results of the 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.

**Harmony Castings LLC** shall monitor the implementation of improvement activities and evaluate the effectiveness of the results. Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.

Harmony Castings LLC.  Aluminum V-Process Castings	Quality Manual Section:	Page 29 of 29			
	Issue Date: 10/10/12				
	Revision Date: 2/14/17	Revision 02			
Approval Signature on page 1	Approval Date: 2/14/17				
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Position

		Positic	<u> </u>						
	Plant Manager	Quality Manager	President	V.P. Sales	Human Resources	Network Systems Manager	Engineering Manager, Project Engineer	Purchasing	
AS9100 Rev D									
(4.1) Context of Organization	0	Х	0	0			0		
(4.2) Needs and Expectations of Interested Parties	0	0	0	0			Х		
(4.3) Scope of Quality Management System	0	Х	0	0		0	0		
(4.4) Quality Management system and its Processes	0	Х	0	0			0		
(5.1) Management / Leadership Commitment	0	0	Х	0	0	0	0	0	
(5.1.2) Customer Focus	0	0	0	Х			0	0	
(5.2) Quality Policy & Communication of Policy	0	0	Х	0	0		0	0	
(5.3) Organizational Roles and Authority	0	0	Х						
(6.0) Planning for Organizational Structure	0	0	Х	0			0	0	
(6.1) Risks and Opportunities	0	0	Х	0	0	0	0	0	
(6.2) Quality Objectives and Planning	0	Х	0	0			0		
(6.3) Planning of Changes	0	0	Х	0		0	0	0	
(7.0) Support	0		0		Х				
(7.1) Resources	Х	0	0			0	0		
(7.2) Competence	Х	0	0		0				
(7.3) Awareness	0	Х	0				0		
(7.4) Communication	Х	0	0	0			0	0	
(7.5) Documented Information	0	Х	0	0	0		0	0	
(8.0) Production and Processes	Х	0	0	0			0		
(8.1) Operation Planning and Control (Risk Mgmt)	0	0	0	0			Χ	0	
(8.2) Requirements for Products and Services	0	0	Х	0			0		
(8.3) Exclusion									
(8.4) Control of External Providers (Suppliers)	0	X	0	0			0	0	
(8.5) Product and Service Provision	Х	0	0	0			0		
(8.6) Release of Product and Services	0	Х	0	0			0		
(8.7) Control of Nonconforming Product	0	Х	0	0					
(9.0) Performance Evaluation	0	Х	0	0			0	0	
(9.1) Monitor, Measuring and Analysis of Data	0	Х	0	0			0		
(9.1.2) Customer Satisfaction	0	0	0	Х			0		
(9.2) Internal Audits		Х							
(9.3) Management Review	0	0	Х	0					
(10.1) Improvement	0	0	Х	0			0		
(10.2) Corrective Action	0	X	0	0			0		
(10.3) Continual Improvement	0	X	0	0			0		
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