



**JVISUSA** LLC

Global Design, Engineering, Tooling & Manufacturing

# Quality & Environmental Manual

*Based on:*

**ISO 9001:2008**

**ISO 14001:2004**

**Quality and Environmental  
Management System**

Written, Reviewed, and Approved by *John Farmer*, Ph.D.



JVIS-USA  
Shelby Township, Michigan



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## About this Manual

This manual was developed and is maintained by the Management Representative for the quality and environmental management system. As applicable, reference is made to pertinent procedures and other documents.

Requests for changes should be submitted to the Management Representative. Updates of the manual are issued as required. A copy of this quality/environmental manual is kept on the company intranet, which ensures easy access to all employees. Any copies printed of this manual are considered as an “uncontrolled document” and should be treated as such.

It is the responsibility of the department heads to ensure that employees are familiar with the manual’s content related to their work and responsibilities, and that they are kept informed of any changes and updates.

The department heads ensure that obsolete issues or “uncontrolled” pages of this manual are invalidated and/or disposed of as per established procedure. A master list maintained by the Management Representative controls current revision levels and a brief description of the last change. In case of doubt, the current issue date or revision number shall be confirmed with the Management Representative and/or verified on the company intranet.

### Distribution:

Controlled copy is on the intranet and is available for all employees.

Effective date of this quality manual: May 15, 2011    Revision 3

### Approvals:

Glen Wyckoff                      5/15/2011  
Management Representative    Date

Jason Murar                                      5/15/2011  
President    Date

## 1.0 Introduction

### 1.1 Historical Background

JVIS-USA was established in 2006 as part of a global venture known as JVIS. From this JVIS-USA was birthed. JVIS-USA is a service center that provides engineering, sales, quality, and supply chain management to the automotive industry. The supply chain management extends to low-cost-countries to provide the best value for all commodities supplied to the automotive industry.

The feeling of success for JVIS-USA's future is strong. However, JVIS-USA must remain vigilant to deliver competitive and quality products and services our customer demand. The JVIS-USA team knows how to meet the requirements.

## 1.2 Quality & Environmental Manual

This quality and environmental manual describes the quality and environmental management system of JVIS-USA. It must be noted that JVIS-USA is compliant to **ISO 9001:2008 and ISO 14001:2004**. The purpose of the quality and environmental manual is:

- **for internal use**, to communicate to employees the company's quality and environmental policy and quality/environmental objectives, to make them familiar with the method of compliance with **ISO 9001:2008 and ISO 14001:2004** requirements, to facilitate the implementation and maintenance of the quality and environmental management system and to ensure its continuity and required updates during changing circumstances, to provide effective communication and control of quality/environmental related activities and a documented base for quality and environmental system audits.
- **For external use**, to inform JVIS-USA's customers and other interested external partners about JVIS-USA's quality policy, its implemented quality management system and measures of compliance with the requirements of **ISO 9001:2008 and ISO 14001:2004**.

## 2.0 Scope and application

This quality and environmental management system described hereafter complies with all the requirements of ISO 9001 Revision 2008 as well as ISO 14001 Revision 2004, and is focused on the enhancement of customer satisfaction through continual improvement of processes and products, environmental impacts and demonstrates compliance with customer and regulatory requirements.

JVIS is an engineering and service center that includes sales and program management. The scope of the quality and environmental management system is to provide parts and/or tooling for the automotive industry. This includes (but is not exclusive) plastic and molded parts, stampings, and assemblies; while also providing logistics and warehousing.

JVIS-USA's quality and environmental management system meets all requirements of ISO 9001:2008 and ISO 14001:2004 and no exclusions are applied.

## 3.0 References, terms and definitions

The content and application of this quality manual makes reference to the following publications and documents:

- **ISO 9000: 2008** quality management systems - fundamentals and vocabulary
- **ISO 9001: 2008** quality management systems – requirements
- **ISO 9004: 2008** quality management systems - guidelines for performance improvement
- **ISO 14001:2004** environmental management systems-specification with guidance for use

For this quality and environmental manual, the terms and definitions for the automotive industry specified in clause 3.0 of ISO 9001:2008 and clause 3.0 of ISO 14001:2004 are applied.

## 4.0 Quality management system

Referenced procedures: **Procedure Matrix** found in Section 2 of the Appendix of this manual.

### 4.1 General requirements

- a) It is the responsibility of the Management Representative
  - to ensure that the quality and environmental management system of JVIS-USA is established, documented as required, implemented, managed and maintained according to the requirements of ISO 9001:2008 and ISO 14001:2004.
  - to ensure continual improvement of the effectiveness of the quality and environmental management system.
- b) Operational and administrative activities affecting quality of the departments Engineering, Production, Quality, Purchasing, Shipping, Sales and Customer Service and Quality/Environmental Management System Administration are in compliance with ISO 9001:2008 and ISO 14001:2004. It is the responsibility of the Management Representative and the department heads to ensure that the activities/processes included in the scope of this quality and environmental management system are identified and are performed in compliance with ISO 9001:2008 and ISO 14001:2004.
- c) It is the responsibility of the Management Representative and department heads to ensure that the sequence and interaction of processes or activities of this quality and environmental management system are determined in a suitable manner, such as quality plans, flow charts, operating procedures, etc.
- d) It is the responsibility of the Management Representative and department heads to apply the necessary techniques and criteria in order to verify that established processes/activities and their implemented controls are effective.
- e) It is the responsibility of the President, Management Representative and the department heads to ensure that the necessary human and material resources as

well as the necessary information are available to ensure the effective operation and control of the processes of the quality and environmental management system.

- f) It is the responsibility of the Management Representative and department heads to ensure that the processes/activities, which are part of the quality and environmental management system, are monitored, measured and analyzed regarding their achievement of planned results.
- g) As required, the Management Representative and department heads ensure that action is taken to obtain expected results of processes/activities, as well as the continual improvement of these processes/activities.

In the event that processes, which do affect product conformity, are outsourced, Quality establishes and implements the necessary controls for approval processes to ensure conformance to specified requirements. These implemented controls however do not absolve JVIS-USA from the responsibility of supplying products and service that meet customer requirements.

## 4.2 Documentation requirements

### 4.2.1 General

As a minimum, the documentation of JVIS-USA's quality and environmental management system includes:

- a quality and environmental policy and objectives
- this quality/environmental manual (QEM)
- required documented procedures for clauses: 4.2.3 Control of Documents; 4.2.4 Control of Records; 6.2.2.2 Training, 8.2.2 Internal Audit; 8.3 Control of Nonconforming Product; 8.5.2 Corrective Action and 8.5.3 Preventive Action
- ISO 14000:2004 required procedures for clauses: 4.3.1 Environmental Aspects; 2.3.2 Legal and other Requirements; 4.4.2 Competence, Training and Awareness; 4.5.1 Monitoring and measurement; 4.5.2 Evaluation of Compliance; 4.5.3 Nonconformity; Corrective Action and Preventative Action; 4.5.2 control of Records; 4.5.5 Internal Audit.
- other documents which are necessary for the effective planning, operation and control of processes of the quality and environmental management system
- records required by ISO 9001:2008, ISO 14001:2004 and by JVIS-USA to ensure appropriate control and evidence of compliance with requirements.

The document structure of JVIS-USA's quality management system consists of two levels:

- 1) The Quality and Environmental Manual, describing the quality and environmental management system of JVIS-USA and its compliance with ISO 9001:2008 and ISO 14001:2004.

- 2) Operating procedures, work instructions, forms, master lists, operating instructions, quality plans, control plans and other necessary documents for the effective and efficient operation of the quality and environmental management system.

In addition, records are created as required by ISO 9001:2008 and ISO 14001:2004, as well as records necessary to meet other internal and external requirements.

It is the responsibility of the Management Representative to ensure the availability of corporate documents of the quality and environmental management system and documents required by ISO 9001:2008 and ISO 14001:2004.

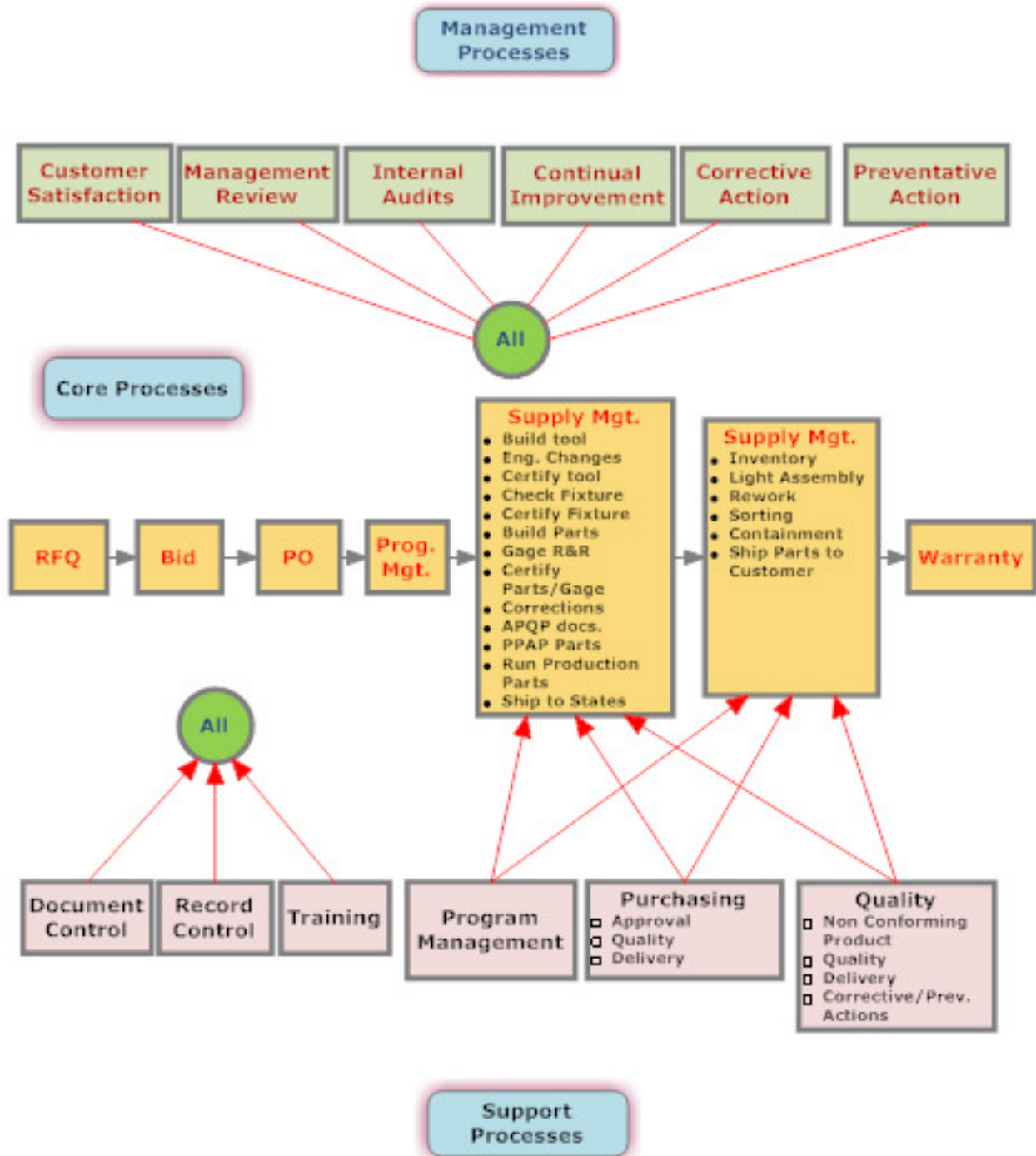
It is the responsibility of the department heads to ensure the development and availability of documented procedures, work instructions, operating instructions and any other documents related to their departments, and which are necessary to ensure the effective implementation, control and functioning of the quality and environmental management system and its processes.

#### **4.2.2 Quality and environmental manual**

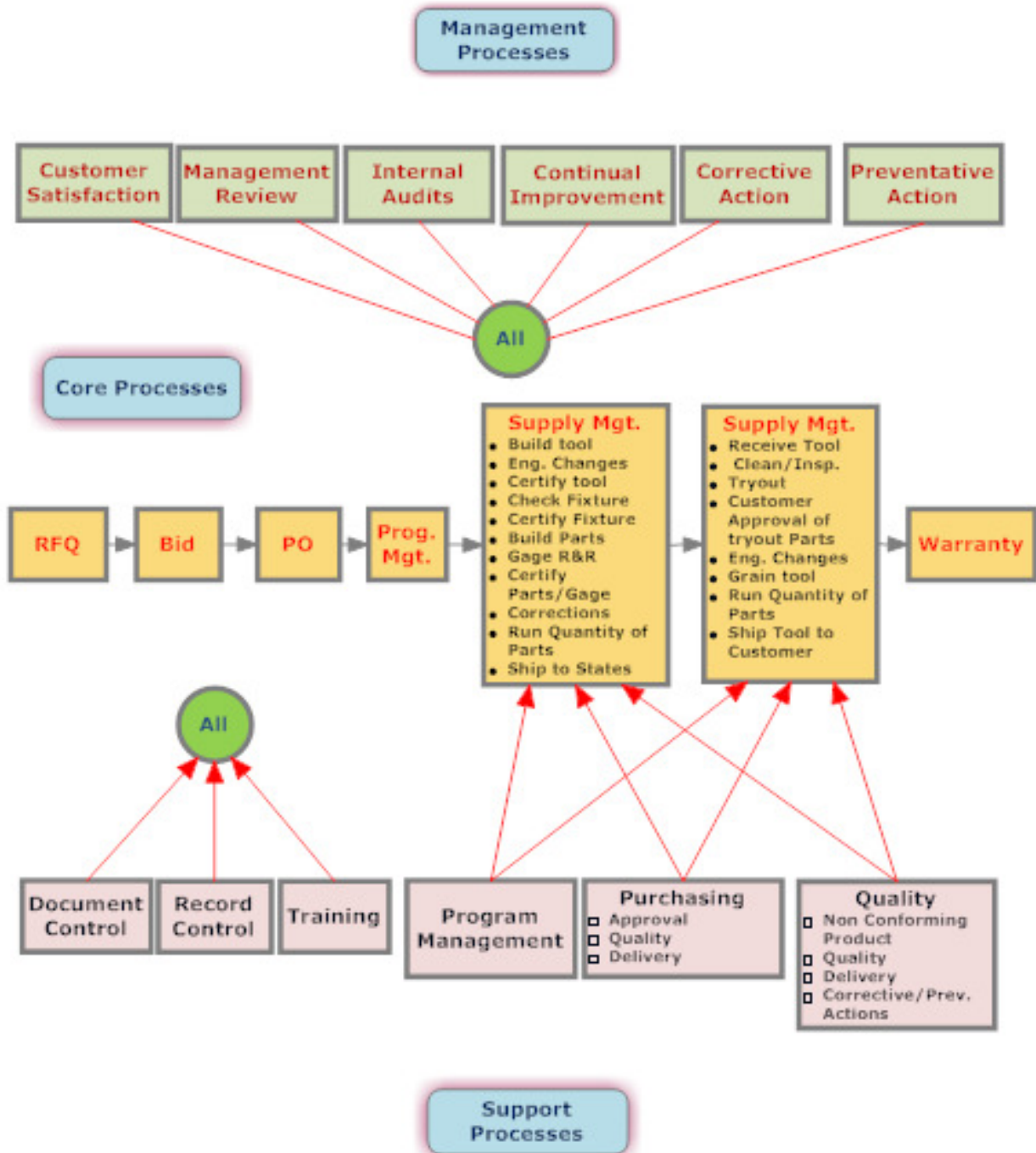
The quality and environmental manual includes the scope of the quality and environmental management system and applicable permissible exclusions from the requirements of ISO 9001:2008 and ISO 14001:2004 and their justification, makes reference to applicable operating procedures and other pertinent documents.

The following is a description of the interaction of processes of the quality and environmental management system.

## SUBCONTRACTED PARTS PROCESS



## TOOLING PROCESS



## 4.2.3 Control of documents

Reference **QP-001**. Documents required by the quality and environmental management system are controlled and reviewed annually. Each location/department maintains a **Master List**, master copies, or equivalent control method that identifies these controlled documents. Records are a special type of document and are controlled according to the requirements given in 4.2.4. This section has been established to define the controls needed:

- a) **Document approval for adequacy prior to issue:** Control of this QEM and procedures is by the management representative who solely has access to the file as located on the JVIS-USA intranet. The manager with access to applicable historical data such as similar documents or data, performance records or customer requirements approves all local controlled documents. Approval for written or electronic documents shall be recorded in by signature, on the document itself and this shall allow the document to be distributed and implemented.
- b) **Document review, update and re-approve as necessary:** Approval or re-approval of controlled documents or data requires that the documents be complete, accurate, readable and consistent with existing procedures. Approval indicates that the document meets these requirements. Review and approval responsibilities are indicated on each location's **Master List** or equivalent control method. Revisions of controlled documents should be approved by the same functions that did the original approval when feasible.
- c) **Document changes and the current revision status identification:** Where practical, a brief description of the nature of the change is made readily available using a method such as attaching it to the document or writing it in a "revision block". Each location's master list must identify the current revision level of documents, data or forms that are listed as controlled documents. The revision level and date are also indicated on the document, data or form.
- d) **Document relevant versions are available at points of use:** It is the responsibility of the applicable department head to ensure that current revisions of controlled documents are legible, readily available where needed. Operator instructions must be available, without job disruption, at the production workstations.
- e) **Documents remain legible and readily identifiable:** All documents and forms shall be legible and shall be identified by name and/or number. The name and/or number shall be reflected on the **Master List** or equivalent control method.
- f) **Documents of external origin, such as specifications, industry standards, drawings and other documents required to produce the product, are identified and their distribution controlled:** Each location shall identify appropriate documents of external origin on its Master List or equivalent control method.

- g) **Obsolete documents prevented from unintended use, and suitable identification applied to them if they are retained for any purpose:** Copies of obsolete controlled documents shall be promptly removed from all points of issue and either destroyed or clearly marked as "Obsolete". A master copy is retained as a quality record and shall also be marked in this way.

The **Master List**, where used, may be broken up into several smaller lists (such as department lists) to facilitate maintenance. Additional requirements beyond these may be defined by each location in local instructions.

**Exhibit Copies** - Uncontrolled exhibit copies, which are not automatically updated, may be given out when necessary. These copies shall be identified as "**UNCONTROLLED COPY**" on the bottom of the document.

**Environmental & Regulatory Requirements** – Reference **QP-008**. A listing of all significant state, local and federal environmental regulations that apply to the location will be maintained on the **Master List**, or equivalent control document. Likewise, a listing of any other requirements relating to the Environmental Management System (such as customer restricted material lists or voluntary environmental programs) shall be recorded on a controlled document or on the **Master List**. Because of the dynamic nature of many of these documents, it is acceptable to indicate a website where a current copy of any relevant requirement may be found rather than maintaining a copy of the requirements (i.e. MSDS sheets). To keep current with environmental regulations a subscription to latest environmental news is maintained.

#### 4.2.4 Control of records

Reference **QP-002**. Records are maintained to provide evidence of activities and their results, of conformance to requirements and of the effective operation of the quality and environmental management system. Records shall remain legible, readily identifiable and retrievable.

**Access To Records** - Quality records shall be stored in an appropriate retrievable manner that include separating (indexing) by departments, machine numbers, date, record number etc. Quality and/or environmental records may be made available, when appropriate, to customers and third party/government auditors to demonstrate quality or environmental performance or to help identify trends and any opportunity for improvement.

##### 4.2.4.1 Records retention

Department heads are responsible for the proper identification, storage, retrieval, protection, retention time and disposition of records according to the established documented procedure on record retention.

## 5.0 Management responsibility

Referenced procedures: **Procedure Matrix** found in Section 2 of the Appendix of this manual.

### 5.1 Management commitment

The management of JVIS-USA is committed to the development, implementation and well functioning of the quality and environmental management system and the continual improvement of its effectiveness. In order to provide this evidence, top management ensures that:

- a corporate quality and environmental policy is established
- quality and environmental objectives are established by selected departments
- the importance of meeting customer requirements and statutory and regulatory requirements is part of the training of each employee
- resources for the implementation and maintenance of the quality and environmental management system and its processes are provided in a timely manner
- management reviews are conducted
- ensuring the availability of any resources needed

### 5.2 Customer focus

Top management ensures that procedures for determining and meeting customer requirements are established and implemented by the responsible departments. The effectiveness of these procedures is measured through customer satisfaction surveys, which are part of Management Reviews.

### 5.3 Quality and environmental policy

The management of JVIS-USA has developed a corporate quality and environmental policy, which meets the needs of JVIS-USA and its customers.

It is the responsibility of JVIS-USA's management to implement and maintain this quality and environmental policy. The quality and environmental policy includes JVIS-USA's commitment for continual improvement, for meeting internal requirements and customer requirements, and provides a basis for the establishment and review of quality objectives. The quality and environmental policy is made known within the organization and understood and adhered to by employees. During management reviews, the quality and environmental policy is reviewed for its continuing suitability. The quality and environmental policy is related to the public on the JVIS-USA corporate web site.

## Quality and Environmental Policy



JVIS USA will conduct all aspects of its business in a responsible manner. This will be achieved in the following statements:

- ◆ Comply with all applicable laws, regulations, standards and other requirements.
- ◆ Adopt a culture of continual improvement to meet or exceed customer requirements and expectations with goals set to confirm achievement.
- ◆ Evaluate our activities and measure our performance against established goals through audits and management review.
- ◆ Advocate the adoption of prudent quality and environmental principles to our vendors, suppliers, and customers.
- ◆ Make all efforts, through pollution prevention efforts during research, process design, and plant operations to:
  - **reduce** and eliminate the generation of waste and emissions at the source.
  - **recycle** when practical and
  - **reuse** containers and products.
- ◆ Pledge ourselves to the prudent and sustainable use of the earth's resources and the protection of the natural environment while we strive to fulfill our corporate mission of contributing to enhance prosperity for all.
- ◆ Communicate our quality and environmental oriented activities to our employees, vendors, suppliers, customers, local community, environmental agencies, and general public as applicable.

Under observance of the aforementioned, customer satisfaction is the company's main priority: we want to be our customers' preferred supplier.

This Policy is summed up in our quality statement

**★" Quality Minded-Environmentally Friendly"★**

**Jason Murar**  
President

**Revision 02**  
**January 2011**

## 5.4 Planning

### 5.4.1 – 5.4.1.1 Quality and environmental objectives - General

Each year, management defines quality and environmental objectives and measurements, which are included in the business plan. In addition, department heads for their departments establishes yearly quality and environmental objectives. Management approves these departmental quality and environmental objectives.

Established quality and environmental objectives are consistent with the quality and environmental policy, include - as appropriate - objectives to meet product requirements (see 7.1.a), and are defined in such a way that their degree of achievement and results can be measured.

Quality and environmental objectives for the departments Production, Quality and Technical Service are related to the performance of product and/or service. Environmental objectives include commitments to prevent pollution, compliance to all legal requirements, and continual improvement.

The completion and achievement of yearly quality and environmental objectives included in the business plan and departmental quality and environmental objectives are reviewed during management review regarding their level of achievement.

#### ***Corporate quality and environmental objectives***

Based on the corporate quality policy, the management of JVIS-USA establishes corporate quality and environmental objectives:

Based on internal and external audit results and measurables issued by the Management Representative, these corporate quality and environmental objectives are reviewed during management reviews regarding their continuing suitability.

#### ***Departmental quality and environmental objectives***

Each year, the department heads of Administration, Sales and Service, Engineering, Production, Shipping, and Quality establish quality and environmental objectives for his/her department. These quality and environmental objectives are in accordance with the corporate quality and environmental policy and are focused on the improvement of departmental processes/activities. The departmental quality and environmental objectives for the coming year are submitted to top management for review and approval. A summary of the achievement of the department's quality and environmental objectives of the past year is documented by the applicable department head and submitted to top management.

### 5.4.2 Quality and environmental management system planning

Periodically, the Management Representative calls for a meeting of the department heads with the purpose to review, coordinate and plan the efficiency and effectiveness of the

quality and environmental management system and the realization of established quality and environmental objectives of the departments, as well the coordination of improvement opportunities. The *General Requirements* of clauses 4.1 and 5.4.1 of ISO 9001:2008 are included in this planning process.

The output of these planning activities includes the identification of required resources. As appropriate, results from audits of the quality and environmental management system as well as permissible exclusions according to ISO 9001:2008 are considered. Planning activities are documented and are consistent with other requirements of the quality and environmental management system.

It is the responsibility of the Management Representative to ensure that resulting organizational changes and their consequences are identified and defined, that changes resulting from planning activities are coordinated and implemented in a controlled manner, that changes to the quality and environmental management system are documented, implemented and approved, and that the quality management system is properly maintained during these changes.

**Note:** the Quality Planning Team under the responsibility of the Engineering department performs Quality planning for production processes and service activities.

Each department head develops and maintains a quality and environmental plan/procedures for his/her department, showing the workflow of the department as well as evidence of compliance with the requirements of the quality and environmental system.

## 5.5 Responsibility, roles, resources, authority and communication

### 5.5.1 Responsibility and authority

The management of JVIS-USA consists of the President and the Management team. Reporting to the President are the department managers of Quality, Program Management, Engineering, Sales/Service and Administration. It is the responsibility of the Management Representative to develop and maintain an organization chart of JVIS-USA. Updated charts are distributed to department heads and are available to employees for information.

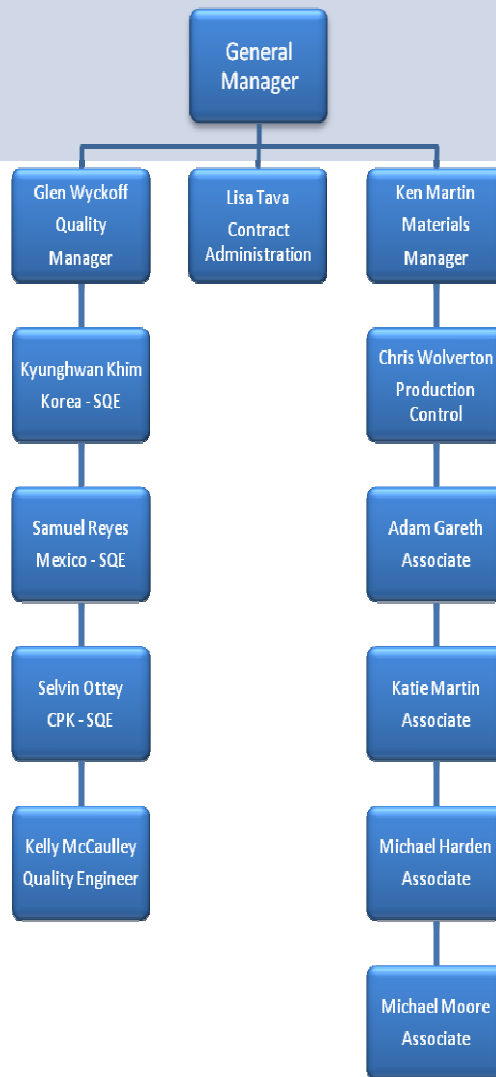
Management ensures the availability of resources essential to establish, implement, maintain, and improve the quality and environmental system (see 6.1 of this manual). Resources include human and specialized skills, organizational infrastructure (see section 6.3 of this manual), technology, and financial resources.

Roles, responsibilities and authorities are defined, documented and communicated to facilitate an effective quality and environmental system.

For the purpose of this manual “responsibility” and “authority” are synonymous.

## JVIS-USA ORGANIZATIONAL CHART

Jack Fuery – VP of Operations  
Mike Verkennes – Director of Quality  
Matt Graves – General Manager



### ***Departmental responsibility for quality***

The responsibility for quality in each department rests with the department head. The department head is responsible for the development and approval of the department's work instructions. The department heads ensure that the department staff understands and follows the applicable policies and guidelines outlined in the quality and environmental manual, that the department's personnel adheres to all applicable procedures and work instructions and participates, as appropriate, in the quality improvement process.

In addition, employees are made aware of the importance to meet customer requirements and expectations. It is the responsibility of the department heads to ensure that customer requirements and customer expectations, which relate to activities under the department's responsibility, are identified, defined, documented and met.

Department heads ensure that the responsibility of employees or functions whose activities affect quality, are defined in procedures and job descriptions. In yearly performance reviews, or when required, these responsibilities for quality, together with other responsibilities of the function, are reviewed and discussed between the department head and the employee, and are assessed and re-defined as necessary.

### ***Individual responsibility***

All employees follow the policies and guidelines outlined in the quality and environmental manual and in established procedures/work instructions. It is the duty of each employee to inform the department head or the Management Representative when performed activities do not match the established procedures, or when established procedures and work instructions are unclear or ambiguous. The department head is notified of any identified nonconformity or deficiency where the correction or prevention of such nonconformity or deficiency is out of the employee's scope of responsibility.

### **5.5.2 Management representative**

The management of JVIS-USA appoints a Management Representative who, irrespective of other duties and responsibilities, has the defined authority and responsibility for:

- ensuring that a quality and environmental management system is established, implemented and maintained in accordance with the requirements of the international standard ISO 9001:2008 and ISO 14001:2004.
- reporting on the performance of the quality and environmental management system to management for review and corrective action, including needs for improvements.
- the proper coordination - where required - of quality related issues and activities within the company, with external customers and suppliers and other external partners and authorities.
- promoting the awareness of customer requirements and expectations throughout the company.

The Management Representative is responsible for the overall coordination, implementation and administration of the quality and environmental management system.

### 5.5.3 Internal communication

Effective internal communication is essential for the proper functioning of the quality and environmental management system. The Management Representative, with the assistance of the department heads, ensures that required communication and information between departments and functions is defined in documented procedures, memos, forms and/or documents.

Any communication problems regarding the quality and environmental management system are reported to the Management Representative for corrective action.

### 5.5.4 Environmental Communications

Reference **QP-009**.

**Internal** – All JVIS-USA employees shall have the ability to provide input and comment into the environmental management system. Each location establishes a system for collecting, considering and where appropriate responding to employee inputs. Such inputs are considered during the setting of environmental objectives and targets. Ongoing communication among relevant departments and personnel also includes awareness of environmental aspects, concerns and improvement efforts.

**External** - Each location develops a process for receiving, documenting, and responding to external requests for information relating to its environmental management system. Such inputs are considered during the setting of environmental objectives and targets.

***It is JVIS-USA's policy not to communicate information relating to significant environmental aspects, controls, incidents, or emissions to the general public, except as required by law, without specific approval of the President.***

## 5.6 Management review

### 5.6.1 General

At least once per year, management and the Management Representative have a formal meeting to discuss and review the continuing effectiveness and adequacy of the quality and environmental management system. The review includes the evaluation of the need for changes to the quality and environmental management system, the quality and environmental policy and quality and environmental objectives, as well as the assessment of improvement opportunities based on the review and analysis of performance trends, achievement of quality objectives as outlined in the business plan and customer satisfaction, and the cost of poor quality according to clauses 8.4.1 and 8.5.1.

### 5.6.2 Review input

At a minimum, the following input is included in the meeting agenda:

- performance of production and service processes, and product and service conformity, including performance trends

- status and effectiveness of corrective and preventive actions
- follow-up actions from previous management reviews
- planned changes that could affect the quality and environmental management system
- assessment of improvement opportunities and recommendations for improvements
- employees' knowledge, understanding and adherence to quality policies, directives and procedures, their involvement in the quality improvement process
- availability and effectiveness of internal and external information within the company, at all levels
- human resources, training and staffing requirements
- suitability of working environment
- availability of material resources
- effectiveness of quality planning (quality system, design/development of products and processes)
- achievement of corporate quality objectives, including those specified in the business plan
- achievement of departmental quality objectives
- effectiveness of continual improvement activities of products, processes, service and quality and environmental management system
- results of internal and external audits of the quality and environmental system, incl. audits of Production processes
- statistical results (where applicable) of operational performance, based on the analysis of collected data, which includes:
  - quality and environmental system audits conducted by the Registrar
  - internal quality audits
  - customer satisfaction surveys and other customer feedback regarding customer satisfaction
  - customer complaints
  - suppliers performance
  - product and service quality and nonconformities
  - direct and indirect costs and benefits of the quality and environmental system (relation cost - benefit)
  - cost of poor quality-scrap, rework, returns, warranty repairs, excess freight charges, etc.
  - analysis of field-failures (returns, warranty repairs), their impact on quality, safety, environment
  - the impact or potential impact of changes that could affect the quality management system
  - opportunities for improvement resulting from additions or changes

### 5.6.3 Review output

Results of the assessment and conclusions of management reviews include the following output:

- effectiveness of corrective and or preventive actions
- the suitability and effectiveness of the quality and environmental management system
- improvement of the effectiveness of the quality and environmental management system and its processes
- improvement of product with focus on customer requirements
- availability of human and material resources
- suitability of the corporate quality policy
- frequency of Management Reviews
- required corrective and or preventive actions regarding items reviewed

## 5.7 Identification, Monitoring and Control of Significant Environmental Aspects

### 5.7.1 General

Reference **QP-007**. Each location establishes and maintains a process to identify the environmental aspects of its activities, products or services that it can control or influence, in order to determine those that have or could have significant impacts on the environment. Each location shall establish processes to ensure that information relating to its significant aspects is kept up-to-date. Where appropriate, this process shall be tied into the Advanced Quality Planning and PPAP processes to provide early indication of potentially new or significantly changed environmental aspects.

#### 5.7.1.1 Quality Plans (APQP), Feasibility Reviews & New Processes

It is possible that new product, processes or facilities may impact JVIS-USA's ability to meet its environmental objectives or consistency with its environmental policy commitments. Projects that could have such impact should be reviewed for any significant environmental issues that must be addressed to allow JVIS-USA to meet its policy commitments and/or environmental objectives. Advanced quality planning (APQP) may be used to identify or update any significant environmental aspects of new or modified processes, and to assure such aspects are properly controlled. Planning topics may include, as appropriate:

- ◆ Potential for significant increases in the amount of wastes or emissions of hazardous or regulated substances.
- ◆ The need to establish any new operational controls needed to minimize any adverse environmental impacts.
- ◆ The need for operator environmental awareness training.
- ◆ The need to establish any monitoring or measurement criteria, or environmental records.

- ◆ The need to modify any environmental objectives, targets, permits or environmental procedures based on the new or modified work and/or process.

## 5.7.2 Operational Control and Monitoring of Significant Environmental Aspects

Reference **QP-007** and **QP-010**. Each location maintains a current listing of significant aspects once identified. Operational controls to minimize/eliminate any negative impacts of significant aspects shall be planned and established when new significant aspects are identified and during **Planning of Product Realization**, Section 7.1 of this policy manual. Appropriate monitoring and measurements shall be established with the operational controls, and monitoring and measurement conducted as described in Section 8.2.3, **Monitoring and Measurement of Processes**.

Significant environmental aspects are considered during the setting of environmental objectives and targets as described in Section 5.4, of this policy manual **Quality and Environmental Planning**.

## 6.0 Resource management

Referenced procedures: **Procedure Matrix** found in Section 2 of the Appendix of this manual.

### 6.1 Provision of resources

Management ensures that approved material and human resources, which have been identified by the department heads during budget planning and quality planning, are available in a timely manner. This refers to resources required for the implementation, maintenance and continual improvement of the processes of the quality and environmental management system, for meeting customer requirements and achieving customer satisfaction. Also included are resource requirements for new projects and other quality and environmental related activities. Related expenses are included in the company's financial budget. Also, proper maintenance of environmental equipment is important to minimize emissions and to prevent inadvertent releases.

Corporate resource needs are formally identified during **Quality and Environmental Planning**. Resource needs may also be identified during periodic **Management Reviews**, during **Internal Audits**, during **Planning of Product Realization** and during other routine activities. Once identified, responsive management is responsible for obtaining and assigning the necessary resources.

### 6.2 Human resources

#### 6.2.1 General

It is the responsibility of the department heads to identify qualification requirements of functions or personnel assigned to defined activities that affect product quality or environmental performance. Qualification requirements include education, training, skills

and experience as appropriate. In the department's budget are provisions for the employment and assignment of qualified and trained personnel.

## **6.2.2 Competence, awareness and training**

Department heads ensure that the qualification requirements - competency (such as education, skills, training, experience) for each job are identified, determined and documented in job descriptions. Training is provided to employees or other actions are taken in order to meet defined qualification requirements. The effectiveness of provided training or of related actions is evaluated.

Employees are made aware of the importance and the impact of their work in relation to product quality and environmental performance, to the achievement of quality and environmental objectives, customer satisfaction, potential consequences of departure from specified procedures, and their role and responsibility in achieving conformity with the requirements of the quality and environmental system.

Records of employees' education, experience and other qualifications are maintained.

## **6.3 Infrastructure**

Each location determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- buildings, workspaces and associated utilities,
- process equipment (both hardware and software), and
- supporting services (such as transport or communication).

Management ensures the timely availability of identified and approved resources.

### **6.3.1 Emergency Preparedness & Response**

Each location maintains an emergency plan identifying potential accidents & emergency situations, preventing & mitigating potential environmental impacts that may be associated with them, and periodically testing such procedures where practical. This plan shall be reviewed after an environmental incident occurs, and it shall periodically be checked and tested to see if varying data such as phone numbers and names or titles need to be updated. Each location's plan is located on the JVIS-USA intranet.

## **6.4 Work environment**

The quality planning team defines special conditions of the work environment, which are necessary for the processes to meet defined requirements of product and service quality and environmental performance. These special conditions are included in the quality plan, production plan, process sheet or other documents. It is the responsibility of the department head to implement these requirements.

## 7.0 Product realization

Referenced procedures: **Procedure Matrix** found in Section 3 of the Appendix in this manual.

### 7.1 Planning of product realization

The Engineering department is responsible for the quality planning of the production processes of new products and for changes of existing products, as well as service activities. Planning activities are consistent with other requirements of the quality and environmental management system.

Prior and during the planning process, quality objectives and quality requirements for product and/or service related to the planning project are established by the quality planning team.

As appropriate, the planning process covers provision of resources, necessary production processes and documents, required verification, validation, monitoring, inspection and test activities, and criteria for product acceptance.

Records for providing evidence that production processes, and produced product meet requirements are defined and specified.

### 7.2 Customer-related processes

#### 7.2.1 Determination of requirements related to product and service

It is the responsibility of the Sales department to ensure that customer requirements related to product and service are identified and defined.

It is the responsibility of Engineering, represented by the Quality Planning Team, to identify and determine requirements not specified by the customer but necessary for the proper and intended use of the product or service, as well as other requirements identified during product development and quality planning, including regulatory and statutory requirements. Once these requirements are determined, they are used as input for product or service development and quality planning, and other functions concerned are informed as appropriate.

In addition to customer requirements included in design and development and quality planning, department heads ensure that other requirements specified by customers, as well as customer needs and expectations are identified, determined and documented by the responsible department, and that these requirements are met as appropriate. The responsible department head also ensures that during set-up and maintenance of new customer files, customer returns and shipping of products, customer requirements are identified and documented, and understood by all functions concerned.

Based on sales forecast and/or other special requirements documented by the Sales department, Production prepares production schedules and material requirement reports to ensure availability of product for the fulfillment of customer orders.

## **7.2.2 Review of requirements related to product, Production feasibility**

The Sales/Service department is responsible for the review of product specifications and customer requirements. Prior to the submission of a quotation to the customer, or the acceptance or confirmation of an order from a customer, the order or quotation is reviewed to ensure that:

- the product and customer requirements are clearly defined and documented.
- JVIS-USA has the capability (production feasibility) to meet the requirements of the quotation or order.
- requirements of verbal orders are recorded and confirmed prior to acceptance.
- any differences between the customer's order and JVIS-USA's quotation are clarified and resolved.

In the event of changes to product requirements, or other changes to a quotation or order, it is ensured that relevant documents and data are updated and that other functions concerned are notified. Records of contract reviews are maintained.

## **7.2.3 Customer communication**

Reference **QP-009**. In order to meet customer requirements and to ensure the proper and effective communication between the various departments within JVIS-USA and the customer, Sales/Service establishes a list with some main contacts within JVIS-USA regarding customer inquiries. This list is updated as required, is distributed to functions concerned and is attached to the main directory available at the reception.

Engineering and/or Sales/Service and/or the quality planning team, as applicable, define internal and external communication related to the planning of products and processes.

It is the responsibility of Engineering, with the assistance of the IT-department, to install or subcontract electronic communication and design systems (such as CAD), which are compatible with the customers' systems, in order to effectively communicate and interchange information with the customers.

It is the responsibility of Production, with the assistance of the IT-department, to develop, implement and maintain a computerized system (such as EDI) for the receipt of planning information of customer orders, shipping schedules and shipping information.

## **7.3 Design and development - General**

If there is a need for the design and/or development of a new product or for a change of the design or production process of a product, the supplier submits a change request to Engineering.

### **7.3.1 Design and development planning**

The planning and control of design and development of product is the responsibility of the customer. JVIS does not design any product. If the customer requests design services then JVIS will subcontract this service.

### **7.3.2 Design and Development Inputs**

Inputs relating to product requirements are determined and records maintained by the subcontracted source.

### **7.3.3 Design and Development Outputs**

The outputs of design and development are provided in a form that enables verification against the design and development input and are approved prior to release, by the subcontractor.

### **7.3.4 Design and development review**

The Program Team performs formal design reviews with the subcontractor to identify any potential problems in meeting requirements and design goals. Problems are identified and appropriate action is taken.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed.

### **7.3.5 Design and development verification**

The Program Team will monitor periodic design verifications to verify that design and development outputs meet the design and development input requirements. Results of design verifications and resulting actions are recorded and maintained.

### **7.3.6 Design and development validation**

The Program Team will monitor design validation to ensure that the designed product meets defined customer/user needs and requirements. Validation is according to customer requirements and includes program timing. If possible, this validation should be performed prior to production. However, if it is required, partial validation is acceptable. Results of validations and the necessary actions are recorded and maintained.

### **7.3.7 Control of design and development changes**

Requests for design and development changes from suppliers are documented. Requests are reviewed and approved by Engineering. Results and necessary actions are documented and records are maintained.

## 7.4 Purchasing

### 7.4.1 Purchasing process

Purchasing department is responsible for the effective and efficient operation of purchasing functions and activities. Supplemental information can be found at the JVIS-USA web site – Supplier standard.

Depending on the effect of the purchased product on the final product, on production processes and/or service activities, the type of control applied to the supplier and the method used for verification of purchased product are identified and established by Quality.

Materials, products and services are only purchased from approved suppliers. Suppliers are evaluated and selected according to defined selection criteria and their ability to supply product that meets specified requirements. Records of evaluation and selection of suppliers as well as related actions are maintained by Purchasing.

JVIS-USA encourages all its suppliers to obtain ISO 9000 certification at a minimum. JVIS-USA annually performs an assessment on non ISO 9000 registered suppliers. This assessment is performed by a qualified Lead Auditor, or qualified Internal Auditor with evidence of successful completion of training. Records are maintained of these supplier assessments.

Supplier performance is monitored through evaluation of product quality, problems reported by the customer involving supplied product, and delivery performance.

- **Environmental Suppliers** – JVIS-USA locations control environmental contractors and suppliers whose work could have a significant impact on the environment, to the extent necessary to ensure compliance with the JVIS-USA environmental Policy and any applicable requirements. Those suppliers who directly deal with Significant Aspects shall be made aware of JVIS-USA's environmental Policy and any applicable requirements pertaining to their product or service using one or more applicable methods such as sending the environmental Policy to suppliers, posting the Policy where incoming suppliers could see it, posting procedures where sensitive supplier activities take place, or having appropriate JVIS-USA personnel oversee activities involving Significant Aspects (i.e. plumbers overseeing bulk liquid transfers, etc).
- **Environmental Supplier Selection** - Verification of the subcontractors' licenses or identification numbers is performed, where necessary (i.e. required by law) prior to placement on the JVIS-USA or local Approved Supplier List. Environmental suppliers may also be requested to provide evidence of operational controls in the form of procedures, policies or training documents when these controls are considered essential for avoiding significant environmental impact. Environmental suppliers are encouraged to obtain ISO 14001:2004 certification.

- **Environmental Supplier Evaluation** - Environmental suppliers shall be monitored as needed to assure compliance with the locations environmental policy, objectives, and procedures using methods such as keeping an incident log or following up on complaints. Audits of supplier facilities or documents may be conducted if considered necessary to provide assurance of compliance to operational controls and/or environmental regulations and requirements.

## 7.4.2 Purchasing information

For products and services purchased, including customer supplied product, Purchasing ensures that required records are set up and maintained. The data describe and identify clearly the product to be ordered, requirements for the approval of product, procedures, processes and equipment, statutory and regulatory requirements, requirements for qualification of personnel, and quality management system requirements, as applicable. As appropriate, standards or other documents are referenced. The adequacy of specified purchase requirements is ensured prior to submission to the supplier.

## 7.4.3 Verification of purchased product

The extent of quality control exercised over a supplier or over the supplied product is determined by Quality and depends on whether the product affects the quality of the JVIS-USA product, the initial evaluation of the supplier, and/or type and extent of inspection performed by the supplier, and/or the results of ongoing performance ratings of the supplier.

In the event that JVIS-USA or one of JVIS-USA's customers wants to verify purchased product at the supplier's premises, these verification requirements and/or the method of product release are requested and defined by either Engineering, Quality or Sales, and are specified in the purchase order. Verification activities at the supplier's are coordinated through the Purchasing department.

## 7.5 Production and service provision

### 7.5.1 Control of production and service provision

Production processes and service activities are performed under controlled conditions and are reviewed by program management. Based on the output from quality planning, each location/department ensures that the necessary documents, data and operating instructions for the performance of production processes and service activities are developed and available to personnel. These documents or data are described in sufficient detail:

- the product characteristics,
- production processes and/or service activities,
- the equipment to be used,
- as well as the activities for monitoring and measuring of these processes.

Included are procedures for release, delivery and post-delivery activities.

The Production department ensures that:

- operating instructions, including instructions for special processes, are available at the workstation,
- that production activities, verification results and SPC records are recorded,
- and those activities for the monitoring and measurement of production processes are implemented and followed.

It is also the responsibility of the Production department to ensure that the work environment is appropriate for the work being performed and meets statutory requirements. The Health and Safety Coordinator is responsible for compliance with regulatory requirements.

### 7.5.1.1 Work instructions

It is the responsibility of the each department to develop and maintain documented work instructions and operating instructions that are necessary for the performance of processes and activities affecting quality of products or service. These documents are made accessible to personnel at the work place. Work instructions and operating instructions are derived from the output data from quality planning, such as the quality plan or control plan.

Written work instructions shall also be developed where needed to assure the operational control of processes that have or could have a significant environmental impact, as described in Section 5.7 ***Determination of Significant Environmental Aspects*** and Section 7.1 ***Planning of Product Realization***.

### 7.5.2 Validation of processes for production and service provision

The supplier where the resulting process output cannot be verified through monitoring or measurement, production and service processes are validated by the Quality Planning Team with the assistance of Sales/Technical Service, regarding their ability to achieve planned results.

The quality planning team establishes procedures for the review, approval and requirements of these processes, including - as applicable:

- criteria for review and approval,
- approval of equipment and qualified personnel,
- the use of methods and procedures,
- required records,
- and re-validation in case that expected results are not achieved.

Attention is given to special processes where the results cannot be verified through measurement or testing, such as the processing of *Appearance Items* or where deficiencies become apparent when the product is already in use or the service has been supplied.

### 7.5.3 Identification and traceability

Designated personnel in Quality, Program Management and Shipping identify incoming product and material, product and material during production, and product and material in storage with the product identification and/or lot number and inspection status.

Using the implemented computerized system in Production, products produced for JVIS-USA are traceable by serial or vehicle identification number.

### 7.5.4 Customer property

Customer owned product supplied (including returnable containers) for production the subcontractor will inspect according to defined inspection requirements.

The responsible department ensures that customer owned product is identified, stored, used, handled and shipped in an appropriate manner in order to ensure its suitable condition for use.

During periodic cycle counts conducted by designated personnel in Production, a visual inspection of products, including customer owned product, is performed to verify the product's condition and proper identification. Any loss, damage or deterioration of customer-supplied product is recorded and the customer is notified.

### 7.5.5 Preservation of product

The plant preserves the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection as described below.

- **Handling** - The methods used for handling material does not cause damage or deterioration due to vibration, shock, abrasion, corrosion, temperature or other conditions encountered during handling. If such damage is discovered, the handling methods involved shall be included in the recurrence prevention as described in Section 8.6, **Corrective and Preventive Action**. General precautions for the handling of liquids and general wastes may be embedded in specific operating instructions where they are encountered and/or included in a separate instruction.
- **Packaging** – When packaging is required, each location follows local work instructions describing packing, preservation, and labeling of their JVIS-USA product to assure conformance to customer requirements and allow product to be identified, preserved, and kept separate. The packaging methods keep parts clean and preserve them from moisture or vibration damage. If the location ships or transports hazardous material, packaging of industrial and hazardous wastes are in accordance with all regulatory and legal requirements.
- **Preservation** - Each location uses appropriate methods for preserving and segregating product under its control.

- **Storage**
  - ◆ **Storage Areas** - Storage areas are identified in order to limit the possibility of use of product or components prior to proper release.
  - ◆ **Hazardous materials, industrial wastes and any hazardous wastes** are stored in designated storage areas or in controlled satellite accumulation points throughout the plant. General storage requirements are contained in the Liquid and Waste Handling General Procedure.
  - ◆ **Deterioration** - Storage methods do not cause damage or deterioration due to corrosion, temperature or other conditions encountered during storage. If such damage is discovered, the handling methods involved shall be included in the recurrence prevention as described in Section 8.6, **Corrective & Preventive Action**.

In order to detect possible deterioration, the condition of product in stock shall be assessed at appropriate intervals using techniques such as:

- ▶ reporting deterioration during physical inventories of product or components,
- ▶ checking for deterioration during internal quality audits,
- ▶ or conducting special sampling audits to determine product condition.

- **Age Sensitive Items**
  - ◆ **Products** - Products in storage as well as returned products shall meet the maximum storage times and test procedures to prevent possible deterioration of age sensitive components.
  - ◆ **Components** – Components that may deteriorate (i.e. grease, seals, etc.) shall not be used without approval of the Quality Manager/Coordinator (or documented designate) if they have been stored at the location for more than 3 years. Each location develops a local written instruction that specifies the method of preventing expired components from being used.
- **Delivery** - Delivery methods chosen maintain the quality of the products. If special protection is needed during transport or storage, the location shall identify the requirements on the packaging or documents.
- **Installation** - When installation by the JVIS-USA location is contractually specified, documents are made available to preclude improper installation or factors degrading the quality, reliability, safety and performance of the product.

## 7.6 Control of monitoring and measuring devices

Reference **QP-012**. As part of the **Planning for Product Realization**, each location determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined

requirements. Each manufacturing location shall establish appropriate programs that provide for the following:

- **Control Methods** - Control of measuring and test equipment is achieved using methods such as regular calibration of gages and masters, Gage R&R studies, display of calibration status, and skill training for operators and inspectors.
- **Equipment To Be Controlled** - Control is exercised over gages, instruments and test equipment. In addition, attention is given to computer software, jigs, fixtures, process instrumentation and personal employee gages that affect the quality characteristics specified on applicable Standard Operating Procedures (QP's). Measurement or test equipment used to qualify or maintain production tooling is also controlled, as is Environmental monitoring equipment needed to assure compliance with JVIS-USA's environmental policy, procedures or legal obligations. The location identifies the equipment that will be controlled.
- **Purchase Requirements** - New items are chosen with resolution and accuracy sufficient to meet the specifications of the parts to be produced under the expected environmental conditions. Normally, instruments should have a resolution of 10% of the specified tolerance of the parts to be measured. Instrument requirements are clearly identified in purchasing documents as called out in Section 7.4.1, **Purchasing Process**.
- **Calibration Standards** - Calibration checks shall be made against certified masters with a documented and valid traceability to a recognized national or international standard. If no such standard exists, the location may determine a basis for calibration. The location shall list or reference the basis used for calibration in any cases where no such standard exists.
- **Initial Calibration** - In order to validate the specified characteristics, the equipment is calibrated and tagged prior to first use. If the equipment uses any special computer software to obtain its output, that software is used in the calibration check.
- **Ongoing Calibration** - The metrology equipment is periodically adjusted, re-calibrated, and repaired according to a written schedule. This schedule may take into account JVIS-USA's experience with the equipment, the results of prior calibrations, the method and extent of use, and manufacturers' recommendations.
- **Calibration Procedures** - Procedures are written describing the method for calibration of measurement and test equipment.
- **Calibration Status** - The measuring instruments are marked in a way that indicates to the operator that the item is within its calibration period and may be used. (If such

marking is not feasible, an identification number on the device that is traceable to the calibration record may be used.)

- **Records** - Written documents or computer files are maintained as evidence of calibration. They shall identify the equipment checked and the dates and results of re-calibrations.
- **Reaction Plans And Corrective Action** - In the event that monitoring and measuring devices are found out of calibration, previous measuring results are reviewed regarding their validity. Corrective action on the measuring device or product affected is taken, including recall of nonconforming product, if required.
- **Environmental Conditions** - Measurement equipment is calibrated under conditions suitable for the accuracy requirements of the equipment.
- **Storage** - The storage and handling of inspection, measuring and test equipment is done in a way that maintains the accuracy and fitness for use.
- **Authorized Personnel** - Operators and inspectors are instructed on how to make regular adjustments to their measurement equipment such as regular checks with masters and zeroing of gages. However, care is taken to prevent unauthorized adjustments to equipment (or modification of software) that would invalidate the calibration setting.
- **Supplier Metrology** - Each location assures that suppliers furnishing materials or components incorporated into JVIS-USA final products as well as those providing subcontracted manufacturing processing also control their measurement and test equipment. This is done through the supplier systems (2<sup>nd</sup> or 3<sup>rd</sup> party) surveys, but the location may also request additional documentation or perform additional on-site audits when needed to verify continued conformance. Reference Section 7.4, **Purchasing**.
- **Outside Testing Services**
  - ◆ **Other Sister Facilities** - Other sister facilities may be used for measurement, testing, or calibration services. (See Section 7.6.3.1 of this manual, if applicable)
  - ◆ **Other Organizations** - Outside organizations on the approved supplier lists may be used for measurement, testing, or calibration services. (See Section 7.6.3.2 of this manual, if applicable and Section 7.4.1, **Purchasing Process**.)

## 8 Measurement, analysis and improvement

Referenced procedures: **Procedure Matrix** found in Section 2 of the Appendix in this manual (specific **QP-012**, **QP-011**).

## 8.1 General

Each JVIS-USA location plans and implements the monitoring, measurement, analysis and improvement processes needed:

- a) To demonstrate conformity of the product. More detailed instructions on product monitoring are provided in Section 8.2.4, **Monitoring and Measurement of Product**.
- b) To ensure conformity of the quality and environmental management system. Processes used to ensure the conformance and performance of the quality and environmental management systems include those described in Section 5.4, **Planning**, 5.6, **Management Review**, and 8.2.2, **Internal Audit**.
- c) To continually improve the effectiveness of the quality and environmental management system. Processes used to ensure the conformance and performance of the quality and environmental management systems include those described in Section 8.2.3, **Monitoring and Measurement of Processes** and Section 8.5, **Improvement**.

This includes determination of applicable methods, including statistical techniques, and the extent of their use. Statistical methods can be important tools at all stages of the quality process for activities such as market analysis, product design, life testing, process control, capability studies, inspection plans, problem solving and defect analysis. Each location seeks to make use of appropriate techniques such as data collection check sheets, 100% automated in-process checks, pareto diagrams, cause & effect diagrams, graphs, histograms, SPC charts, capability studies, gage R&R studies, run charts, flow charts, FMEAs, and DOE analysis. These statistics are analyzed by department heads and corrective and preventive action, and action for the continual improvement of the quality management system is taken as appropriate.

Assistance is available from the Corporate Quality Department

## 8.2 Monitoring and measurement

### 8.2.1 Customer satisfaction

Management conducts periodic customer satisfaction surveys to verify if customer satisfaction has been achieved. Survey results, which include customer complaints and feedback, customers' business disruptions, customer returns of nonconforming product and delivery performance are analyzed and evaluated. As required, management takes corrective or preventive action. The Management Representative monitors the effectiveness of these corrective or preventive actions.

Each location shall monitor the performance of production processes to demonstrate compliance with customer requirements for product quality and efficiency of the process.

## 8.2.2 Internal audit and Quality and Environmental Management System audit

Reference **QP-004**. Each location conducts internal audits at planned intervals to determine whether the quality and/or environmental management system:

- a) conforms to the planned arrangements, to the requirements of ISO 9001 and ISO 14001 Standard(s) and to the quality and environmental management system requirements established by JVIS-USA, and
- b) is effectively implemented and maintained.

The Quality representative assures that the system of audits and reviews are performed. The Quality representative shall coordinate with the QMS/EMS Coordinator in the development of the audit plan/schedule. Other responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined in this QEM.

The audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be as defined below, and may be supplemented by local written instructions and schedules.

- **Audit Plan** - Each location shall list or reference its Audit Plan/schedule. Details are as described below.
- **Audit Method** – Auditors plan and conduct audits using a process-approach to the maximum extent practical. The specific processes to be evaluated shall be identified in the audit plan/schedule. The location's Quality representative considers the importance of the process along with process and performance metrics when determining the areas to be reviewed, and the depth of the review. In addition, closely related processes should be audited together to the maximum extent practical, especially when the overall process directly relates to the provision of JVIS-USA products and services to the customer. Checklists are available to help guide the auditors in conducting process-based audits. Internal auditors review and consider business and process metrics, where available, to help identify those areas within the process where a more detailed review is required.
- **Frequency** – All areas of the quality and environmental management system are evaluated at least once per year as listed in the audit plan unless justified and approved by the corporate QMS/EMS Coordinator of JVIS-USA (or documented designate). A process that is adequately monitored, and which shows very strong and improving performance may warrant less frequent monitoring. The importance of the process, as well as the adequacy of the process metrics, must be considered prior to requesting approval to reduce the minimum frequency of an audit to less than once per year.

- ◆ A recommended method is to list each core production/business/environmental/key support process applicable to the location on the audit schedule or plan. Each of these areas should be evaluated at least once per year, unless otherwise approved as above.
  - ◆ Group related processes together, where appropriate, to enhance the effectiveness and efficiency of the audit. Most problems happen at the boundaries between processes and activities – try to incorporate critical boundaries into the audit scope.
  - ◆ Planned or extra audits may be performed more frequently at any process or activity based on the current status of that activity (i.e. if metrics, complaints or other indicators suggest problems).
- **Plan Changes** - Audits are performed in accordance with the audit plan. If some aspect of this audit plan cannot be implemented in a given instance, an approved deviation by the QMS/EMS Coordinator (or documented designate) should be arranged.

**Auditors:** Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Other requirements include:

- **Qualification** - Auditors are qualified by completing the JVIS-USA "Internal Auditing" course under the training supervision of a certified auditor or by a training organization approved by the location's Quality Manager/Coordinator (or documented designate). Auditors of the environmental system must complete the environmental auditing module within the Internal Auditing course.
- **Independence** - Each location may utilize any employee to review the quality and/or environmental systems and use the written results for continuous improvement. However, in order to provide an independent in-house verification of whether the location's quality and environmental activities effectively comply with planned arrangements, the auditors used to satisfy the planned audit requirement need to be independent of the specific activities or processes being audited as well as independent of those having direct authority over the departments or activities being audited. Therefore auditors shall not audit their own work.
- **Outside Audits** - On-site audits performed by qualified consultants or qualified JVIS-USA personnel from other locations which cover some audit items listed in the audit plan may be used to satisfy the plan requirements for performing audits.

**Post-audit Activities:** Activities relating to reporting of the results of audits and corrective action include:

- **Records** - Audit records are retained as described in Section 4.2.4, **Control of Records**.

- **Audit Check sheets** - Each location uses a check sheet to guide the auditor in checking the elements of the quality system and serve as a written record of audit results.
- **Audit Results** - Audit results are documented using the completed internal audit check sheet or some summary sheet. The records include the specific examples of the non-conformance found. They may also include, when appropriate, suggestions for corrective actions as well as the status of corrective actions implemented from the previous audit.
- **Corrective Action** - The written results of the audit, with any appropriate recommendations, are brought to the attention of the responsible personnel in the audited area so they may take timely corrective action. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

**NOTE: Any environmental regulatory deficiencies shall be immediately brought to the attention of the Plant Manager/senior management representative as soon as it is discovered.**

- **Follow Up** - Someone not directly involved in doing the corrective action shall do the verification of completed corrective actions based on the audit results. The location shall use a method, such as signing or initialing and dating the audit check sheet, to show that the corrective actions were completed and are satisfactory.
- **Report To Executive Management** - Written audit results or a summary are presented to an executive manager at the location so he or she may be aware of the current status of improvement efforts. Evidence of executive management review are indicated by some method such as signing or initialing and dating the report to show that the audit results were reviewed by the manager (or documented designate) or including in meeting notes which audit results have been reviewed. Each location list or reference the executive manager position(s) authorized to review the audit results.
- **Management Reviews** - The results of internal audits and corrective actions taken from internal audit findings are included in the executive management reviews for each location's quality and/or environmental management system as described in Section 5.6, **Management Review**.

Where applicable, follow-up audits are conducted to ensure that corrective action was implemented and is effective.

## 8.2.3 Monitoring and measurement of processes

During Quality and Environmental Management System Planning, and based on metrics of operational performance and the achievement of quality and environmental objectives, the processes of the quality and environmental management system are analyzed by the Management Representative and responsible department heads regarding their effectiveness. As required, corrective action is implemented to achieve planned results and product conformity, to correct nonconformities or to improve the operational effectiveness and efficiency of the processes of the quality and environmental management system.

### 8.2.3.1 Environmental Monitoring and Measurement

Each location shall establish a written procedure describing how they conduct periodic monitoring and/or measurement of the key characteristics of those processes and activities, which could impact its Significant Aspects or Environmental Objectives.

### 8.2.3.2 Environmental Compliance Reviews

Each location shall establish a process for periodically evaluating compliance with relevant environmental legislation and regulations. The location's Environmental Management Representative shall schedule such audits on a biennially schedule. Unless otherwise specified, each area of regulation shall be audited at least once every two years. Justification for less frequent evaluation must include all of the information discussed in 8.2.2, Frequency, above. Critical areas, such as air permit monitoring should be audited more frequently than the minimum. The Environmental Management Representative determines the initial frequency and adjusts it based on previous evaluation results and the results of ongoing monitoring.

All elements of the applicable regulation shall be evaluated for conformance, not just those areas where performance is poor. Internal compliance reviews must make use of a detailed checklist that identifies the requirements evaluated during the review.

Environmental compliance evaluations may be coordinated with internal management system audits, if practical, but must be carried out by personnel specifically trained in environmental compliance auditing. For internal auditors, such training shall include the following, as a minimum:

- The environmental regulations applicable to the location (what applies)
- The specific requirements related to the above (how it applies)
- Use of the checklists, sheets or other tools used to assist the auditor
- Evaluation reporting

**Outside Evaluations** - On-site evaluations performed by qualified consultants or qualified JVIS-USA personnel from other locations may be used to satisfy the requirements for environmental compliance reviews.

Evaluation results are documented using a compliant audit check sheet. The records include the specific requirements reviewed along with the violations or examples of non-conformance that were found. Any environmental regulatory deficiencies are immediately brought to the attention of the Plant Manager/senior management representative as soon as it is discovered. Plant Management is responsible for notification to an external agency that may be required by policy or by law.

Corrective Action, Follow Up, Report to Executive Management and Management Reviews shall be as described in Section 8.2.2, **Internal Audits**.

### 8.2.4 Monitoring and measurement of product

It is the responsibility of each plant's Quality to establish and maintain procedures and inspection reports for receiving inspection, in-process inspection and final inspection of product and materials.

Product is not released and service is not delivered until all specified requirements have been met, unless otherwise approved by an authorized function - and where applicable. The shipping staff performs a visual inspection of outgoing product to ensure that the product and packaging is in good condition and that marking and labeling requirements are met.

In the event that purchased product is released for urgent production prior to inspection and acceptance by Quality, the product is recorded and controlled in order to permit recall and replacement in case of nonconformity of the product.

Product that does not meet specified requirements is rejected and quarantined.

As required, Quality selects accredited laboratories for certain inspection or testing activities. Records of these inspection results are verified, reviewed and maintained.

Inspection results are recorded and records are maintained. These inspection records document acceptance criteria, inspection results, whether the product was accepted or rejected and the inspection authority responsible for the product release.

### 8.3 Control of nonconforming product and reworked product

Reference **QP-005**. Nonconforming product and product without proper identification is quarantined and controlled. The nonconformity of the product is verified and confirmed by Quality and verification results and recommended disposition or action are recorded. Functions concerned are notified.

Quality, Production or Sales/Service review and authorizes the release of quarantined product for its final disposition, according to the following options:

- rework to meet specified requirements
- accept with or without repair by concession

- evaluate for alternative applications
- reject or scrap

Production ensures that the required concession is received prior to initiation of the repair; if the acceptance with or without repair requires the concession of the customer or the approval or permit of a regulatory body or other authority.

Qualified personnel in the Production process rework Orders. Detailed instructions for required rework are available to operators.

Reworked product is re-inspected by Quality.

As appropriate and required, the customer is notified by the Sales/Service of the proposed use or repair of nonconforming product. Where applicable, Production ensures that the reworked product is identified with the actual condition of the product, including the customer's release authorization.

Records of nonconforming product, including the type of nonconformity, actions taken and concessions obtained are maintained.

In the event that nonconforming product is detected after the product was shipped to the customer, or after its use in production or service, the Engineering department and Sales department analyze the impact of the nonconformity and take appropriate action. As required, the customer is informed and the nonconforming product is recalled.

Nonconforming purchased product and material is returned to the supplier with a Nonconforming Product Report (NCPR) issued by Quality.

### **8.3.1 Correcting Deficiencies Relating to the Environmental Management System**

Some deficiencies in equipment, such as cracked or broken hoses, rusted tanks and fittings, and broken sight glasses, could result in an adverse environmental impact if not corrected. Therefore, such conditions will be identified, controlled and repaired or replaced as appropriate.

**Identification** – Any deficient equipment whose use could create a significant, adverse environmental impact shall be tagged or labeled with a suitable warning tag or other indicator that prevents inadvertent use of the equipment.

**Responsibility** – Deficiencies shall be immediately brought to the attention of the Maintenance Department or Environmental Management Representative (or documented designate) who shall assure that the item is tagged or labeled and, if necessary, removed from use.

**Review & Disposition** – The Maintenance Department or Environmental Management Representative (or documented designate) shall review and appropriately disposition all equipment problems related to outside contractors (ex: the ammonia tank). The Maintenance Department disposes deficiencies associated with JVIS-USA facilities. Such disposition may include repair, or scrap and replace. In certain unusual instances operation with the deficiency may be appropriate in which case specific guidance shall be provided in order to minimize the potential for any accident. Such guidance shall be made available to those who operate, or may operate, such equipment.

#### 8.4 Analysis and use of data

The Management Representative issues metrics regarding the performance of the quality management system. Purchasing issues ratings on supplier performance. The metrics are analyzed by the Management Representative regarding the effectiveness, suitability and opportunities for improvement of the processes of the quality management system, and by department heads regarding the performance and suitability of activities and processes under their responsibility. This includes the analysis of customer complaints and customer returns.

A summary report is issued by the Management Representative, providing information on: customer satisfaction or dissatisfaction, product quality, characteristics and trends of processes and products including opportunities for preventive action, and supplier performance.

The Management Representative controls and coordinates the implementation of required corrective or preventive actions. The department heads to the Management Representative who monitors the progress and results of these actions reports analysis results of metrics and actions.

In addition, trends in quality and operational performance are compared with progress toward objectives and lead to action to support: the development of priorities to resolve customer-related problems, to determine customer related trends and correlation for status review, decision making and longer term planning, and an information system for reporting of product information related to usage.

Environmental indicators may be drawn from indicators and measures used to establish environmental monitoring as described in Section 8.2.3.2, ***Environmental Monitoring and Measurement*** and 8.2.3.3, ***Environmental Compliance Reviews***.

#### 8.5 Improvement - General

It is the responsibility of the Management Representative to form and implement a Quality (QOS) Team for the handling of assigned activities related to the quality and environmental management system.

The purpose of the quality (QOS) team is to review, analyze and make final decisions on Corrective Action Requests and Quality Improvement Proposals, to make recommendations for preventive actions and quality and environmental improvements, to coordinate and implement preventive actions and quality and environmental improvement projects, monitor results, and to provide a forum for any quality and environmental issue which requires a cross-functional approach. Nonconformities and deficiencies are analyzed; root causes are determined and required action is taken or recommended as appropriate.

It is mandatory for departments to have one representative on the Quality (QOS) Team. As required and/or decided by management, selected *Quality Improvement Proposals* are referred to the Quality Planning Team for review regarding their feasibility and benefits.

### 8.5.1 Continual improvement

The planning, coordination and control of activities for continual improvement are the responsibility of the Management Representative and the Quality (QOS) Team. Continual improvement activities include - but are not be limited to - the following:

- activities of the Quality Team under the responsibility of the Management Representative
- actions on results from analysis of data
- evaluation of suppliers
- achievement of departmental quality objectives
- results from internal quality audits
- quality improvement proposals
- corrective actions and preventive actions
- periodic review of controlled documents

The objectives of the corporate quality and environmental policy are taken into consideration for planning of improvement. During Management Reviews, the effectiveness of continual improvement is reviewed and opportunities for improvement are identified.

### Manufacturing process improvement

It is the responsibility of personnel in manufacturing/production to continually monitor the performance of manufacturing/production processes regarding conformity with product characteristics and process parameters. In monthly meetings with the production staff, process performances of production areas are analyzed, and opportunities for improvement are identified and implemented.

### 8.5.2 Corrective action

Reference **QP-006**. It is the responsibility of the Management Representative to assure implementation and maintenance of Corrective Actions by the supplier that defines a corporate approach for corrective action.

Following the established procedure for corrective action, nonconformities are identified, root causes are determined, corrective action is evaluated and defined, recurrence of the nonconformity is prevented, corrective actions and their results are recorded, and the effectiveness of corrective action taken is reviewed. Corrective actions are appropriate to the importance and impact of the addressed nonconformity. Actions are initiated to eliminate the cause of quality or environmental nonconformities in order to prevent reoccurrence.

It is the responsibility of the supplier to inform the Sales/Service department of all customer complaints and related corrective actions.

It is the responsibility of the supplier to establish and maintain records of corrective actions and their results.

### **8.5.3 Preventive Action**

Reference **QP-006**. It is the responsibility of the Management Representative to implement and maintain the documented procedure for Preventive Action, which defines a corporate approach for preventive action to prevent the occurrence of potential nonconformities, deficiencies or problems. Any supplier can suggest a preventive action to the responsible department head.

The process of preventive action includes the following steps:

- identify potential nonconformities, deficiencies or problems
- determine the root causes
- determine the necessary preventive action
- implement the action
- follow-up on status and results
- review the effectiveness of preventive action.

Suppliers analyze and evaluate data of metrics and perform periodic reviews of procedures in order to detect deficiencies and problems and to take preventive action as required.

It is the responsibility of the supplier to establish and maintain records of preventive actions and their results. The Management Representative ensures that relevant information on preventive action is on the agenda of management reviews.

## Appendix

**Section 1:  
JVIS-USA  
Quality Manual - Revision  
Control**



## **Section 2:**

# **Quality Procedures – Master List**

## Quality Procedure Master List

<b>Number:</b>	<b>QP-001</b>	<b>Responsible Department:</b>	All Departments
<b>Document Title:</b>	<b>Document Control</b>		
<b>Revision/Date:</b>	<b>02 2010/06/05</b>		
<b>Affected Positions:</b>	Document Originator Quality Manager All Department Managers Plant Manager Top Management of Mayco International Engineering Management Representative		

<b>Number:</b>	<b>QP-002</b>	<b>Responsible Department:</b>	All Departments
<b>Document Title:</b>	<b>Record Control</b>		
<b>Revision/Date:</b>	<b>02 2010/06/05</b>		
<b>Affected Positions:</b>	Quality Manager. Department Managers		

<b>Number:</b>	<b>QP-003</b>	<b>Responsible Department:</b>	All Departments.
<b>Document Title:</b>	<b>Training</b>		
<b>Revision/Date:</b>	<b>02 2010/06/05</b>		
<b>Affected Positions:</b>	Department Managers Mayco International Employees Human Resources Manager		

<b>Number:</b>	<b>QP-004</b>	<b>Responsible Department:</b>	Quality
<b>Document Title:</b>	<b>Internal Audits</b>		
<b>Revision/Date:</b>	<b>02 2010/06/05</b>		
<b>Affected Positions:</b>	Quality Manager Department Managers Auditors Management Representative		

<b>Number:</b>	<b>QP-005</b>	<b>Responsible Department:</b>	All Departments
<b>Document Title:</b>	<b>Nonconformity Control</b>		
<b>Revision/Date:</b>	<b>02 2010/06/05</b>		
<b>Affected Positions:</b>	Department Managers Quality Production Operator Material Handler		

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<b>Number:</b>	<b>QP-006</b>	<b>Responsible Department:</b>	All Departments
<b>Document Title:</b>	<b>Corrective &amp; Preventative Action</b>		
<b>Revision/Date:</b>	03 2010/06/05		
<b>Affected Positions:</b>	Department Managers Quality Manager		

<b>Number:</b>	<b>QP-007</b>	<b>Responsible Department:</b>	Quality/Environmental
<b>Document Title:</b>	<b>Environmental Aspects &amp; Impacts</b>		
<b>Revision/Date:</b>	02 2010/06/05		
<b>Affected Positions:</b>	Plant Manager EMS Management Representative EMS Steering Committee		

<b>Number:</b>	<b>QP-008</b>	<b>Responsible Department:</b>	Quality/Environmental
<b>Document Title:</b>	<b>Legal &amp; Other Requirements</b>		
<b>Revision/Date:</b>	02 2010/06/05		
<b>Affected Positions:</b>	EMS Management Representative EMS Steering Committee		

<b>Number:</b>	<b>QP-009</b>	<b>Responsible Department:</b>	Quality/Environmental
<b>Document Title:</b>	<b>Communication</b>		
<b>Revision/Date:</b>	02 2010/06/05		
<b>Affected Positions:</b>	Quality Manager Plant Manager EMS Management Representative		

<b>Number:</b>	<b>QP-010</b>	<b>Responsible Department:</b>	All Departments
<b>Document Title:</b>	<b>Operational Control</b>		
<b>Revision/Date:</b>	02 2010/06/05		
<b>Affected Positions:</b>	EMS Management Representative Department Managers Purchasing		

<b>Number:</b>	<b>QP-011</b>	<b>Responsible Department:</b>	Quality/Production
<b>Document Title:</b>	<b>Monitoring Inspection</b>		
<b>Revision/Date:</b>	02 2010/06/05		
<b>Affected Positions:</b>	Quality Production Operator		

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<b>Number:</b>	<b>QP-012</b>	<b>Responsible Department:</b>	Quality/Production
<b>Document Title:</b>	<b>Inspection Equipment Control</b>		
<b>Revision/Date:</b>	<b>02 2010/06/05</b>		
<b>Affected Positions:</b>	Quality Production		

<b>Number:</b>	<b>QP-013</b>	<b>Responsible Department:</b>	Production/Environmental
<b>Document Title:</b>	<b>Chemical Removal</b>		
<b>Revision/Date:</b>	<b>02 2010/06/05</b>		
<b>Affected Positions:</b>	Plant Manager Department Managers		

<b>Number:</b>	<b>QP-014</b>	<b>Responsible Department:</b>	Production/Environmental
<b>Document Title:</b>	<b>Chemical Removal</b>		
<b>Revision/Date:</b>	<b>02 2010/06/05</b>		
<b>Affected Positions:</b>	Plant Manager Department Managers		