



**JENSEN**  
International, Inc.

**Jensen International Inc.**

# **Quality Manual**

**ISO 9001:2000**



**Jensen International, Inc.  
1004 West 14<sup>th</sup> Street  
PO Box 1509  
Coffeyville KS, 67337**

**Jencast Division  
500 West 4<sup>th</sup> Street  
South Coffeyville OK, 74072**

## A message from Top Management:

“We will actively pursue being the world class provider of choice for OEM's and startups in North America utilizing our manufacturing capabilities of iron castings, fabricated components, machining, and finishing services.

We will be the recognized leader for low to medium volume products within our market scope.

This will be accomplished through innovative methods of production, superb quality and process controls, state-of-the-art technologies, continuous improvement programs, exceptional inventory management systems and unmatched customer service.

Jensen International will be uniquely skilled due to our commitment to replicating our knowledge and experience through the training, growth and promotion of motivated employees.

We will achieve growth, excellence, and recognition as the world's foremost provider of full scale manufacturing services through an unwavering commitment to moral, honest and trustworthy relationships with our clients.”



## Quality Manual

### Introduction

Jensen International Inc. developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The contents of this manual are intended to satisfy all the globally recognized requirements of ISO 9001:2000 and API Q1 (8<sup>th</sup> Edition). The content of this manual and its references will be applied to all divisions of Jensen International, Inc., giving direction to our employees and proof to our customers of our commitment to continual improvement.

The content of this manual is intended to supplement the good judgment of all our employees and not intended to standardize our level of creativity. It has been reviewed and approved by the President of the Jensen International Inc.

Approved : \_\_\_\_\_

Quality Administration Manager: \_\_\_\_\_

Issued To:

Revision Level: 1



Quality Manual

# Section 1: Scope



## Quality Manual

### 1.1 General

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This quality manual outlines the policies, procedures and requirements of the Quality Management System (QMS) for all divisions of Jensen International, Inc. The system is structured to comply with the conditions set forth in the International Standard ISO 9001:2000 and API Q1 (8<sup>th</sup> edition) and has been adopted by Jensen International, Inc. to help our organization provide product that consistently meets our customers requirements and continually improves our customers level of satisfaction.

### 1.2 Application

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Jensen International, Inc. has determined that the QMS outlined in this manual, structured to ISO 9001:2000 and API Q1 (8<sup>th</sup> edition) is to be applied to all business activity without exclusion.

## Section 2: Normative Reference

### 2.0 Quality Management System References

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The following documents were used as reference during the preparation of the Quality Management System:

- International Standard ISO 9000, Quality Management Systems – Fundamentals and Vocabulary.
- American National Standard ISO 9001:2000, Quality Management Systems – Requirements
- Project Managers Guide, ISO 9001:2000 Implementation (9000 Store).
- The Basics of ISO 9001:2000 (9000 Store)
- Mold and Core Test Handbook, 3<sup>rd</sup> edition
- Annual Book of ASTM Standards (Iron and Steel Products)
- ASTM Production and Preparation of Gray Iron Castings for Porcelain Enameling.
- AWS D1.1 Structural Welding Code/Steel
- American Petroleum Institute Q1, 8<sup>th</sup> Edition Specifications

## **Section 3: Definitions**

### **3.0 Quality Management System Definitions**

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This section is for definitions unique to Jensen International, Inc.

- Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers or tooling that belongs to a customer.
- Customer supplied product - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property. Tooling is considered Customer owned property.
- Product – The end item result of meeting all contract terms and conditions. (eg: manufactured goods, merchandise, services etc.)
- Quality Records – Documentation of activities required by and including this Quality Manual, including the Master List of Quality forms that includes Document Title, Retention period and last revision date.
- South Coffeyville division: aka Foundry division, Oklahoma Division,. Includes Foundry, Pattern Shop and Casting Services.
- Coffeyville division: aka Jensen division, Kansas Division, 14<sup>th</sup> Street division. Includes Machine Shop, Paint Shop, Fabrication shop and is the Corporate Headquarters.
- QMS- Quality Management System
- QAM- Quality Administration Mgr.
- MED- Manufacturing Engineering Dir.
- MSM- Methods/Standards Mgr.
- HRD- Human Resources Director
- SEM- Safety/Environmental Mgr.
- CMM- Corporate Materials Mgr.
- OSM- Oilfield Sales Mgr.
- SMM- Sales/Marketing Mgr.
- QS- Machine Shop Quality Supervisor
- Top Management- Any member of the Board of Directors

# Section 4: General Requirements

## **4.1 General requirements**

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Jensen International, Inc. has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2000 and additional requirements made by API Q1 (8<sup>th</sup> edition). The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review. Establishment and maintenance of a documented QMS is ultimately the responsibility of the Q.A.M.

To design and implement the QMS Jensen International, Inc. has:

- Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective.
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- Ensures control over any outsourced processes that affect product conformity requirements.
- Maintained responsibility for product conformance when processes are outsourced.
- Established systems to monitor, measure and analyze these processes, and
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

## **4.2 Documentation Requirements**

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### **4.2.1 General**

The QMS documentation includes:

- A documented Quality Policy
- This Quality Manual
- Documented Procedures
- Documented Specifications
- Documents identified as needed for the effective planning, operation and control of our processes, and Quality Records

#### **4.2.2 Quality manual**

This Quality Manual has been prepared to describe Jensen International, Inc.'s QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The Process Flow Diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system.

#### **4.2.3 Control of documents**

All of the QMS documents are controlled according to the Document Control Procedure (161P4.2.3.H). This procedure defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring that documents of external origin are identified and their distribution controlled, and
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose
- Maintaining a Master List of approved QMS documents (forms) that are required, with revision level and retention time noted.
- The review of changes to documents and their approval for use by the QAM, who is also responsible for maintenance of the Master List.

#### **4.2.4 Control of quality records**

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records are maintained according to the Control of Quality Records Procedure (161P4.2.4-1H). This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records. The procedure also assigns responsibility for the collection and maintenance of quality records.



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### 4.3 American Petroleum Institute Monogram Program

The requirements of Jensen International, Inc.; as with all suppliers desiring to acquire and maintain a license to use the API monogram; shall include:

- The Quality System requirements of API Specification Q1.
- The API Monogram Program requirements of API Specification Q1, part 2.
- The requirements contained in API recognized product specifications. At Jensen International, Inc., the applicable API product specification would be API Specification 11E which is the Specification for Pumping Units.
- The requirements contained in the API License Agreement issued to Jensen International.

When Jensen International, Inc. is providing monogrammed product, Parts One and Two as API Specification Q1 are mandatory.

Jensen International, Inc. shall control the application of the monogram in accordance with the following:

- Jensen International, Inc. shall apply API monogram, our license number and the date of manufacture to monogrammed products in accordance with the marking procedure as specified by the API Specification for Pumping Units, 11E.
- The API Monogram shall be applied by Jensen International, Inc. per Specification 11E to both the pumping unit structure and gear reducer after each unit advances through production procedures and has successfully passed all quality checks. Jensen International, Inc. shall remove the monogram from either of these products if is subsequently found to be nonconforming with API specified requirements. Oilfield products of Jensen International, Inc. determined to be nonconforming to API specified requirements shall not bear the API monogram.
- Only Jensen International, Inc.; as a valid API Licensee; shall apply our tag bearing the API monogram to our oilfield products which include pumping unit structures and gear reducers.
- Jensen International, Inc. shall only apply the API monogram on fully manufactured oilfield products at our Coffeyville, KS facility.
- The Quality Administration Manager shall have full authority over the Quality Program at Jensen International, Inc. and; as such; has full authority and responsibility over the application and removal of the API monogram for our products.



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Records required by API product specifications shall be retained for the period of time specified therein. Records specified to demonstrate achievement of the effectiveness of the quality system shall be maintained for a minimum of 5 years.

### **Related Procedures**

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Document Control, Control of Quality Records, Engineering Change Notification



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# Section 5: Management Responsibility



## **5.1 Management commitment**

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Top Management at Jensen International, Inc. has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy. In this Quality Manual, references to Top Management includes any member of the Jensen International, Inc. Board of Directors. Procedure (161P5.1) defines Top Management Responsibilities at Jensen International, Inc.

To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following.

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct Annual management reviews of the QMS.
- Ensure the availability of resources.

## **5.2 Customer focus**

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Top Management at Jensen International, Inc. strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations, as noted in Sections 7.2.1 and 8.2.1 of this Quality Manual. Jensen International, Inc. has established procedures to give our customers access directly to the Top Management Representative. Our "Letter to the President" approach to giving our customers a means to communicate their level of satisfaction will be retained as Quality Records and all communication with the customer under this format will be included in Management Review Output.

## **5.3 Quality policy**

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Top management ensures that the quality policy is communicated to, and understood by all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility as a continual reminder to all employees of the importance of continual improvement.

Management reviews the quality policy at each management review meeting to determine the policy's continuing suitability for our organization. Top Management at Jensen International, Inc. shall ensure the Quality Policy provides a framework for the establishment and review of quality objectives.



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### **5.4 Planning**

#### **5.4.1 Quality objectives**

Top Management shall ensure that quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Objectives have been established for the following: Internal Reject Rates, Customer Rejection Rates, On-Time Delivery, Customer Satisfaction, Corporate Growth and Process Productivity. These objectives are set and tracked for the 3 production divisions of Jensen International, Inc. (Foundry, Machine, Fabrication). Quality objectives are measurable, and reviewed against performance goals on a monthly basis.

#### **5.4.2 Quality management system planning**

Top Management shall ensure that: The planning of the quality management system is carried out in order to meet the requirements given in Section 4.1, as well as the quality objectives and that the integrity of the QMS is maintained when changes to the quality management system are planned and implemented. The Quality Administration Manager shall be responsible to ensure that when changes take place, the integrity of the QMS is maintained during the transition period.

### **5.5 Responsibility, authority and communication**

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#### **5.5.1 Responsibility and authority**

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. This is how Top Management at Jensen International, Inc. ensures Responsibilities and Authorities are defined and communicated within the organization. Job descriptions and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities. An organizational chart is located on page 5 of this manual.

#### **5.5.2 Management representative**

The President has appointed the Quality Administration Manager as management representative. As management representative, as noted in Procedure (161P5.1) he/she will have the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

### **5.5.3 Internal communication**

Top Management has ensured processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include: Weekly Tooling Meetings, Monthly Divisional and Corporate Staff Meetings, Internal Audit Review meetings, Weekly Awareness meetings and an Annual Management Review of the QMS. Top Management is also committed to communicating the strategic plans for growth and continual improvement to all employees.

## **5.6 Management review**

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### **5.6.1 General**

Top management reviews the QMS Annually at management review meetings. The Annual Management Review of the Jensen International, Inc. QMS will be scheduled annually on the 3<sup>rd</sup> Friday in January. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

### **5.6.2 Review input**

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of audits
- Customer feedback
- Process performance and product conformity
- Company level quality data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for improvement

### **5.6.3 Review output**

During this Management Review meeting, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

Responsibility for required actions are assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review. A documented report of the review will be made available to all employees of Jensen International, Inc.

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# Section 6: Resource Management

## **6.1 Provision of resources**

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Jensen International, Inc. has implemented a Quality Management System that complies with the ISO 9001:2000 standard. This implementation was achieved with Top Management commitment and direct involvement, with the appropriation of sufficient resources for the implementation. To effectively maintain and continually improve the QMS and enhance customer satisfaction, management will determine and is committed to providing necessary resources.

## **6.2 Human resources**

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### **6.2.1 General**

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

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

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human resources maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the Training procedure (161P6.2.2-H). This procedure defines the responsibilities for completion, documentation and frequency of training.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

## **6.3 Infrastructure**

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To meet quality objectives and product requirements Jensen International, Inc. has determined the infrastructure needed. The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be documented in Management Review output. Existing infrastructure is maintained to ensure product conformity



## **6.4 Work Environment**

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Jensen International, Inc. has developed and will maintain a work environment suitable for achieving product conformance and optimum efficiency. The work environment is managed for continuing suitability. Data from the quality system and from internal Lean Manufacturing events is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.



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# Section 7: Product Realization

## **7.1 Planning of product realization**

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Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to the Planning of Product Realization procedure (161P7.1). During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product,
- Processes, documentation and resources required
- Verification, validation, monitoring, inspection and test requirements, and
- Criteria for product acceptance

The output of quality planning includes documented quality plans, processes, procedures and design outputs.

## **7.2 Customer-related processes**

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### **7.2.1 Determination of requirements related to the product**

Jensen International, Inc. determines customer requirements before acceptance of an order. Customer requirements include those:

Requested by the customer

Required for delivery and post-delivery activities

Not stated by the customer but necessary for specified use or known and intended use

Statutory and regulatory requirements related to the product

Additional requirements determined by Jensen International Inc.

### **7.2.2 Review of requirements related to the product**

Jensen International, Inc. has a process in place for the review of requirements related to the product (256P7.2.2/356P7.2.2). The review is conducted before the order is accepted. The process ensures that:

Product requirements are defined

Contract or order requirements differing from those previously expressed are resolved

Jensen International, Inc. has the ability to meet the defined requirements

Records are maintained showing the results of the review and any actions arising from the review

Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance

When product requirements are changed, Jensen International, Inc. communicates changes to relevant personnel and amends relevant documents

### **7.2.3 Customer communication**

Jensen International, Inc. has established and maintains an effective means of communicating with customers in relation to:

Product Information

Enquiries, contracts and order handling, including amendments

Customer Feedback, including customer complaints

Nonconforming Product (see section 8.3)

## **7.3 Design and Development**

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

The design and development procedure (161P7.3) outlines the process for controlling the design and development process. The Engineering Department plans design and development according to this procedure. Jensen International will manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output will be updated as appropriate, as design & development projects progress. The design plan must include:

Design and development stages

Required design reviews

Responsibilities and authorities for design and development

Identification of the technical interfaces required for the project

Updating of the design plan as the project progresses

Methods, Assumptions, formulations and calculations

### **7.3.2 Design and development inputs**

Inputs relating to product requirements are determined and documented according to the Design and Development procedure (161P7.3-1). All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. Inputs include:

Functional and performance requirements

Applicable statutory and regulatory requirements

Where applicable, information derived from previous similar designs

Other requirements essential for design and development

Any customer specified requirements

### **7.3.3 Design and development outputs**

Outputs of design and development are documented according to the Design and Development Procedure (161P7.3). They are documented in a format that enables verification against the inputs, and are approved prior to release.

Outputs:

Meet the input requirements

Provide appropriate information for purchasing, production and for service provision

Contain or reference product acceptance criteria

Specify the characteristics of the product that are essential for its safe and proper use.

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

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are recorded in minutes of the design review meetings which are maintained as a quality records. Design reviews must:

Evaluate the results of design and development activities and determine if they fulfill requirements

Identify any problems and propose necessary actions

Include representatives of functions concerned with the design and development stage being reviewed

Final design reviews shall be conducted and documented by individual(s) other than the person(s) who originally developed the design.

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

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained according to the Design and Development procedure (161P7.3)

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

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the design and development procedure.

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

The design and development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review. Procedure 161P7.3 ensures that design and development changes are subject to the same controls as the original design and development.

## **7.4 Purchasing**

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### **7.4.1 Purchasing process**

Jensen International, Inc. ensures that purchased product conforms to the specified purchase requirements using Procedure (410P7.4). The type and extent of control required for suppliers depends upon the effect of the purchased product on our product. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure and shall include verification by Jensen International, Inc. that supplied product conforms to our purchasing requirements by any or all of the following activities:

1. Receiving inspection at our facility,
2. Inspection of final product at the suppliers facility,
3. Surveillance of the supplier's conformance to our purchasing requirements,
4. Verification that the supplier's QMS conforms to an internationally recognized QMS standard/technical spec.

Records of the evaluation and any necessary actions are maintained as quality records.

### **7.4.2 Purchasing information**

Purchasing information describes the product to be purchased, including where appropriate:

Requirements for approval of product, processes and equipment

Requirements for qualification of personnel

Quality management system requirements

Type, class, grade, specs, drawings or other relevant data

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

#### **7.4.3 Verification of purchased product**

The Purchasing procedure (410P7.4) describes the process used to verify that purchased product meets specified purchase requirements. If Jensen International Inc. or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information. Jensen International, Inc. has documented procedures for receiving inspection. The results of these activities are stored as Quality Records.

### **7.5 Production and Service Provision**

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#### **7.5.1 Control of production and service provision**

Jensen International, Inc. plans and carries out production and service provision under controlled conditions according to documented procedure (161P7.5.2). Procedures, work instructions and process inspection include compliance to established and documented plans, codes, standards and internally established control features. Established process controls are documented and include reference to specified requirements and the acceptance criteria. Controlled conditions include, as applicable:

The availability of information that describes the characteristics of the product

The availability of work instructions

The use of suitable equipment

The availability and use of monitoring and measuring devices

The implementation of monitoring and measurement

The implementation of release, delivery and post-delivery activities

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

Jensen International, Inc. validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.



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Validation demonstrates the ability of these processes to achieve planned results.

Jensen International, Inc. has documented the process for validation including:

Defined criteria for review and approval of the processes

Approval of equipment and qualification of personnel

Use of specific methods and procedures

Requirements for records

Revalidation

### 7.5.2.1 Special Processes

Jensen International, Inc. has identified Special Processes as: Welding processes completed in our Fabrication Division and Porcelain Coating of Iron castings at our Foundry Division. Welding is controlled per the American Welding Society D1.1 Specification for Structural Welding. Porcelain Coating is Controlled per ASTM-C660 Standard Practices for Production of Iron Castings for Porcelain Enameling. These documents shall documents shall set the criteria for the review and approval of these special processes.

### 7.5.3 Identification and traceability

Jensen International, Inc. identifies the product throughout product realization according to the Identification and Traceability procedure (161P7.5.3). This procedure defines requirements for identification with respect to production and inspection status and the various methods of maintaining and recording of traceability. When specified customer requirements for Identification and traceability differ from procedures implemented by Jensen International, Inc., these specified requirements will be documented and maintained as quality records and be included on work instructions. Replacement of identification marks and records shall be done only under direction of the QAM. Identification of API monogrammed product shall be completed per additional documented requirements. A special section at the end of this Quality Manual will address these requirements in detail.

### 7.5.4 Customer property

Jensen International, Inc. exercises care with customer property while it is under the organization's control or being used. A procedure (161P7.5.4) outlines the Identification, verification, protection, safeguarding and maintenance of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

### **7.5.5 Preservation of product**

Jensen International, Inc. preserves the conformity of finished products and any constituent parts to the product per procedure (161P7.5.5). This preservation includes identification, handling, packaging, storage and protection. Top Management at Jensen International, Inc. is dedicated to providing and maintaining the proper shipping and handling equipment and adequately controlled warehouses for the storage of our products.

An assessment of product, constituent parts and materials will be conducted at a minimum once per 28alendar year, generally coinciding with the end of our fiscal year (June 30).

## **7.6 Control of monitoring and measuring devices**

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Jensen International, Inc. has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. A documented procedure (256P7.6) outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements. Top Management at Jensen International, Inc. is dedicated to and responsible for provided the necessary environmental conditions to assure the most effective results of monitoring/measuring activities.

Where necessary to ensure valid results, measuring equipment is:

Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards

Adjusted or re-adjusted as necessary;

Identified to enable the calibration status to be determined;

Safeguarded from adjustments that would invalidate the measurement result;

Protected from damage and deterioration during handling, maintenance and storage.

In addition, Quality Control assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Jensen International, Inc. takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained as Quality Records.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

# **Section 8: Measurement, Analysis and Improvement**

## **8.1 General**

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Jensen International, Inc. has plans and implements the monitoring, measurement, analysis and improvement processes as needed

To demonstrate conformity of the product,

To ensure conformity of the quality management system, and

To continually improve the effectiveness of the quality management system.

These processes are identified in documented procedures and include determination of applicable methods, including statistical techniques, and the extent of their use.

## **8.2 Monitoring and Measurement**

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### **8.2.1 Customer Satisfaction**

As one of the measurements of the performance of the quality management system, Jensen International, Inc. monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the Customer Satisfaction procedure (271P8.2.1) and the Management Responsibility Section of this Quality Manual. (Section 5.2).

### **8.2.2 Internal Audit**

Jensen International, Inc. conducts internal audits at planned intervals, no less than once per year, to determine whether the quality management system

Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by Jensen International, Inc.

Is effectively implemented and maintained.

An audit program has been designed and implemented for all divisions of Jensen International, Inc., for each individual department that can effect quality. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure (161P8.2.2).

The procedure defines responsibilities for ensuring that actions are taken and documented without undue delay to eliminate detected nonconformities and their causes. The procedure requires the establishment of deadlines for correcting nonconformities revealed during the audit. The procedure requires a review of previous audits for consideration during the current audit. The QAM shall be responsible for assigning responsibilities and to ensure that the personnel

conducting the audit are independent of the activity or function being audited. Follow-up activities include the verification of the actions taken and the reporting of audit results.

### **8.2.3 Monitoring and measurement of processes**

Top Management at Jensen International, Inc. is dedicated to establishing and maintaining production processes in an atmosphere of Continual Improvement. Jensen International, Inc. establishes and conducts suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. The responsibilities for identifying and carrying out the required monitoring and measuring of processes is documented in the Monitoring/Measuring Processes Procedure(161P8.2.3) and Management Responsibility procedures (Section 5 of this Quality Manual).

### **8.2.4 Monitoring and measurement of product**

Jensen International, Inc. monitors and measures the characteristics of our products to verify that product requirements are fulfilled. This is carried out at appropriate stages of the production process identified in establish procedures for Monitoring/Measuring Product. (161P8.2.4).

Evidence of inspection and documented acceptance criteria is maintained. Inspection documentation indicate the person(s) authorizing release of product. Jensen International, Inc. has implemented safeguards in our data processing system to assure Product release does not proceed until all the planned arrangements have been satisfactorily completed. Under no circumstances shall product be inspected or tested by the same person(s) conducting the activity being inspected.

## **8.3 Control of Nonconforming Product**

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Jensen International, Inc. ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure (161P8.3.). This procedure also defines the requirements for identification, documentation, reporting and analysis of field nonconformities. All API monogrammed product shall further be subjected to the requirements of our Corrective Action procedure, regardless of scope or scale of the issue. It shall be the responsibility of the **MED** to report all field nonconformities and associated Corrective Actions during the annual Management Review.

Documented procedures define the requirements for acceptance in the event that rework can eliminate the nonconformity, seeking customer's concession or taking action to preclude its original use or application. Documented procedures also define the requirement for recording nonconformities, including their nature and any actions taken, including concession. All nonconforming product that is corrected is subjected to the original verification methods and documentation requirements.

When nonconforming product is detected or suspected after delivery or use has begun, Jensen International, Inc. shall take action appropriate to the effects of the nonconformity. This activity shall be documented and maintained as Quality Records, and shall include:

- Notification to customer and/or end user of the product,
- Documentation of notification and any required activities stemming from the nonconformity.

Jensen International, Inc. has also established documented procedures for evaluation, disposition, acceptance (including acceptance by concession) of nonconforming product that doesn't meet manufacturing, design or known or assumed customer requirement.

## **8.4 Analysis of Data**

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Jensen International, Inc. determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for determining, collecting and analyzing this data is defined in the Management Responsibility procedure ( 161P5.1 ). Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to

Customer satisfaction

Conformance to product requirements

Characteristics and trends of processes and products including opportunities for preventive action

Suppliers

## **8.5 Improvement**

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### **8.5.1 Continual improvement**

Jensen International, Inc. continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, management review and lean manufacturing events.

### **8.5.2 Corrective action**

Jensen International, Inc. takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions taken are appropriate to the effects of the nonconformities encountered.

A documented procedure (161P8.5.2) defines responsibilities and requirements for:

Reviewing nonconformities (including customer complaints),

Determining the causes of nonconformities,

Evaluating the need for action to ensure that nonconformities do not recur,

Determining and implementing action needed,

Establishment of a response time for the Corrective Action,

Records of the results of action taken (see 4.2.4), and

Reviewing the effectiveness of corrective action taken.

### **8.5.3 Preventive action**

Jensen International, Inc. determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure (161P8.5.3) defines requirements for:

Determining potential nonconformities and their causes

Evaluating the need for action to prevent occurrence of nonconformities

Determining and implementing action needed

Records of results of action taken (See 4.2.4), and

Reviewing the effectiveness preventive action taken



## Quality Manual

### Related Documents

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Procedure for Deviation Approval (356P7.2.3)

Management Responsibility (161P5.1)

Rework Procedure (256P07-K)

Request for Deviation Procedure (356P06-K)



## Quality Manual

### QUALITY SYSTEM MANUAL REVISIONS

REV.	SECTION	SUB-SEC.	PARA.	CHANGE REQUEST #	DATE	AUTHORIZED BY
<b>Org</b>	Original	Issue			7-1-08	Jim Houk
<b>1</b>	5.5.2	Mgmt R.	N/A		1/9/09	Jim Houk
<b>1</b>	5.4.2				1/9/09	Jim Houk



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