

J&L GEAR & MACHINE LLC  
QUALITY MANAGEMENT SYSTEM

QUALITY POLICY MANUAL

REV. H

**ISSUE DATE: 03-26-2010**

Larry Shorter, President

A handwritten signature in black ink, appearing to read "L Shorter", written in a cursive style.

## **REVISION TABLE**

<b>Revision</b>	<b>Description</b>	<b>Date</b>
Original	Compliance with ISO 9000-1994 and D1-9000 (Boeing)	09/19/01
A	Re-write of manual to comply with ISO 9001-2000 and AS9100 B	11/01/05
A	Include all required procedures and processes within the Quality Manual	11/01/05
B	Re-write management review for one manager shop.	5/1/06
B	Move flow chart of process interaction to addendum	5/1/06
B	8.3 Add reference to Nonconformance Log Book	5/1/06
C	4.2.4, added details for records required for suppliers	6/1/06
C	7.5.2, added validation of processing when returned from supplier	6/1/06
D	Changed references to ISO 9001 to 2000 revision and AS9100 as Rev. B	7/5/06
D	1.2, clarified exclusions to 7.5.2 as to no such processes are performed at J&L as well as the servicing reference.	7/5/06
D	4.1, Changed reference to Addendum 1 to A 01	7/5/06
D	Changed Addendum A-1 to Addendum A 01	7/5/06
E	4.2.1, added reference to Addendum A 02	1/22/09
E	4.2.1, added reference to Addendum A 03	1/22/09
E	4.2.1, added reference to Quality Systems Record Matrix	1/22/09
E	5.5.1, added reference to Organizational Chart	1/22/09
E	7.4.2, amended outgoing Purchase Order Shipper requirements	1/22/09
E	7.5.4, amended need to record outgoing parts on Receiving Record	1/22/09
E	7.5.1.3, amended new program verification procedure and need for programs to be Read-Only	1/22/09
E	7.6, added reference to Calibration Procedure	1/22/09
E	7.5.1.4 removed and added to section 7.5.5	1/29/09
F	4.2.3, added the QA Manager's stamp as acceptable to issue router.	2/04/09
F	7.5.3, removed the clause that only the MR has an inspection stamp.	2/04/09
F	7.6, transferred the job of maintaining the calibration records to the Quality Assurance Manager	2/04/09
F	7.4.2, amended outgoing Purchase Order requirements.	2/04/09



## **1. SCOPE**

### **1.1 General**

This manual contains the policies, procedures and references necessary to describe the quality management system implemented by J&L Gear & Machine for the purpose of customer satisfaction and continual improvement of business processes related to product quality.

J&L Gear & Machine Co. operates a machine shop specializing in precision gear cutting and CNC machining of other components, manufactured for local aviation and commercial industries. These gears and components demand a level of competence and technical knowledge, and involve mutually beneficial supplier relationships to ensure the desired outcome for J&L Gear & Machine's customers.

The design and implementation of J&L Gear & Machine Co.'s quality management system is influenced by

- The business environment, changes in that environment, or risks associated with that environment,
- J&L Gear and Machine Co.'s varying needs,
- J&L Gear & Machine Co.'s particular objectives,
- The products J & L Gear and Machine Co. provide,
- The processes J&L Gear and Machine Co. employs,
- J&L Gear and Machine Co.'s size and organizational structure.

### **1.2 Application**

The system is designed to reflect the requirements of both the international standard, ISO 9001:2008 and the aerospace industry standard, AS9100, Rev. B, and incorporate the clauses necessary to support both internal and customer objectives. J&L Gear & Machine takes exclusion to the following:

- Design activities as listed in paragraph 7.3, Product Design, since the company performs no design services for customers.
- Reference to post-delivery services in 7.5.1 and 7.5.2 as the company does not provide servicing to customers.
- Servicing as referenced in 7.5.2 does not apply except for validation of these processes when performed by a subcontractor and received by J&L.

Any additional references to ISO9001 refer to ISO9001:2008 and any additional references to AS9100 in this manual refer to revision B.

## **2.0 MANUAL REFERENCE**

The basic requirements for the J&L Gear & Machine quality management system are found in the standards ISO 9001 and AS9100.

## **3.0 ACRONYMS**

J&L:	J&L Gear & Machine
QMS:	Quality Management System
MR:	Management Representative

## **4.0 QUALITY MANAGEMENT SYSTEM**

### **4.1 GENERAL REQUIREMENTS**

The J&L Quality Process Flowchart shows the order and interaction of the company's general processes. Refer to Addendum A01.

The order and interaction of specific processes (production, machine, processing, inspection) can be found on a Shop Floor Router. The criteria and methods for effective control, operation and monitoring of processes are found in this manual, Shop Floor Routers, prints, customer requirement documentation and work instructions.

Management enables the availability of necessary resources.

Upon the completion of measurement and monitoring of the processes and analysis of the data, appropriate action is taken to assure planned results are achieved and opportunities for improvement are implemented.

Management of these processes is accomplished in accordance with the requirements of ISO 9001 and AS9100.

Outsourced processes, having impact on the conformity of product requirements, are controlled. The type and extent of control applied to these outsourced processes is defined in the quality management system using the following processes as required:

- Purchasing based on section 7.4 of this manual. Purchase Orders specify what is to be done as well as inspection, processing criteria, etc.
- Control of suppliers based on section 7.4 of this manual
- Planning for Product Realization based on section 7.1 of this manual
- Production Shop Floor Routers (work orders), if applicable, that identify the required outsourcing and verification when product is returned
- Verification of Purchased Product and Services:
  - ✓ Receiving inspection/visual and dimensional, as applicable (verify processing)
  - ✓ Certificate (verify raw materials and processing)
  - ✓ Internal audit of the audits (verify contracted internal auditing)

### **4.2 DOCUMENTATION REQUIREMENTS**

#### **4.2.1 General**

The company has the following documentation to support their quality management system:

- Quality policy statement (Refer to Addendum A 02)
- Quality objectives (Refer to Addendum A 03)
- Quality Manual
- Procedures as addressed in this manual and required by International Standards
- QMS requirements imposed by customer and/or regulatory authorities
- Documents, including records to be determined by J&L to be necessary to ensure the effective planning, operation and control of its processes (Refer to Quality Systems Record Matrix)

The organization ensures that personnel have access to QMS documentation and are aware of documents that apply to their responsibilities. Customers or their representatives have access to QMS documentation and records.

#### **4.2.2 Quality Manual**

The company has established this quality manual to address the requirements of the current revision of AS9100 and ISO 9001.

This quality manual contains:

- a scope of the QMS with exclusions,
- procedures and processes, and
- reference to additional documentation.

#### **4.2.3 Control of Documents**

All documents within the QMS are controlled. Where required, the MR will coordinate any needed document changes with customer or regulatory agencies.

The document control process addresses:

- document approval prior to initial issuance
  - Quality Manual, addendums, procedures, work instructions and forms
    - ✓ Electronic copy developed in “Proposed Document” folder.
    - ✓ Print document, sign and date the cover page of the document.
    - ✓ If applicable, train employees and complete a Training Sign-up form.
    - ✓ Make document available where needed.
    - ✓ Add document to the Master List of Controlled Documents.
  - Shop Floor Router
    - ✓ Unique number assigned.
    - ✓ When released to the shop, inspection stamp of the President or the Quality Assurance Manager and date.
  - Documents of external origin determined by J&L to be necessary for the planning and operation of the QMS(including prints, drawings, etc.)
    - ✓ Note: Documents available from a website are printed as required, reviewed for revision, referenced on Purchase Orders for subcontracted services.
    - ✓ Review by President or Quality Assurance Manager and released to the shop with a Shop Floor Router after approved.
    - ✓ File master, if necessary.
    - ✓ Copy and use as required.
  - Programs and other electronic documents/data
    - ✓ Received by the President
    - ✓ Saved in computer using date in the program as the revision
    - ✓ Back-ups maintained by President
- the review, revision and re-approval of controlled documents;
  - Quality Manual, addendums, work instructions and forms
    - ✓ Electronic copy developed in “Proposed Document” folder.
    - ✓ Print document, sign and date the cover page of the document.

- ✓ If applicable, train employees and complete a Training Sign-up form.
  - ✓ Make document available where needed.
  - ✓ Destroy old revisions/copies.
  - ✓ Update Master List of Controlled Documents with new revision number.
- Shop Floor Router
    - ✓ Changes made by President or Quality Assurance Manager.
    - ✓ Re-issue with same number/re-stamp per replaced router
    - ✓ Re-release to shop.
  - Documents of external origin
    - ✓ Update review by President (website accessible documents included).
    - ✓ File and copy as required.
    - ✓ Destroy old revision/copies
  - Programs and other electronic documents/data
    - ✓ Received by the President
    - ✓ Saved in computer with revision date in the program.
    - ✓ Replace old revision, if applicable
    - ✓ Back-ups maintained by President
- identification of changes and current revision status;
    - Quality Manual, addendums, work instructions – Revision page/revision history updated
    - Forms – Revision at the bottom or top of the form. No identification of changes unless compared to previous revision.
    - Documents of external origin – dependent on the issuing organization.
    - Electronic media – identified within the media
  - distribution of controlled documents where needed;
    - Quality Manual, addendums and work instructions – distribution is based on the information in the Master List of Controlled Documents.
    - Shop Floor Router – distribution is to Production then filed.
    - Forms are distributed as needed.
    - Electronic media is distributed to Production as required.
  - maintenance of legibility and identification of documents
    - All employees are responsible for maintaining legibility and identification of documents
    - documents must have identification prior to issue
    - Documents are maintained for legibility as deemed necessary on a document by document basis including but not limited to: plastic pages, file cabinets, laminated, etc.
    - Electronic documents are backed-up periodically to maintain integrity of data.
    - Document identification and legibility is monitored during internal audits for various topics.
  - the identification and retention of obsolete documents
    - If an obsolete document is maintained, the Quality Assurance Manager will:

- ✓ Create a folder for obsolete documents
- ✓ Write (preferably in red) the word “obsolete” at the top of the document.
- ✓ Place the folder in a file marked Obsolete Documents.
- ✓ Review the file each January to eliminate any unnecessary documents.

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

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

Records shall remain legible, readily identifiable and retrievable. If a record is not legible, identifiable, etc., the MR will do what is necessary to correct the problem.

Control of records is shown in the Quality System Records Control matrix available on the company computer. This control includes identification, storage, protection, retrieval, retention (customer/regulatory agency compliant, if specified) and disposition.

The procedure for controlling records is as follows:

- Quality records are identified in the manual, procedures and work instructions.
- Records may also be identifiable by the product, person or event to which they pertain.
- Records are dated and identify the person whom established the record.
- Records are indexed/grouped/filed to facilitate their retrieval.
- Records are stored in clean, dry areas or otherwise stored to provide protection from any damage or deterioration.
- All records have a designated storage location. Cabinets containing records are clearly labeled to display their contents.
- Records related to the quality management system may be stored in private desk drawers or other locations that are generally known and referred to on the Quality System Records Control Matrix.
- Minimum retention times are established for all records.
- When records have exceeded their retention times, they may or may not be destroyed based on management’s decision. If deemed no longer useful they will be destroyed or recycled. If recycled, they will be rendered unidentifiable so as to protect confidentiality of the customer or J&L.
- Refer to the Quality System Records Control matrix for all information regarding each quality record in the J&L system. The records matrix provides record identification, storage, protection, retrieval, minimum retention time and disposition method.

Supplier records to be maintained are communicated using the J & L Terms and Conditions.

J&L makes quality records available to customers and regulatory agencies as required.

### **4.3 CONFIGURATION MANAGEMENT**

Configuration management is controlled per sections, as each applies to the controls required:

- 5.2, Customer Focus
- 7.1, Planning for Product Realization,
- 7.2.2, Review of requirements related to the product

- 7.5.3, Identification and Traceability, and
- 4.2.3, Document Control.

The President updates product files to assure that the most current revision is available for production.

## **5.0 MANAGEMENT RESPONSIBILITY**

### **5.1 MANAGEMENT COMMITMENT**

J&L uses the following to display their commitment to continual improvement and to its customers:

- Communication about the importance of fulfilling customer legal and regulatory requirements occurs throughout the company. That communication happens through the use of:
  - Issuance of a Shop Floor Router
  - General and product specific training (Retraining when appropriate)
  - Displays and postings in various areas of the facility
  - Frequent communication with personnel due to the fact that this is a small operation
- Quality policy
- Quality objectives
- Management review records, and
- Availability of resources.

### **5.2 CUSTOMER FOCUS**

Management assures that all customer requirements will be determined through J&L processes beginning with planning and quote development. Through policies, objectives and processes, management assures the needed environment to meet customer requirements. By routinely assessing customer satisfaction upon quote development and product delivery, management optimizes customer satisfaction and stays current with customer perception of the company.

### **5.3 QUALITY POLICY**

The Quality Policy statement was developed by management and provides a framework for the defined objectives of J&L. The policy describes the company's commitment to meet the requirements of the QMS and to promote its ongoing improvement. Management communicates the policy and its meaning to all employees.

The quality policy is found in Addendum 2 of this manual.

After communication of the quality policy to all employees, they are expected to fulfill the requirements of this policy in their work related efforts and decisions. The quality policy is reviewed for continued suitability as part of Management Review (5.6).

### **5.4 PLANNING**

#### **5.4.1 Quality objectives**

Management has established quality objectives, which are measurable and consistent with the Quality Policy. These objectives are reviewed as a part of Management Review.

The J&L quality objectives are found in Addendum 3 of this manual. Each employee is empowered to make certain that the tasks assigned to them are performed to the customer's requirements the first time. They are further encouraged to change their production methods to the most efficient ways possible. J&L is committed to continually improving their products by pursuing their goals:

- Provide the customers with only the highest quality products.
- Provide those products on time.
- Provide totally open communications.
- Provide system of continuous quality improvement.
- Provide a system of employee involvement, motivation and training.

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

Management is responsible for QMS planning. This occurs with every order issued to the shop and in the Management Review. When significant changes occur in categories such as the organization, the facilities or business strategy, management takes action to assure integrity and compatibility of the quality management system.

### **5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION**

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

With only one manager in the organization, the President has all authority. Employees have the authority to identify and segregate suspected nonconforming product. Personnel are aware of this distribution of authority. (Refer to “Organizational Chart”)

#### **5.5.2 Management representative**

The Quality Assurance Manager has been appointed to serve as Management Representative. The assigned duties include:

- Overseeing the implementation and maintenance of the quality system in accordance with ISO 9001 and AS9100 requirements.
- Reporting on the performance of the quality management system to management.
- Reporting on the need for improvement of the quality management system to management.
- Encouraging and assisting in extending the understanding of customer requirements throughout the organization.
- The MR has the organizational freedom to resolve matters pertaining to quality.

#### **5.5.3 Internal communication**

Information is shared with personnel that provides insight into the performance of the QMS. Since the company is very small, information is shared with employees verbally.

### **5.6 MANAGEMENT REVIEW**

#### **5.6.1 General**

In order to assure the continuing suitability, adequacy and effectiveness, the President reviews the quality management system annually. The reviews can address the QMS in it's entirety or in parts, as long as the entire quality management system is reviewed during each calendar year. Management Review minutes are maintained per the requirements of the Quality System Records Control matrix.

Sections 5.6.2 and 5.6.3 show the agenda used for all management review meetings. Issues within the agenda that are not discussed will be left blank or “N/A” will be entered. The Management Review Agenda form will be used for all meetings.

### **5.6.2 Review input**

Performance and opportunities for improvement are determined by reviewing the following:

- audit results (internal and external)
- quality objectives
- customer feedback, customer perception
- process performance and product conformity
- status of preventative and corrective actions
- follow-up actions from previous management reviews
- changes that could affect the quality management system
- recommendations for improvement
- review of suppliers
- review of the quality policy and objectives

### **5.6.3 Review output**

Actions associated with the following are included in the output from management review:

- improvement of effectiveness of the processes of the quality management system
- overall improvement of the quality management system effectiveness
- improvements upon product associated with customer requirements
- maintenance of appropriate resources

## **6.0 RESOURCE MANAGEMENT**

### **6.1 PROVISION OF RESOURCES**

Resources for the following purpose are provided on time:

- to implement and maintain the quality management system
- to continually improve upon the quality management system effectiveness
- to ensure customer satisfaction through consistent achievement of customer requirements.

### **6.2 HUMAN RESOURCES**

#### **6.2.1 General**

Personnel performing work at J&L that affects conformity to product requirements are competent on the basis of appropriate education, training, skills and experience. This is listed in the training requirements found in the Training Records in the QA office.

#### **6.2.2 Competence, Training, and Awareness**

The company has established requirements for education, training, skills and experience. The President is responsible for keeping records of employee achievement of requirements. These requirements and records are in the file titled Training Records in the QA office.

Management determines the competence, awareness and training associated with each job within the company and takes action to eliminate any discrepancies. This is done per the following:

- Determine the necessary competence for personnel performing work affecting conformity to product requirements,
- Where applicable, provide training or take other actions to achieve the necessary competence,
- Evaluate the effectiveness of these actions taken,
- Ensure that its personnel are aware of the relevance and importance of their activities and show how they contribute to the achievement of the quality objectives.
- Maintain appropriate records of education, training, skill and experience.

Training will continue until management is content that each employee knows and understands the importance and the relevance that their competence gives to J&L.

When it is necessary, actions other than training will be used to achieve the needed competence and appropriate effectiveness.

### **6.3 INFRASTRUCTURE**

Top management determines the infrastructure needs for each new product and/or service or significant change to existing product and/or service. Consideration is given to the following:

- Building - size, location
- Workspace - size, layout
- Facilities associated with building or workspace - HVAC, water, lighting, electricity, telephone systems, and data lines, compressed air lines, vacuum lines, machine specific requirements

- Equipment – hardware - Furniture, workbenches, storage racks, tools, gages, machines test equipment, vehicles, computers, other office equipment, or information systems,
- Equipment – software
- Services for support preventive maintenance, calibration, engineering, transportation, and emergency.

#### **6.4 WORK ENVIRONMENT**

J&L provides the work environment needed to achieve conformity to product requirements. This may include control of temperature, humidity, lighting and cleanliness. Quality system audits provide feedback to management on work environment issues.

## **7.0 PRODUCT REALIZATION**

### **7.1 PLANNING OF PRODUCT REALIZATION**

J&L has developed a plan for processes needed for product realization. Planning of product realization is provided on the Shop Floor Router, programs and any other documents (prints, drawings, specifications, etc. as applicable). Planning is initiated through the quote process and this method of product planning is consistent with the requirements of the other processes of the QMS. J&L plans product realization taking into account the following items as appropriate:

- quality objectives and requirements for the product;
- the need to establish processes and documents, and to provide resources specific to the product;
- required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
- records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4);
- the identification of resources to support production of the product.

### **7.2 CUSTOMER RELATED PROCESSES**

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

In an effort to identify all customer requirements, the following are considered by management with interface with the customer and as product development takes place:

- product and or service specifications provided by the customer including delivery and post delivery
- requirements not stated by the customer but necessary to provide the product
- statutory and regulatory requirements applicable to the product
- any additional requirements considered necessary by J&L

Quotes may be issued in writing (company document or customer provided form), electronically (e-mail or fax), or verbally (over the phone, face-to-face while at the customer's facility). Quotes are issued by the President who signs and dates to indicate approval.

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

J&L reviews requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer. All quotations, contracts and orders, including changes made, are reviewed to ensure that:

- product requirements are defined,
- any contract or order requirements differing from those previously expressed are resolved,
- that J&L has the ability to meet the defined requirements, and that
- risks due to new technology, new processes or short delivery times are evaluated.

J&L accepts contracts or orders from its customers, including orders accepted verbally. Order acceptance for all orders is noted by the signature and date on the customer's order documentation. If the order is received verbally, an acknowledgment is faxed to the customer. This constitutes contract review and acceptance.

If product requirements are changed on the customer order, J&L reviews them with the customer and resolves any issues prior to order acceptance.

If changes are required after order acceptance, the relevant document(s), including the Shop Floor Router, are amended and relevant personnel are made aware of the changed requirements.

Records of the results of the review and actions arising from the review are to be maintained as a quality record.

### **7.2.3 Customer communication**

J&L determines and implements effective arrangements for communication with customers in relation to product information, inquiries, contracts (including amendments) and customer feedback (including customer complaints).

## **7.3 DESIGN AND DEVELOPMENT**

J&L does not design products. All products are manufactured to customer designs.

## **7.4 PURCHASING**

### **7.4.1 Purchasing process**

The purchasing function has primary responsibility for dealing with outside suppliers of products and services for J&L. The Purchasing, performed by the President or Quality Assurance Manager, locates, develops and approves suppliers capable of providing materials and services that conform to requirements. Approved suppliers are added and removed from the Approved Suppliers List as deemed necessary by the President.

The Approved Suppliers List (with each supplier's scope of approval) is considered to be the suppliers included in the company computer maintained by the President.

Approval of suppliers may be based on any or all of the following criteria:

- Quality of the product (this may be determined after the company has had a chance to use the product),
- Availability based on supplier-stated lead times and company requirements,
- Price
- Customer service criteria (procedure, certification or other evidence)
- Required by a customer.
- Emergency need for material

The application of the above process is affected by the impact of the purchased material on the product and/or service to be manufactured.

J&L is responsible for the quality of all products purchased from suppliers, including any customer-designated sources.

J&L and its suppliers use customer-approved special process sources.

Suppliers are evaluated continually for their quality, delivery, price and customer service. At a minimum of every two years, approved suppliers will be evaluated using the Supplier Evaluation form.

Prior to removal of a supplier for “approved” status, they will be notified of a concern by email stating any concern and asking for resolution, and/or corrective action request. If there is not adequate resolution of the problem, the supplier will be removed from approved status using the Supplier Evaluation form.

#### **7.4.2 Purchasing information**

J&L purchase documents (Purchase Order) require that the supplier include where applicable:

- requirements for approval of product, procedures, processes and equipment,
- requirements for qualification of personnel, including records (see 4.2.4),
- quality management system requirements,
- the name or other positive identification, and applicable issues of specifications,
- drawings, process requirements, inspection instructions and other relevant technical data,
- requirements for test, examination, inspection and related instructions for acceptance by the company.
- requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,
- requirements relative to supplier notification of nonconforming product and arrangements for the approval of supplier nonconforming material,
- requirements for the supplier to notify J&L of changes in product and/or process definition and, where required, obtain the company’s approval,
- right of access by the company and/or the J&L customer and/or regulatory authorities to all facilities involved in the order and to all applicable records (Included in J&L’s Terms and Conditions which are referenced on POs and/or sent to all suppliers)
- requirements for the supplier to flow down to sub-tier suppliers applicable requirements in the purchasing documents, including key characteristics and digital data, where required.

POs are issued to J&L’s suppliers. Confirmation of the purchase order can include, but is not limited to, signed POs, email communication, verbal communication, etc.

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

J&L has established and implemented inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

J&L verification activities may include as applicable:

- obtaining objective evidence of the quality of the product from suppliers including: accompanying documentation, certificate of conformity or analysis, test reports, statistical records, and/or process control records
- inspection and audit at supplier’s premises,
- review of the required documentation, and
- inspection of products upon receipt.

Purchased product is not used or processed until it has been verified as conforming in accordance with the plan for the product, unless it is released under a positive recall

procedure. Positive recall, when required to satisfy a customer, will be guided by the following procedures:

- Raw material, or whatever is received under positive recall, is marked with applicable identification and indication of lot number, heat number, etc.
- The Shop Floor Router is noted as using this material or other component.
- Customers are notified by the quickest media in case of problems related to material/components utilized under positive recall.

Where J&L utilizes test reports to verify purchased raw material, the data in those reports must be acceptable per applicable specifications. J&L will send a material sample annually from miscellaneous suppliers to validate for contents and to receive a test report to compare with the manufacturing report.

Raw material may be validated at any time.

When J&L or a customer wants to perform verification at the supplier's premises, the arrangements and the method of product release is contained in the Purchase Order or other purchasing information. Where specified in the contract, the customer or the customer's representative is given the right to verify at J&L's premises that the J&L's product as well as subcontracted product conform to specified requirements.

Verification by the customer is not used by J&L as evidence of effective control of quality by the supplier and shall not absolve J&L of the responsibility to provide acceptable product, nor does it preclude subsequent rejection by the customer.

## **7.5 PRODUCTION AND SERVICE PROVISION**

### **7.5.1 Control of production provision (Service provision does not apply)**

J&L considers the following when planning the manufacture of product:

- the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,
- the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics,
- the establishment of process controls and set-up sheets. Control plans are developed where key characteristics have been identified and are required by the customer,
- the qualification of operators or monitoring of special processes, where results cannot be confirmed by direct inspection or test.

J&L plans and carries out production in accordance with the applicable procedures and in sequence with operations on the Shop Floor Router.

Production controlled conditions include, as applicable the:

- a) availability of information (drawing or print) that describes the characteristics of the product,
- b) availability of work instructions or Set-Up Sheet, as necessary,
- c) use of suitable equipment determined by management prior to job assignment,
- d) availability and use of monitoring and measurement equipment,
- e) implementation of monitoring and measurement activities, special requirements are listed on the Shop Floor Router,

- f) implementation of product release and delivery activities performed at final inspection,
- g) accountability for all product during manufacture (e.g., parts quantities, split orders, and nonconforming product) performed at final inspection,
- h) evidence that all manufacturing and inspection operations have been completed as planned on the Shop Floor Router, or as otherwise documented and authorized performed at final inspection,
- i) provision and instruction for the prevention, detection, and removal of foreign objects,
- j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and
- k) criteria for workmanship, which can be described by supervision, representative samples or illustrations.

In the event of a split order, part quantities are accounted for by entry on the Shop Floor Router showing quantity shipped, date and signature of management.

#### **7.5.1.1 Production Documentation**

Production operations are carried out in accordance with approved data. This data will include as necessary; Shop Floor Router, drawings, parts lists, inspections, other production documents. Additionally, the Shop Floor Router may identify tools, programs, processing and specific inspection equipment to be used.

#### **7.5.1.2 Control of Production Process Changes**

Management is authorized to approve changes to production processes. J&L obtains approval of changes that require customer approval in accordance with the contract.

Changes affecting processes, production equipment, tools and programs are documented when required. The procedure for making changes is as follows:

- An employee will request that a change be made.
- The President or Quality Assurance Manager will review the request and determine if the change is acceptable and will not affect product quality or remaining processes.
- If the change is made it will be crossed out with a single line across it dated and initialed on the Shop Floor Router or related documents. Management making the approval will initial and date the change.
- The Shop Floor Router may be re-issued with the change(s).
- The employee or the President will confirm that the desired effect has been achieved without adverse effects to product quality. If there is any problem, proper action will be taken.

#### **7.5.1.3 Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs**

Production equipment, tools and programs are validated prior to use. Validation prior to production use may include first article inspection.

Tools in storage are checked to assure that they are preserved without damage or deterioration. This is performed on the Storage Inspection form.

New Numerical Control Machine Programs are checked prior to use. Programs verified previously are run without additional verification.

Preventive maintenance is used for production equipment to assure that they are being maintained for desired use (capable and dependable). Preventive maintenance is accomplished according to the following procedure:

- a) Each machine has a checklist that directs the maintenance to be performed as needed.
- b) The President is responsible for assigning someone to perform the maintenance.
- c) The Preventive Maintenance form is available at the machine.
- d) The date of the maintenance is entered on the form.
- e) As each requirement is completed, it is checked off the checklist.
- f) If there are any concerns, the employee notifies the President.
- g) Once completed, the employee initials the form.

#### **7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside of the J&L Facility**

If J&L plans to temporarily transfer work to a location outside of the facility, then J&L will define the process to control and validate the quality of the work. This is all directed with the Purchase Order.

#### **7.5.1.5 Control of Service Operations**

J&L does not provide servicing or work in a customer's facility.

#### **7.5.2 Validation of Processes for Production Provision**

J&L validates product that is returned from processing (special processes). This validation checks hardness, conductivity, finish, etc. performed by approved suppliers.

#### **7.5.3 Identification and traceability**

Where practical J&L identifies the product by markings applied to the product, tag or container. During the manufacturing process the product may be identified by the Shop Floor Router accompanying the product.

J&L maintains the identification of the configuration (4.3) of the product in order to identify any differences between the actual configuration and the agreed configuration.

J&L identifies the product status with respect to completion of monitoring and measurement requirements throughout product realization.

When stamps are used to indicate acceptance authority, J&L indicates that approved authority on a list, which is maintained as a quality record. No stamp may be re-issued for a period of at least one-year after that media has been cancelled or revoked.

Where traceability is a requirement, J&L controls the unique identification of the product lot as a quality record. The Shop Floor Router is used for traceability in all cases. All records related to an order are kept in one file. This includes certifications of materials and processing.

According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system shall provide for:

- a) identification maintained throughout the production and delivery;

- b) all the products manufactured from the same lot of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
- c) for an assembly, the identity of its components and those of the next higher assembly to be traced;
- d) for a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

#### **7.5.4 Customer property**

Much of the material that is machined by J&L is customer-owned. The company exercises care with customer property while it is under our control or being used by us. Customer property, provided for use or incorporation into the product, is identified, verified, protected and safeguarded. It is noted on the Receiving Record.

If any customer property is lost, damaged or otherwise found to be unsuitable for use, J&L reports this to the customer and maintains records. Customer property can include intellectual property and personal data, including customer-furnished data used for production and/or inspection.

#### **7.5.5 Preservation of product**

J&L preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies (if appropriate) to the component parts of a product. Preservation of product includes, where applicable provisions for:

- cleaning;
- prevention, detection and removal of foreign objects;
- special handling for sensitive products;
- marking and labeling including safety warnings;
- shelf life control and stock rotation;
- special handling for hazardous materials.

The company also ensures that required documents at delivery are protected against loss & deterioration.

Storage requirements will be checked annually for any storage area. This can include fixtures, tooling, raw materials, etc. in a storage area. This assures that proper condition is being maintained.. This storage verification is performed for shelf-life materials, as well. Storage inspections are performed on the Storage Inspection form.

### **7.6 CONTROL OF MONITORING AND MEASURING DEVICES**

J&L determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to specified requirements.

The company maintains a list of equipment that includes definition of calibration process, equipment type, unique identification, frequency of checks, calibration methods, and

acceptance criteria. This can be found on the calibration record maintained. When required, suitable environmental conditions are assured for calibrations, inspections, measurements & tests being carried out.

To assure that measurement capability remains consistent, J&L requires that measuring and monitoring devices:

- be listed and maintained by the Quality Assurance Manager that includes both company and employee owned devices
- be calibrated or verified, or both, at specified intervals, or prior to use, to NIST traceable standards (Refer to Calibration Procedure)
- have identification in order to determine its calibration status
- utilize safeguards for inappropriate adjustment
- be handled, maintained and stored properly
- be recalled to a defined method when requiring re-calibration
- have records of calibration

In the event that calibration reveals that measurement capability has been lost, the reaction plan is as follows:

- a) Review shipping records to see if any product inspected by this equipment has been sent to a customer.
- b) If sent to a customer, contact the customer and notify them of this problem and work out a plan of action.
- c) When product is received, if applicable, inspect the product and if nonconforming, handle product and determine disposition according to section 8.3.
- d) If not, collect any product that has been inspected with this equipment.
- e) Using equipment known to have the required measurement capability, re-inspect the product and take appropriate action, including corrective action if deemed necessary.
- f) If the product is nonconforming, handle product and determine disposition according to section 8.3.

## **8.0 Measurement, analysis and improvement**

### **8.1 GENERAL**

J&L has implemented the monitoring, measurement, analysis and improvement processes required to:

- a) demonstrate conformity to product requirements by 100% inspection
- b) ensure conformity of the quality management system, and
- c) continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

According to the nature of the product and depending upon the specified requirements, J&L may use statistical techniques to support:

- a) 100% inspection of all products
- b) process control;
- c) selection and inspection of key characteristics;
- d) process capability measurements;
- e) statistical process control;
- f) design of experiment;
- g) inspection - matching sampling rate to the criticality of the product and to the process capability;
- h) failure mode and effect analysis.

### **8.2 MONITORING AND MEASURING**

#### **8.2.1 Customer Satisfaction**

As one measurement of the performance of the quality management system, J&L will monitor information relating to customer perception as to whether the company is meeting the customer's requirements. As product is delivered, customer feedback can be obtained related to perception. Other methods may be used as deemed necessary.

#### **8.2.2 Internal audit**

Internal audits of the quality management system are conducted to evaluate the continued compliance of activities with the QMS and its documentation. Auditors do not audit their own work. The following procedure has been established to define responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

- A. For the J&L internal audit system, the following definitions apply:
  - a) Criteria – The general topic to be audited.
  - b) Scope – The specific criteria being audited.
  - c) Frequency – Schedule for audits on the company computer.
  - d) Methods – The way the audits are performed, recorded and followed-up.
  - e) Responsibilities – The MR, working with management, is responsible for the schedule, assigning auditors, training auditors, follow-up in some cases and records maintenance. Auditors are responsible for conducting the audits as planned, completing records and follow-up in some cases.
  - f) Requirements – The MR is required to assure that audits are carried out according to the schedule. The auditors are required to perform the audits on time and provide records and objective evidence, as available.

- B. Audits are performed with trained auditors assigned on the schedule, as follows:
- a) An Internal Audit Checklist is developed to guide the audit. This is done by the MR or the auditors prepare their own checklist.
  - b) Auditors use the checklist to guide the audit and find objective evidence to show whether or not there is compliance to the QMS.
  - c) Auditors can use a copy of a procedure, if applicable, to help guide the audit and make notes.
  - d) At a minimum, the Internal Audit Report is used to record the findings showing both compliance and noncompliance.
  - e) The objective evidence is attached to the checklist and report to establish the audit records.
  - f) Once completed, the audit is reviewed with the person responsible for the area(s) audited.
  - g) The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions taken without undue delay to eliminate detected nonconformities and their causes.
  - h) Findings of noncompliance are used to initiate a Corrective Action Request (CAR).
  - i) Audits are not closed out until all findings of noncompliance have been corrected and followed up for effectiveness.

Internal audits shall meet contract and/or regulatory requirements as applicable.

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

J&L uses suitable methods for monitoring and measurement of the quality management system processes. The monitoring and measurement of process is performed at monthly Management Reviews. Processes are evaluated on their ability to achieve planned results.

If planned results are not achieved, correction and/or corrective action are taken, as appropriate.

In the event of process nonconformity, J&L will:

- a) Take appropriate action to correct the nonconforming process. A Corrective Action Request is used to track action taken.
- b) evaluate whether or not the process nonconformity has resulted in product nonconformity, and
- c) identify and control the nonconforming product in accordance with paragraph 8.3

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

J&L monitors and measures product characteristics to verify that product requirements have been met. This is carried out in accordance with the Shop Floor Router. Evidence of conformity with the acceptance criteria shall be maintained on the Shop Floor Router.

If key characteristics have been identified, they are monitored and controlled as well as a sample of the measurements recorded. If J&L may use sampling inspection as a means of product acceptance and the plan is statistically valid and appropriate for use. When required by contract, the plan shall be submitted for customer approval.

The basic inspection plan allows for the operator to monitor the conformity of their parts. No product is used until it has been inspected or otherwise verified as conforming to specified

requirements. Product is not released under positive-recall procedures. Quality records shall indicate the person(s) authorizing release of product for delivery to the customer.

The release of the product and delivery to the customer shall not proceed until all the operations on the Shop Floor Router have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

#### **8.2.4.1 Inspection Documentation**

Measurement requirements for product acceptance are documented. Information provided includes:

- criteria for acceptance and/or rejection,
- where in the sequence measurement and testing operations are performed,
- a record of the measurement results, and
- the type of measurement instruments required and any specific instructions associated with their use.

Test records shall show actual test results data when required. Where required to demonstrate product qualification, J&L will ensure that records provide evidence that the product meets the defined requirements.

#### **8.2.4.2 First Article Inspection**

J&L provides for first article inspections. A representative part from the first production run will be verified and the results recorded. A new first article inspection is required following any subsequent change that invalidates the previous first article inspection result.

The J&L First Article form or Form AS9102 will be used to record the First Article Inspection.

### **8.3 CONTROL OF NONCONFORMING PRODUCT**

Nonconforming material is identified and provided with disposition. Use of nonconforming material is disallowed by applying the procedure following. Where applicable, J&L deals with nonconforming product by one or more of the following ways?

- Scrapping detected nonconforming product.
- Reworking or repairing nonconformances if they can be brought to specification.
- Accepting nonconformities (with approval from the customer).
- By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

The President and Quality Assurance Manager has the responsibility for review and authority for disposition of nonconforming product. The process for approving additional personnel making these decisions is based on the following:

- Assignment by the President or Quality Assurance Manager
- Demonstration of the ability to inspect products in comparison to customer requirements
- Continual review of decisions
- Indication added to the Authority Matrix as approved

The procedure for handling nonconforming product is as follows:

- a) As soon as nonconforming product is found, the part is marked as nonconforming. The Shop Floor Router is used as a record of the rejects.
- b) The part is segregated if possible.

- c) The President assesses the product.
- d) If warranted, a Corrective Action Request (CAR) is initiated. Refer to section 8.5.2.
- e) The product is evaluated for disposition as described above. If the decision is to use-as-is, the customer will be contacted for agreement. Evidence of their agreement or refusal will be noted on the tag or a printed email, if provided by the customer.
- f) Items noted as scrap will be disposed of as soon as possible. The product will be cut in two or otherwise rendered unusable to avoid inadvertent use.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained are maintained in the Shop Floor Router as well as the Nonconformance Log Book. If the decision is to rework/repair the product, it will be re-inspected to customer requirements.

Re-inspection is required on all reworked or repaired material. Rework material must meet original requirements. Repaired product must meet intended function and other requirements in accordance with customer needs.

## **8.4 ANALYSIS OF DATA**

At J&L, data is analyzed with the objectives below in mind and used to determine the suitability, effectiveness and opportunities for improvement of the quality management system. The data analysis objectives for J&L are:

- to assess customer satisfaction levels (see 8.2.1)
- to determine success rates in fulfilling customer requirements(see 8.2.4)
- to gather knowledge on trends associated with products and processes in order to initiate appropriate preventive action (see 8.2.3 and 8.2.4)
- to maintain awareness of the performance of suppliers and request them to take action to correct or improve their performance (see 7.4)

## **8.5 IMPROVEMENT**

### **8.5.1 Continual improvement**

J&L strives to continually improve 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 and management review.

### **8.5.2 Corrective action**

In order to avoid the recurrence of problems, appropriate corrective actions are taken as follows:

- reviewing nonconformities including customer complaints
- the determination of causes of nonconformities
- assessing the need for actions to avoid recurrence
- the determination of corrective actions needed
- the implementation of determined corrective actions
- making records of the outcomes from actions taken
- verifying the effectiveness of corrective actions taken
- flow down of corrective action requirement when it is determined that the supplier is responsible for the root cause

The procedure for corrective action is as follows:

- a) When warranted by a situation described above, a Corrective Action Request (CAR) is initiated. Obtain a number from the CAR/PAR Log.
- b) The person initiating the CAR must complete the top part of the form through the description of the problem/nonconformance.
- c) The form is then given to the person who has control of the subject area.
- d) This person completes the cause(s) section as well as the corrective action section, assigning responsibilities.
- e) Once all actions are completed, the person who initiated the form is contacted to verify completion of the action.
- f) A date for verification of effectiveness of the action is agreed to.
- g) The CAR is closed out when the action is either deemed effective or there is mutual agreement that effective action cannot be made.
- h) The CAR, whether completed to effectiveness or not, is filed by the MR.

If it is determined that a supplier is responsible for the root cause, that supplier will be contacted by Purchasing for corrective action.

If corrective action is not achieved in a timely manner, based on the magnitude of the problem, specific actions will be taken to bring about completion of the action.

### **8.5.3 Preventive action**

In order to avoid the occurrence of potential problems, appropriate preventive actions are taken which include:

- the determination of potential nonconformities
- the determination of causes of potential nonconformities
- the determination of preventive actions needed
- the implementation of determined preventive actions
- making records of the outcomes from actions taken
- reviewing the effectiveness of preventive actions taken

The procedure for preventive action is as follows:

- a) When warranted by trends in data or a situation described above, a Preventive Action Request (PAR) is initiated. Obtain a number from the CAR/PAR Log.
- b) The person initiating the PAR must complete the top part of the form through the description of the potential problem/nonconformance.
- c) The form is then given to the person who has control of the subject area.
- d) This person completes the cause(s) section as well as the preventive action section, assigning responsibilities.
- e) Once all actions are completed, the person who initiated the form is contacted to verify completion of the action.
- f) A date for verification of effectiveness of the action is agreed to.
- g) The PAR is closed out when the action is either deemed effective or there is mutual agreement that effective action cannot be made.
- h) The PAR, whether completed to effectiveness or not, is filed by the MR.

Preventive action can be tracked by Management Review minutes. In this case a PAR is not required but the actions must be followed up at the next meeting.