Litron, Inc. is committed to providing the highest level of quality products, services, and integrated solutions for RF/Microwave housings, laser services and medical device assembly. Our on-going review of customer satisfaction, product and process performance, and supplier management supports the continuous improvement and effectiveness of this policy and our effort to provide outstanding service to our customers.
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1 Scope

1.1 General

This manual constitutes the policy for Litron’s quality management system. This manual provides Litron personnel and customers with a general description of the quality management system, which has been planned and developed to assure all products and services conform to customer orders and contracts.

Litron maintains a quality system in support of contract manufacturing, integration, and plating services for aerospace products in compliance with AS9100C, Nadcap AC 7004, and Nadcap AC7108. The quality system also supports the design, manufacture, and servicing of laser welding systems in compliance with ISO9001:2008. Litron maintains a quality system in support of Laser based manufacturing and welding services for medical devices, and contract assembly services for medical devices compliant with ISO 13485:2003 and Nadcap AC7110. This manual and all other Litron quality management documentation are proprietary. All unauthorized use is prohibited.

This Quality Manual applies to all activities and personnel associated with the processes depicted in the Process Interaction Diagram shown in Section 3 of this manual. Litron applies this quality management system to supplies, materials and services procured as well as to products produced and/or services rendered for Litron’s customers.

1.2 Exclusions

Section 7.3 of AS9100/C, ISO 13485:2003 and Subpart C of FDA 21 CFR 820 (Design Controls) are excluded from Litron’s Quality Management System. As a provider of contract services and manufacturing for aerospace products and medical devices, Litron does not conduct design activities for medical devices. Litron’s design activities for Laser Systems are conducted per the requirements of ISO 9001:2008.

1.3 Procedures

Written procedures for supplementing the system described herein have been established and are maintained. These Level II documents have not been included in this Quality Manual, but are referenced throughout Section 4 of this manual.
2 Litron Profile

Litron, Inc. is a company specializing in:

- Providing medical, aerospace, electronic and commercial customers with a variety of laser systems for their purchase and use; and
- Supplying contract laser processing and cutting services for medical instruments and implantable devices, aerospace components, sensors and microelectronic packages.
- Supplying contract manufacturing, integration, and plating services for aerospace and defense electronic package contractors and primes.

Litron makes it easy to accomplish goals by offering every dimension of assistance through our diversified laser processing systems and services. Thirty-five years of high-energy beam experience translate into expert recommendations from our laser and software engineers.
3 Litron Process Interactions (Chart 1)
4 Quality Management System

4.1 General Requirements

Litron has established, documented and implemented a quality management system in accordance with the requirements of the international standards defined in section 1.1 of this manual. Litron is committed to maintaining and continually improving the effectiveness of this quality system.

Litron:

a) has determined the processes needed for the quality management system and their application throughout the organization,
b) has determined the sequences and interaction of these processes,
c) has determined the criteria and methods needed to ensure that both the operation and control of these processes are effective,
d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
e) monitors, measure where applicable, and analyzes these processes, and
f) implements actions necessary to achieve planned results and continual improvement of these processes.

Litron will manage these processes in accordance with the requirements of the international standards defined in section 1.1 of this manual.

Where Litron chooses to outsource any process that affects product conformity to requirements, these processes will be controlled. This control is defined within the supplier management procedures.

NOTE 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2: An outsourced process is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

a) the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements,
b) the degree to which the control for the process is shared,
c) the capability of achieving the necessary control thru the application of PR7.4.

Reference Document

FDA 21 CFR Medical Devices Part 820: Quality System Regulation
AS9100/C: Quality Management Systems – Requirements for Aviation, Space and Defense Organizations
Nadcap AC7004 (Aerospace Quality Systems)
Nadcap AC7108 (Chemical Processing)
Nadcap AC7110 (Welding)
4.2 Documentation Requirements

4.2.1 General

The quality management system documentation shall include:

a) documented statements of a quality policy and quality objectives,
b) a quality manual,
c) documented procedures and records required by the international standards defined in section 1.1 of this manual,
d) documents including records, determined by Litron to be necessary to ensure effective planning, operation, and control of its processes

The quality system documentation is structured as follows:

Level 1
- Policies
  - Quality Manuals
  - Quality Policy
  - Quality Objectives
  - Organizational Chart

Level 2
- QMS Process Procedures

Level 3
- Work Instructions
- Process Control Documents
- Drawings

Level 4
- Records

Reference Document
ISO 9001:2008   Quality Management Systems - Requirements
FDA 21 CFR Medical Devices Part 820: Quality System Regulation
AS9100/C: Quality Management Systems – Requirements for Aviation, Space and Defense Organizations
Nadcap AC7004 (Aerospace Quality Systems)
Nadcap AC7108 (Chemical Processing)
Nadcap AC7110 (Welding)
4.2.2 Quality Manual

The contents of this quality manual define the scope of Litron’s Quality Management System, including the exclusions defined in section 1.2. The documented Level II procedures that support the QMS are referenced where appropriate throughout this manual. The interaction of processes is defined in section 1.3, and references the corresponding procedures. The structure of documents maintained in support of Litron’s QMS is defined in section 4.2.1.

4.2.3 Control of Documents

Documents required by the quality management system are controlled.

Documented procedures are established to define the controls needed to:

a) approve documents for adequacy prior to issue,
b) review and update as necessary and re-approve documents,
c) ensure that changes and the current revision status of documents are identified,
d) ensure that relevant versions of applicable documents are available at points of use,
e) ensure that documents remain legible and readily identifiable,
f) ensure that documents of external origin determined by the organization to be necessary for planning and operation of the quality management system are identified and their distribution controlled,
g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Reference Document
PR4.2.3 Control of Documents Procedure

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 are controlled. The documented procedure defines the controls needed for the identification, storage, protection, retrieval, retention and disposition of quality records. Litron supports their contract manufacturing services for medical devices through the creation and maintenance of a device master record (DMR). For each serialized device or lot of devices manufactured, Litron maintains a device history file (DHF) that includes all records resulting from the manufacturing process. DMRs and DHRs are made available to customers and regulatory agents as necessary to comply with requirements. DMRs and DHRs are formatted to be compliant with the requirements set forth in FDA GMPs.

Reference Document
PR4.2.4 Control of Records Procedure
FDA 21 CFR Part 820 Subpart M
5 Management Responsibility

5.1 Management Commitment

Top management provides evidence of its commitment to the development and improvement of the quality management system and to continually improving its effectiveness by:

a) communicating to Litron employees the importance of meeting customer as well as statutory and regulatory requirements through the establishment of contract review procedures, training procedures, and internal postings on quality management dashboards;
b) establishing the quality policy and communicating it via postings throughout the organization,
c) ensuring that quality objectives are established, monitored and measured, and results communicated to the organization through postings on quality management dashboards;
d) conducting management reviews quarterly, and
e) ensuring the availability of resources.

5.2 Customer Focus

Top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality Policy

Top Management ensures that the quality policy:

a) is appropriate to the purpose of Litron,
b) includes a commitment to comply with requirements and to maintain and continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within Litron via postings throughout the organization, and
e) is reviewed during management review meetings for continuing suitability.

Reference Document
QP5.3 Quality Policy

5.4 Planning

5.4.1 Quality Objectives

Quality objectives, including those needed to meet requirements for product [see 7.1 a]), are established at relevant functions and levels within Litron, and are identified in the process interaction defined in section 3. The quality objectives are measurable and consistent with the quality policy.

Reference Document
QO5.4.1 Quality Objectives
5.4.2 Quality Management System Planning

Top management ensures that
a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top management ensures that responsibilities and authorities are defined and communicated within Litron through the use of job descriptions and periodic performance reviews. The organizational chart (Chart 2) defines the interrelation of personnel executing the QMS, and establishes independence and authority where necessary. The Quality Assurance Manager is responsible for complaint and adverse event investigation, determination and reporting.

5.5.2 Management Representative

Top Management has appointed the Quality Assurance Manager as Management Representative. Top Management ensures that the Management Representative, irrespective of other responsibilities, has responsibility and authority that includes:
a) ensuring that processes needed for the quality management system are established implemented and maintained,
b) reporting to top management on the performance of the quality management system and any need for improvement,
c) ensuring the promotion of awareness of customer requirements throughout Litron, and
d) maintaining liaison with external parties on matters relating to the quality management system.

5.5.3 Welding Engineering Representative

The Welding Engineering Authority is the top management member that acts for and on behalf of the customer on all matters within the scope of the AWS D17.1 standard. The Engineering Authority has the responsibility for the structural integrity or maintenance of airworthiness of the hardware and compliance to all contract documents. The Quality Assurance Manager and Open Air Welding Manager share the responsibilities of the Welding Engineering Representative as defined in PR5.

5.5.4 Internal Communication

Top management ensures that appropriate communication processes are established within Litron and that communication takes place regarding the effectiveness of the quality management system. The primary means of communication is the Quality Management Dashboards, located at 207 Bowles Road in the central hallway outside of the Met Lab and at 45 Bowles Road in the personnel break room.
5.6 Management Review

5.6.1 General

Top management reviews the quality management system quarterly to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews are maintained by Quality Assurance.

5.6.2 Review Input

The input to management review includes information on
a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system,
g) recommendations for improvement, and
h) new or revised regulatory requirements.

5.6.3 Review Output

The output from the management review includes any decisions and actions related to
a) improvement of the effectiveness of the quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.

Reference Document
PR5 Management Responsibility Procedure
6 Resource Management

6.1 Provision of Resources

Litron determines and provides the resources needed
a) to implement and maintain the quality management system and continually improve its effectiveness, and
b) to meet regulatory and customer requirements.

New resources needed to meet new customer projects or increased forecasts and volumes are determined through the contract review process. Resource effectiveness is reviewed during management review to determine if changes or additions are needed to maintain the effectiveness of the current Quality Management System.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements are competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Training, and Awareness

Job Descriptions are maintained to determine the necessary competence for personnel performing work affecting conformity to produce and process requirements. Litron training activities are planned and executed to ensure that employees achieve competence requirements. Records of education, training, skills, and experience are maintained by Quality Assurance and Human Resources. New Hire Orientation and regular performance reviews are conducted to ensure that personnel are aware of the relevance and importance of their activities as they contribute to the achievement of the quality objectives and that current competency is effective.

6.3 Infrastructure

Litron determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable
a) buildings, workspace and associated utilities,
b) process equipment (both hardware and software), and
c) supporting services (such as transport, communication, or information systems).

The process for determining and planning necessary maintenance activities and their frequency is documented in the preventive maintenance procedure. Equipment listings, maintenance requirements, and records of maintenance performed are maintained through the Harrington Maintenance Pro program.

6.4 Work Environment

Litron determines and manages the work environment needed to achieve conformity to product requirements.
a) Litron documents the requirements for health, cleanliness and clothing requirements for personnel when contact between personnel and the product or work environment could adversely affect the quality of the product. These requirements may be documented through:
   i. Job Descriptions
   ii. Process Control Documents
   iii. Work Environment work instructions

b) Work environment conditions that may have an adverse effect on product quality are documented, controlled, and monitored through:
   i. Foreign Object Prevention Program
   ii. ESD/Clean Room Procedures
   iii. Process Control Documents
   iv. Risk Assessment Activities

c) Personnel that work temporarily on product or in environments that require controls as defined in the activities listed in 6.4 a and b are trained on requirements prior to beginning work. Where circumstances dictate (for purposes of efficiency or expedition) workers may perform work under the supervision of a trained person in lieu of documented training.

d) All products and tools/supplies are inspected for contamination prior to introduction into controlled work environments. In the event of a contamination event within controlled work environments, contaminated product is removed from the area and quarantined via NCMR procedures. Production is ceased in the contaminated area until investigation and corrective action activities are completed and the work environment is returned to control requirements/limits.

Reference Document
PR6 Resource Management Procedure
PR6.1 Clean Room Environment
PR6.2 Preventive Maintenance
7 Product Realization

7.1 Planning of Product Realization

Litron plans and develops the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, Litron determines the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, and documents, and to provide resources specific to the product;

c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;

d) first article records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4);

e) configuration management appropriate to the product (Laser Systems only);

f) resources to support the use and maintenance of the product (Laser Systems only).

The output of this planning is documented through the product realization records, process control documents, process validation protocols and reports (IQ/OQ/PQ), and device master records where applicable.

Risk Management activities are defined during contract review/production planning per Litron risk management procedures. Records of risk management are maintained by Quality Assurance and reference in the DMR where appropriate.

When the transfer of work is determined to be required by top management, the transfer will defined, planned, and executed through the process/product validation and supplier management program. The following situations are controlled in this manner:

- Transfer of production or services from one facility to another
- Transfer of production or services from Litron to an out-sourced supplier
- Transfer of production or services from one Litron approved supplier to another supplier

Reference Document

PR7.1 Product Realization Procedure
ISO 14971: Medical Devices – Application of risk management to medical devices
AS9100 Section 7.1.2 Risk Management
7.2 Customer-related Processes

7.2.1 Determination of Customer Requirements Related to the Product

Litron determines
a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) requirements not stated by the customer but necessary for specified or intended use, where known,
c) statutory and regulatory requirements applicable to the product, and
d) any additional requirements considered necessary by Litron.

7.2.2 Review of Requirements Related to the Product

Litron reviews the requirements related to the product through the use of quotation checklists and product realization checklists/guidelines. This review is conducted prior to the commitment to supply a product to the customer (e.g. submission of a tender, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that
a) product requirements are defined and documented,
b) contract or order requirements differing from those previously expressed are resolved,
c) Litron has the ability to meet the defined requirements,
d) Special requirements of the product are determined, and
e) risks have been identified and communicated to top management.

Records of the results of the review and actions arising from the review are maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by Litron before acceptance.

Where product requirements are changed, Litron ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication

Litron determines and implements effective arrangements for communicating with customers in relation to
a) product information,
b) inquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints,
d) advisory notices.

Reference Document
PR7.2 Customer Requirements and Communication Procedure

7.3 Design and Development

7.3.1 Design and Development Planning

Litron plans and controls design and development of laser systems products per the design and development procedure.
During the design and development planning, Litron determines
a) the design and development stages,
b) the review, verification and validation that is appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development.

Litron manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and development progresses.

7.3.2 Design and Development Inputs

Inputs relating to product requirements are determined and records maintained (see 4.2.4). The inputs include
a) functional and performance requirements,
b) applicable statutory and regulatory requirements,
c) where applicable, information derived from previous similar designs, and
d) other requirements essential for design and development.

These inputs are reviewed for adequacy. Requirements are to be complete, unambiguous and not in conflict with each other.

7.3.3 Design and Development Outputs

The outputs of design and development are in a form suitable for verification against the design and development input and are approved prior to release.

Design and development outputs
a) meet the design and development input requirements,
b) provide appropriate information for purchasing, production, and service provision,
c) contain or reference product acceptance criteria
d) specify the characteristics of the product that are essential to its safe and proper use, and
e) identify key characteristics and other critical items along with specific actions to be taken to meet these characteristics.

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements (see 7.3.1)
a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions, and
c) to authorize progression to the next stage.

Participants in such reviews will include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained through review meeting minutes.

7.3.5 Design and Development Verification
Verification is performed in accordance with planned arrangements 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.

### 7.3.6 Design and Development Validation

Design and development validation is performed in accordance with planned arrangements (see 7.3.1) to ensure that resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

### 7.3.7 Control of Design and Development Changes

Design and/or development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions are maintained (see 4.2.4).

**Reference Document**

PR7.3  Design and Development Procedure

### 7.4 Purchasing

#### 7.4.1 Purchasing Process

Litron ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product are dependent upon the effect of the purchased product on subsequent product realization or the final product, as well as the supplier’s approval status and performance metrics.

Litron evaluates and selects suppliers based on their ability to supply product in accordance with our requirements. Quality Assurance is responsible for supplier approval, review, and changes in supplier status. Criteria for selection, evaluation and re-evaluation are established and documented in the purchasing procedures and communicated to Suppliers via the Supplier Quality Manual. Litron maintains a register (Approved Supplier List) detailing the approval status and scope of the approval. Regular evaluations of supplier performance are performed, and procedures define the frequency, criteria for acceptable performance, and actions that may be taken when suppliers do not meet requirements. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained by Quality Assurance.

#### 7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including where appropriate a) requirements for approval of

- product,
- procedures,
- processes, and
- equipment,
b) need, requirement for qualification of personnel,
c) quality management system requirements,
d) the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant data,
e) requirements for design, test, inspection, verification (including production process verification where appropriate), use of statistical process controls for product acceptance, and related instructions for acceptance by the organization, and the identification of key characteristics.
f) requirements for test specimens (e.g. production method, number, storage conditions) for design approval, inspection/verification, investigation, or auditing,
g) requirements regarding the need for the supplier to notify Litron of non-conforming product, obtain Litron approval for the disposition of non-conforming product, and to notify Litron of changes in product, process, suppliers, manufacturing facility, flowdown of customer requirements to the supply chain, record retention requirements, and Litron’s (as well as Litron customer’s) right of access to the applicable areas of all supplier (and supply chain) facilitates.

Litron ensures the adequacy of specified purchase requirements prior to communication to the supplier. Purchasing information (purchase orders, receivers, inspection results and certifications, etc.) are maintained per record retention procedures.

7.4.3 Verification of Purchased Product

Litron establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Records of inspections are maintained by Quality Control and/or Purchasing.

Where Litron or its customer intends to perform verification at the suppliers’ premises, Litron states the intended verification arrangements and method of product release in the purchasing information.

Reference Document
PR7.4 Purchasing Procedure

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Litron plans and carries out production and service provision under controlled conditions. Controlled conditions are documented in the Process Control Documents (PCDs) and/or Work Order Routers, and include as applicable:

a) The availability of information that describes the characteristics of the product,
b) The availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary,
c) The use of suitable equipment,
d) The availability and use of monitoring and measuring equipment,
e) The implementation of monitoring and measurement,
f) The implementation of product release, delivery and post-delivery activities,
g) The implementation of defined operations for part serialization, labeling, and packaging,
h) Accountability for all product during production (e.g. part quantities, split orders, nonconforming product),
i) Evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized,
j) Provision for the prevention, detection, and removal of foreign objects,
k) Monitoring and control of utilities and supplies to the extent that they affect conformity to product requirements,
l) Criteria for workmanship, specified in the clearest practical way (e.g. written standards, representative samples, illustrations).

a) Litron ensures that the production process plan considers: Establishing, implementing, and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,
b) Designing, manufacturing, and using tooling to measure variable data,
c) Identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and
d) Special processes needed.

Litron maintains Device History Records (DHRs) that provides traceability and identifies the amount manufactured and amount approved for distribution for each batch (lot) of medical devices assembled. Quality Assurance and Quality Control are responsible for the review, verification, and approval of DHR records.

7.5.1.1 Specific Provisions for Medical Device Manufacturing Quality System Manufacturing Compliance

Where required for medical device production controls, Litron’s responsibility to comply with requirements of ISO 13485:2003 7.5.1.2.1 is identified during contract review. Litron documents the requirements for cleanliness of the product in the PCD or DMR inspection specifications. Where Litron has agreed with the customer to control the sourcing of sterilization procedures that have been previously validated by the customer, Litron will ensure that contract sterilization suppliers meet the requirements of ISO 13485:2003 section 7.5.1.3.

As a contract medical device manufacturer, Litron does not perform installation or servicing activities as defined in ISO 13485:2003 sections 7.5.1.2.2 and 7.5.1.2.3.

7.5.1.2 Specific Provisions for Aerospace Quality System Manufacturing Compliance

Production Process Verification: Litron uses a representative item from the first production run of a new part or assembly to verify that the production process, production documentation, and tooling are capable of producing parts and assemblies that meet requirements. This process is repeated when changes occur that invalidate the original results. The results of this verification are documented via the first article inspection (FAI) process. Unless otherwise directed by customers, the AS9102 format is used to document first article inspection.

Control of Production Process Changes: Litron defines the scope of changes affecting production processes in change control and risk assessment instructions. The instructions identify the personnel authorized to approve changes. Litron controls and documents changes affecting the process, production equipment, tools, and software programs through change control procedures. The results of the changes are assessed through risk assessment and validation activities to confirm that the desired effect has been achieved without adverse effects to product conformity.

Control of Production Equipment, Tools and Software Programs: Production equipment, tools and software programs used to automate and control/monitor product realization processes are validated through the FAI process prior to release for production and are maintained. Storage requirements, including periodic preservation/condition checks, are defined through the preventive maintenance program for production equipment or tooling storage.
Post-Delivery Support: Litron provides post-delivery support for manufactured Laser Systems. The post-delivery support includes (as applicable):

a) Collection and analysis of in-service data,
b) Actions to be taken, including investigation and reporting, when problems are detected after delivery,
c) Control and updating of technical documentation,
d) Approval, control, and use of repair schemes, and
e) Controls required for off-site work (e.g. organization’s work undertaken at the customer facilities)

7.5.2 Validation of Processes for Production and Service Provision

Litron validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

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

Litron establishes arrangements for these processes including, as applicable

a) Defined criteria for review and approval of the processes,
b) Approval of equipment and qualification of personnel,
c) Use of specific methods and procedures,
d) Requirements for records (see 4.2.4), and
e) Revalidation.

Litron identifies computer software applications that control production operations that affect the ability of the product to conform to specified requirements through the risk assessment process. Such software applications are validated through the production planning process prior to use. Records of the validation are maintained through the production planning process.

Particular requirements for sterile medical devices: Litron does not define or control the sterilization process of medical devices that are intended to be sterilized prior to use.

Reference Document
PR7.1 Product Realization Procedure
7.5.3 Identification and Traceability

Litron identifies the product by suitable means throughout product realization.

7.5.3.1 Identification

Litron identifies the product status with respect to monitoring and measurement requirements throughout product realization through the use of work order routers. Stamps used to identify accepted product status are issued, controlled, and maintained through Quality Control.

The identification of the configuration for Laser Systems in order to identify any differences between the actual configuration and the agreed configuration is documented and maintained through the configuration management process. For contract manufacturing services, identification of configuration of the part is maintained through the use and control of customer drawings and parts lists.

7.5.3.2 Traceability

7.5.3.2.1 General Traceability

Litron maintains documented procedures for traceability that define the extent of product traceability and the records required. Where traceability is a requirement, Litron controls and records the unique identification of the product and maintain records (see 4.2.4). Medical devices returned to Litron are identified and distinguished from conforming product through documented nonconforming material control procedures.

7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices.

In defining the records for traceability, Litron includes records of all components, materials, and work environment conditions if these could cause the medical device not to satisfy its specified requirements.

Litron performs contract manufacturing services for medical devices only, and does not employ agents or distributors on behalf of their customers for medical device distribution.

Records of the name and address of the shipping package consignee are maintained in the DHR.

7.5.3.3 Status Identification

Litron identifies the product status with respect to monitoring and measurement requirements throughout product realization through the use of work order routers. Identification is maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used, or installed.

Reference Document
PR7.5.3 Identification and Traceability Procedure

7.5.4 Customer Property

Litron exercises care with customer property while it is under its control or being used. Litron identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. If
any customer property is lost, damaged or otherwise found to be unsuitable for use, Litron will report this to the customer and maintain records (see 4.2.4).

**Reference Document**
PR7.5.4  Customer Property Procedure

### 7.5.5 Preservation of Product

Litron maintains documented procedures for the preservation of the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Documented procedures for preservation include, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for

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

Documented procedures and work instructions are established for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions are controlled and recorded in process control documents, work order routers, and DHR records.

**Reference Document**
PR7.5.5  Preservation of Product Procedure
7.6 Control of Monitoring and Measuring Equipment

Litron identifies the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. Litron maintains compliance to the ISO 10012 guidance for measurement management systems.

Litron establishes documented procedures and inspection instructions to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is

a) calibrated or verified, or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
b) adjusted or re-adjusted as necessary;
c) having identification in order to determine its calibration status;
d) safeguarded from adjustments that would invalidate the measurement result;
e) protected from damage and deterioration during handling, maintenance and storage.

In addition, Litron assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Litron takes appropriate action on the equipment and any product affected through the nonconforming materials process.

Litron maintains a register of the monitoring and measurement equipment through the Harrington Calibration Database. The database includes definition of the process employed for the equipment’s calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria. Records of the results of calibration and verification are maintained (see 4.2.4).

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

Reference Document
PR7.6 Control of Monitoring and Measuring Equipment Procedure
8 Measurement, Analysis and Improvement

8.1 General

Litron plans and implements the monitoring, measurement, analysis and improvement processes needed to
a) demonstrate conformity of product requirements,
b) ensure conformity and effectiveness 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.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction / Feedback

As one of the measurements of the performance of the quality management system, Litron monitors information relating to customer perception as to whether Litron has met customer requirements. Litron manages established documented procedures for a feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes. The feedback system includes (but is not limited to) the following inputs:

a) Product conformity
b) On-Time delivery
   performance
   c) Customer
      complaints and corrective action requests
d) Customer
   satisfaction surveys
e) Post-production
   performance reports from customers

Litron’s feedback system includes top management review to facilitate customer satisfaction improvement that addresses deficiencies identified by these evaluations, and an assessment of the effectiveness of such improvement.

Reference Document
PR8.1 Measurement, Analysis and Improvement Procedure
8.2.2 Internal Audit

Litron conducts internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements (see 7.1), to the requirements of the international standards defined in section 1.1 of this manual and to the quality management system requirements established by Litron, and is effectively implemented and maintained.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. The selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. Quality Assurance is responsible for the management of the internal auditing process.

Records of the audits and their results are maintained by Quality Assurance.

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Reference Document
ISO 9001:2008 Quality Management Systems - Requirements
PR8.2.2 Internal Audit Procedure

8.2.3 Monitoring and Measurement of Processes

a) Litron applies 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. In the event that planned results are not achieved or a process nonconformity occurs, Litron will:
   Take appropriate action to correct the nonconforming process,

b) Evaluate whether the process nonconformity has resulted in product nonconformity,

c) Determine if the process nonconformity is limited to a specific case or whether it could have affected other process or products, and

d) Identify and control any nonconforming product.

Reference Document
PR8.1 Measurement, Analysis and Improvement Procedure
8.2.4 Monitoring and Measurement of Product

Litron monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements, as documented in PCDs and/or DMRs. The documented requirements include:

a) Criteria for acceptance and/or rejection,

b) Where in the sequence measurement and testing operations are to be performed,

c) Required records of the measurement results (at a minimum, documentation of acceptance or rejection on the work order router), and

d) Any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including key characteristics, have been identified Litron ensures they are controlled and monitored in accordance with the established production process.

When using sampling inspection as a means of product acceptance, Litron ensures the sample plan is justified on the basis of recognized statistical principles and appropriate for use. Litron employs ASQ Z1.4 when developing sampling plans, unless otherwise directed by the customer.

Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and segregated to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Evidence of conformity with the acceptance criteria is documented and maintained in work order routers and DHRs. Records indicate the person(s) authorizing release of product for delivery to the customer.

The release of product and delivery of service to the customer shall not proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Reference Document
PR8.2.4 Monitoring and Measurement of Product Procedure

8.3 Control of Nonconforming Product

Litron ensures that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure defines the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, Litron deals with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application;

d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started:
e) by taking actions necessary to contain the effect of the nonconforming product on other processes or products.

For all contract manufacturing services, Litron does not make dispositions of Use-As-Is or Repair. Litron notifies customers in a timely manner when nonconforming product is discovered internally or found to be delivered. In the event that a customer determines to accept the product as is (under concession), records of the customer’s disposition (including authorization of acceptance authority and consideration for regulatory requirements) are maintained. Customers that determine product may be repaired are required to submit process instructions and acceptance criteria for all repair activities directed to Litron manufacturing.

Litron follows a documented procedure for the performance of rework activities. Rework plans are reviewed and approved by the customer prior to execution when customer contracts require such notification and approval. Rework instructions undergo the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, engineering and quality assurance are responsible to make and document a determination of any adverse effect the rework may have on the product. Inspection records include re-verification to demonstrate conformity to the product requirements.

Records of nonconformities, including the nature of the nonconformity and any actions taken, are maintained by Quality Assurance. Product dispositioned for scrap is conspicuously and permanently marked and segregated until the product is physically rendered unusable.

Reference Document
PR8.3 Control of Nonconforming Product Procedure
8.4 Analysis of Data

Litron determines, collects and analyzes appropriate data to determine the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to
a) customer satisfaction and feedback (see 8.2.1),
b) conformance to product requirements (see 8.2.4),
c) characteristics and trends of processes and product including opportunities for preventive action, (see 8.2.3 and 8.2.4), and
d) suppliers (see 7.4).

Records of the analysis of data are maintained by Quality Assurance and documented through Management Review presentations and Quality Dashboard Performance postings.

8.5 Improvement

8.5.1 Continual Improvement

Litron 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 and management review. All improvement activities are monitored and evaluated for effectiveness through the corrective and preventive action processes.

Litron follows established procedures for the issue and implementation of advisory notices and adverse event reporting. Adverse event notification received by Litron is immediately communicated to the manufacturer.

Records of all customer complaint investigations are maintained by Quality Assurance. If investigation determines the activities outside the organization contributed to the customer complaint, relevant information is documented and reported to the organizations involved. When customer complaints do not result in a corrective and/or preventive action, the reasons are authorized by Quality Assurance and documented.

Reference Document
PR8.1 Measurement, Analysis and Improvement Procedure

8.5.2 Corrective Action

Litron takes corrective action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure is established to define requirements for
a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for actions to ensure that nonconformities do not recur,
d) determining and implementing action needed (including updating documentation),
e) record the results of investigation and action taken (see 4.2.4),
f) reviewing the effectiveness of the corrective action taken.
g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,

h) specific actions where timely and/or effective corrective actions are not achieved, and

i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

**Reference Document**
PR8.5.2 Corrective and Preventive Action Procedure

### 8.5.3 Preventive Action

Litron determines action to eliminate the causes of potential nonconformities in order to prevent occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure is established to define requirements for

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed (including updating documentation),
d) records of and investigation and results of action taken (see 4.2.4), and
e) reviewing the effectiveness of the preventive action taken.

**Reference Document**
PR8.5.2 Corrective and Preventive Action Procedure
<table>
<thead>
<tr>
<th>Revision</th>
<th>CRF #</th>
<th>Description of Change</th>
<th>Requested By</th>
<th>Date</th>
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<tr>
<td>00</td>
<td>--</td>
<td>Initial Release</td>
<td>--</td>
<td>7/1/02</td>
</tr>
<tr>
<td>01</td>
<td>--</td>
<td>Change made to Organization Chart layout</td>
<td>--</td>
<td>7/10/02</td>
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<tr>
<td>02</td>
<td>--</td>
<td>Process #’s added to Interactions. Organization Chart Updated.</td>
<td>--</td>
<td>11/21/02</td>
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<tr>
<td>03</td>
<td>--</td>
<td>Quality Policy updated after review. Address changed.</td>
<td>--</td>
<td>8/11/03</td>
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<tr>
<td>04</td>
<td>358</td>
<td>Organization chart updated to reflect addition of the Applications Engineer.</td>
<td>Eric Hoff</td>
<td>7/7/06</td>
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<tr>
<td>05</td>
<td>397</td>
<td>Added approval signatures. Clarified change history.</td>
<td>Bob Haberern</td>
<td>6/11/07</td>
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<tr>
<td>06</td>
<td>537</td>
<td>Added approval signatures. Clarified change history.</td>
<td>Paul Lombardini</td>
<td>12/16/08</td>
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<tr>
<td>07</td>
<td>579</td>
<td>ISO 2000 is no longer in service and has been updated to 2008.</td>
<td>Paul Lombardini</td>
<td>6/23/09</td>
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<tr>
<td>08</td>
<td>621</td>
<td>The updated organizational chart was added.</td>
<td>Paul Lombardini</td>
<td>5/17/10</td>
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<tr>
<td>09</td>
<td>714</td>
<td>Updated the organization chart - revised Packing Department Manager to Chris Stefaniak and removed John Griffin.</td>
<td>Paul Lombardini</td>
<td>2/3/11</td>
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<tr>
<td>10</td>
<td>760</td>
<td>Updated the organization chart - added a Plating Department Manager – Michael Sacco and added the new buildings address to the first page.</td>
<td>Paul Lombardini</td>
<td>11/9/11</td>
</tr>
<tr>
<td>11</td>
<td>1007</td>
<td>Updated organization chart. Updated all sections to reflect the addition of QMS requirements specific to ISO 13485:2003 and AS9100/C. See redline attached to CRF for specific changes and additions.</td>
<td>Tara Douglas</td>
<td>07/22/13</td>
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<tr>
<td>12</td>
<td>1044</td>
<td>Updated section 1.1 to clarify the scope of 13485:2003 activities. Removed “where appropriate” from 7.5.3</td>
<td>Tara Douglas</td>
<td>09/12/13</td>
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<td></td>
<td>Added logo to cover page. Updated scope statement to exclude section 7.3 of AS9100 and add ISO 9001 to laser systems design scope. Added Nadcap to scope and section 4.1. Added Welding Engineering Authority to section 5. Updated PR documents associated with Resources in section 6. Updated Org Chart.</td>
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<td>8/13/14</td>
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