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# **HERMETIC SOLUTIONS GROUP**

*Enabling Technology*

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## **Litron Division**

### **THE GOLD STANDARD LASER AND MACHINING SPECIALIST FOR**

**MEDICAL · AEROSPACE · INDUSTRIAL ·  
SYSTEMS**

### **SOLUTIONS**



# **SUPPLIER QUALITY MANUAL**

## INTRODUCTION

Litron, Inc. was established in 1997 as a Laser Systems Manufacturer. Over the years we've grown to incorporate four distinct, yet interrelated, divisions to better serve our clients needs; Laser Welding and Cutting Services, Laser Systems, Microwave Electronic Packaging, and Glovebox Hermetic Sealing (welding / sealing in an inert environment). Litron specializes in servicing the Aerospace, Medical, and Industrial markets for everything from the initial electronic packaging design to final hermetic sealing. The Litron philosophy is simple: to fully support our customer's laser processing and package fabrication needs. We do this by working on both sides of the make/buy decision. By providing both equipment and outsourcing, Litron becomes a true partner in our customer's success.

This document establishes the quality requirements for Litron suppliers of inventory products / parts, special processes, calibration services, and acceptance test equipment and services. The SQM (Supplier Quality Manual) requirements set forth here must be adhered with as part of the execution of all purchase contracts, unless otherwise indicated in writing in an agreement signed by the supplier and Litron Quality Assurance.

## SUPPLIER REQUIREMENTS

All suppliers are expected to maintain the standards set forth in Appendix II: Supplier Code of Conduct. Litron reserves the right to discontinue business relationships with suppliers who violate those policies and procedures.

### 1.0 COMMUNICATION AND INTERACTION

Litron suppliers are required to communicate in timely manner responses to RFQ's, Purchase Order Acknowledgements, Conformity/Contract Review Issues, Change Notifications, and Product Delivery. Communications should be directed through the primary buyer listed on the purchase order. Changes to contract requirements, delivery dates, or changes as noted in section 6.0 shall be made in writing.

### 2.0 SUPPLIER APPROVAL

Supplier assessment and approval is based on review of a supplier's capability, performance, and quality management system. Initial assessment and approval includes a supplier questionnaire and review of existing certifications and registrations. It is recommended that all Litron suppliers, at a minimum, are able to demonstrate compliance to the current revision of an industry recognized quality management system such as ISO 9001 (or ISO 17025 for test and calibration services).

***Special Requirements for Medical Implant Suppliers:*** Suppliers of products or services intended for medical device applications are encouraged to comply with ISO 13485 certification and/or FDA registration before contracts are awarded. A supplier that does not hold a ISO 9001 or ISO 13485 certification that wishes to be awarded a medical device related contract may be approved through the conduct of a quality systems audit, where the results shows successful compliance to equivalent systems. This audit may be a desk audit or on-site audit as determined by Litron QA staff.

### **3.0 SUPPLIER STATUS: AUDIT / ASSESSMENT**

Litron suppliers must allow Litron personnel access to supplier manufacturing and/or testing facilities and manufacturing, testing, and quality documentation, as deemed appropriate, for the purposes of desk/telephone audits and/or on-site audits to verify compliance to applicable standards and regulations.

Litron will assess and publish supplier's status at least once per year, with frequency increased based on the criticality of suppliers' parts/services and past performance success. Supplier performance is assessed based on both on-time delivery and quality (ppm rejected) equally. Delivery performance is on-time based on 3 days early and five days late. The supplier's status will be based on the performance assessment. Approved suppliers will maintain a performance of 80% or better as defined below. Suppliers performing below approval requirements will be notified by Litron QA and subject to SCAR resolution and/or on-site audit assessment in order to maintain an approved status. Suppliers unable to maintain an acceptable performance status will be "dis-approved". A Disapproved supplier must work with Litron top management to develop a re-approval strategy. Upon successful implementation of the strategy, Litron QA will review activities for effectiveness and may issue a recommendation to move the disapproved supplier to Approved.

3.1. Unapproved Suppliers: status that identifies new suppliers which have not been evaluated and dispositioned as approved suppliers through the qualification process. Litron may choose to enter into a single event contract with said supplier, according to supplier management guidelines as defined in Litron PR7.4.

3.2. Approved Suppliers: status that identifies suppliers based on capability, complaint quality system, and product quality that may furnish parts or services used in current production.

3.2.1. Acceptable: Combined service and delivery performance is 90% or better.

3.2.2. Marginal: Combined service and delivery performance is 80-89%. Supplier should provide resources necessary to improving performance to the acceptable status.

3.2.3. Unacceptable: Combined service and delivery performance is below 80%. Supplier must submit corrective action plan no later than 30 days from receipt of performance results and/or Litron SCAR notification. Litron QA may conduct an on-site audit as part of the effectiveness evaluation process.

3.3. Disapproved Suppliers: status that identifies suppliers whose services or products have been discontinued for any of the following:

3.3.1. Performance that violates contractual agreements or technical requirements.

3.3.2. Failure to respond to delivery requirements or persistent poor quality performance.

3.3.3. Failure to respond to CARs resulting from audit or product discrepancies.

3.3.4. Changes to their capabilities since their original approval was granted.

#### **4.0 BUSINESS INTERRUPTION CONTINGENCY PLAN**

Litron suppliers are required to have business interruption contingency planning. This plan should address items such as, but not limited to, natural disasters (e.g. hurricanes, tornadoes, flooding, etc.), facility downtime (e.g. due to union strike, fire damage, computer system failure, etc.), sub-tier supplier interruptions and logistics failures.

#### **5.0 QUALITY SYSTEM REQUIREMENTS**

Suppliers to Litron should have an established Quality System and documented Quality Policy or Quality Manual that includes all appropriate elements of a quality management system. All suppliers should comply at a minimum with an ISO 9001 or similar quality system. Specific contracts may require compliance to aerospace standards such as NADCAP or AS9100 certification, or compliance to medical device standards such as ISO 13485 or FDA Part 820.

#### **6.0 SUPPLIER COMPETENCE**

Suppliers shall ensure that organizational knowledge and employee qualification exists to meet the needs to produce and support the products and services provided to Litron. Documentation of competence in the form of certifications or other training records shall be provided to Litron upon request.

#### **7.0 CHANGE CONTROL AND NOTIFICATION**

Changes to products or the services rendered which have potential impact to material of composition, design, form, fit or function or have potential impact on safety, quality, identity, potency, or purity require formal notification to Litron. Litron requires notification of changes with a time-line appropriate for the product's supply chain lead time, but notification must always be received by Litron prior to shipment of the goods by the supplier to the Litron facility.

Suppliers must have an established change control system in place to ensure appropriate timing for the change request notification, ensure traceability of the implemented change, and ensure there is no negative impact to the supplied product's quality or production volume delivered to Litron.

Examples of changes that may affect the quality of the product or service are listed below. Suppliers are encouraged to contact Litron quality assurance if and when there is doubt as to whether a change is subject to the controls of this requirements section.

- ✚ Manufacturing facility location change
- ✚ On-site relocation of established manufacturing processes
- ✚ Sub-tier supplier source/process change
- ✚ Raw material changes
- ✚ Manufacturing method/process changes
- ✚ Changes to machine, tool, die, molds, etc.
- ✚ Inspection method changes
- ✚ Rework or sorting

For goods requiring rework or sorting

When rework or sorting may be used to correct or cull for a non-conformance, the supplier shall first obtain Litron written approval. Litron and the supplier will agree on the qualification requirements for the rework or sort process and the supplier shall submit the required samples and documentation for approval. Once approved, the parts (labels, packaging, shipping, and quality documents) must be clearly identified as REWORKED or SORTED. The characteristic(s) requiring the rework or sort must also be clearly noted on the quality and shipping documents.

#### Sub-tier Suppliers

When changes are communicated to Litron suppliers from their direct suppliers (i.e. sub-tier suppliers) which have potential impact to the material of construction, design, form, fit or function or have potential impact on safety, quality, identity, potency, or purity of the products supplied to Litron, it is the obligation of the supplier to notify Litron of such changes. Litron suppliers should have an appropriate system in place to ensure that they will be informed by their suppliers of any changes that may potentially impact the Litron approved part, design, and/or quality requirements.

### **8.0 REGULATORY REQUIREMENTS**

Products or services provided to Litron shall be manufactured and supplied in compliance with all applicable laws and regulations, including without limitation the laws, regulations and standards applicable under any legislation or regulation pertaining to quality system and good manufacturing practice requirements.

### **9.0 CALIBRATION SYSTEM REQUIREMENTS**

Litron requires its suppliers to have a calibration system that is compliant, at a minimum, to one of the following:

- ✚ ANSI/NCSL Z-540
- ✚ ISO 10012

Litron will not recall or monitor the cal status of equipment it loans outside its QMS. When equipment is loaned to a supplier, the supplier is responsible for (1) entering the equipment in its own calibration recall system, (2) ensuring the equipment is calibrated when using it for product acceptance, and (3) covering any costs associated with recalibration. If the supplier opts to have Litron calibrate the equipment, it shall contact the buyer to coordinate the required calibration activities with QA. The supplier is responsible for the cost of the calibration, shipping, and any repairs related to its neglect of the equipment.

### **10.0 INSPECTION / FIRST ARTICLE INSPECTION**

The supplier shall have inspection plans that show the sample size, methods of inspection, descriptions of the attributes inspected and provisions for inspection results. The supplier shall use ANSI/ASQ-Z1.4 (corresponds to MIL-STD-105) when a sampling plan is used.

- 10.1. Performance Sensitive Parameters: The supplier shall perform 100% inspection and record actual values for characteristics noted on the engineering drawing as *Performance Sensitive Parameters*.

10.2. Key Characteristic: The identification of and requirements for key characteristics will be specified on the purchase order.

## 11.0 PACKAGING, LABELING, AND TRACEABILITY

All suppliers are required to utilize packaging that preserves the procured product's integrity. All packaging should be designed to ensure the integrity of the product throughout the supply chain. Suppliers of packaging materials that are customer-facing must obtain guidelines for graphics, approvals and artwork from Litron.

- ✦ Electrostatic Discharge (ESD) Control: Suppliers that provide ESD sensitive products shall protect parts, assemblies, and equipment from the effects of ESD per the requirements of MIL-STD-1686 or ANSI/ESD S20.20.

Suppliers must ensure that labeling and marking of products shipped to Litron is sufficient to enable adequate identification and traceability.

### 11.1. Certificates of Compliance (CoC) and Analysis (CoA)

CoCs are required on all shipments and shall include the following:

- ✦ Supplier's name, address
- ✦ Date of shipment
- ✦ Litron PO number
- ✦ Part number, revision, and nomenclature listed on the purchase order. (If purchase order lists both supplier's and Litron's part numbers, list the Litron part number).
- ✦ Quantity
- ✦ For CoA, test method, test results, and controlling standard (eg. ASTM B 448 Rev 11)
- ✦ Signature and title of the certifying person or authorized representative
- ✦ Statement of conformance to the PO-invoked specs and requirements. Example: *"This certifies that the above parts are of the quality called for, and are in all respects in accordance with the applicable drawings, specifications, PO..."*.

## 12.0 NON-CONFORMANCE CONTROL AND MATERIAL REVIEW

Suppliers must have established procedures for the identification, documentation, segregation (where practical), evaluation, and disposition of non-conforming product to prevent its intended release or use.

### 12.1. Material Review Authority

Suppliers must review the drawings and specifications and resolve issues prior to notification to Litron. Unless otherwise specified, supplier's authority for disposition of non-conformances is limited to rework, return to supplier, and scrap, as follows:

- 9.1.2 Rework: Restore product back to drawing or spec compliance
- 9.1.3 Return to Supplier: Return discrepant subcontractor product for subsequent rework (as defined in 9.1.2) or replacement.
- 9.1.4 Scrap: Permanent removal and destruction of product found to be unfit for use. Scrap product shall be physically destroyed such that it is unusable for its originally intended use and cannot be reworked to provide the appearance of being serviceable.

### **13.0 RECORD RETENTION POLICY**

Quality records must be legible, readily retrievable and stored in a suitable environment that provides minimal risk of damage or deterioration and prevents loss. In the event of contract termination, insolvency, or upon request, all quality records pertaining to Litron contracts must be surrendered to Litron.

A records retention process must define quality records and specify the retention periods for these documents, if applicable by regulation or guidance. Unless otherwise specified by PO or contract, the following records shall be retained for seven (7) years:

- ✚ Litron Purchase Orders
- ✚ First Article Inspection Reports
- ✚ In-Process / Final Inspection and Test Results
- ✚ Completed Manufacturing / Fabrication documents (e.g. travelers, routers)
- ✚ Traceability and Serialization
- ✚ Calibrations
- ✚ Certifications and Labeling

## APPENDIX I: STANDARD PURCHASE ORDER TERMS

1. **Prices:** All prices for goods and/or services described in the attached purchase order are firm unless otherwise agreed to in a writing signed by the Buyer. No additional charges of any kind, including, but not limited to, any form of service charges, or any form of interest, finance, and/or late charges, or any charges for boxing, packing, loading, bracing or cartage will be allowed, unless specifically agreed to in writing signed by the Buyer.
2. **Taxes:** Seller will pay all taxes now or hereafter due by law upon or on account of the production, sale, shipment, or use of goods and services covered by this order.
3. **Delivery Schedule:** Seller will comply with Buyer's specific delivery schedule without delay. Seller agrees not to make material commitments and production arrangements in excess of the amount or in advance of the time necessary to meet the schedule. .
4. **Notice of Delay:** If Seller for any reason anticipates difficulty in meeting Buyer's designated delivery date, or in meeting any other requirement of this Order, Seller shall immediately notify Buyer in writing, giving pertinent details; however, such notice shall be informational only and its receipt by the Buyer shall not be construed as a waiver by the Buyer of (i) any delivery schedule or designated delivery date, or (ii) any rights of remedies provided by the Buyer by the terms and conditions of this Order or by law. .
5. **Delays in Delivery:** Neither party shall be liable for any delay due to acts of God, terrorist acts, acts or demands of any Government or any Governmental agency, strikes, fires, floods, accidents, or other unforeseeable causes beyond its control and not due to its fault or negligence. Within (5) days from the beginning of any such delay, the party shall notify the other party in writing of the cause of the delay. .
6. **Assignment:** Assignment by Seller of part, or all, of this Order or any payment due or to become due without the prior written consent of Buyer, shall be void. .
7. **Set-Off:** Buyer shall be entitled at all times to set-off any amount owing at any time from Seller to Buyer against any amount payable by Buyer to Seller. .
8. **Compliance with Laws:** Seller agrees to comply with all applicable present and future national, state, and local laws and regulations. Seller will defend, indemnify, and save Buyer harmless from all losses, damage, and penalties in the event Seller fails to comply with any of the foregoing and, in the event of such failure, Buyer also may at its option cancel this Order and any contract resulting from this Order. .
9. **Disclosure of Information:** Any knowledge or information that Seller discloses to Buyer regarding a quotation, an Order, or the purchase of goods or services shall not be confidential or proprietary to Seller and shall be acquired free from any restrictions, unless Buyer agrees in writing. If Buyer discloses to Seller any confidential or proprietary technical or business information, whether reduced to writing or not, Seller agrees not to disclose any such information to anyone at any time without buyers consent. .
10. **Work on Buyer's Premises:** If this order includes work to be performed on Buyer's premises or its customers' premises, Seller will observe the highest safety standards, maintain adequate insurance, furnish evidence of such insurance at Buyer's request and indemnify Buyer from all losses and damages arising out of such work. .
11. **Insolvency:** If Seller ceases to conduct its operations in the normal course of business, is unable to meet its obligations, or if any proceeding under bankruptcy or insolvency laws is brought by or against Seller, or a receiver for Seller is appointed or applied for, or an assignment for the benefit of creditors is made, Buyer may terminate this Order without liability, except to pay for goods and services that were previously made and subsequently delivered in accordance with the terms of this Order. .
  - o A..
  - o B..
12. **Waiver:** Failure to assert rights or a course of conduct by either party shall not constitute a waiver by such party of any of its rights. If any provision(s) herein or in any Order shall be held to be invalid, illegal, or enforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired. .



13. Termination: Buyer may terminate all or any part of this Order for convenience or for cause, upon five (5) days written notice to Seller. If for convenience, Seller will deliver to Buyer all work completed up to the termination date, and Buyer's sole liability is to pay Seller for such work completed (including prorated profit thereon). If Seller fails to comply with any requirement or term of the Order, Buyer may terminate for cause without liability; and Seller will pay all damages. In no event shall Buyer be liable for any damages, compensation, lost profits, special, indirect, incidental or consequential damages. .
14. Buyer's Property: (a) Buyer's property includes, but is not limited to: (i) intellectual property ("IP") incorporated into all goods and services under this Order, (ii) IP conceived, produced or developed by Seller, whether directly or indirectly or alone or jointly with others, in connection with or pursuant to Seller's performance of this Order; and (iii) creations and inventions that are otherwise made by Seller through the use of Buyer's equipment, funds, materials and/or confidential information; provided, however, that any techniques, technology or tools independently developed by Seller before this Order is received and not developed for, or paid for by the Buyer, shall not be the Buyer's IP. Buyer claims and reserves all rights and benefits afforded under federal and international IP laws in all IP and confidential information furnished by Buyer to Seller and that Seller is granted only a limited right to use such IP and confidential information only to provide goods and services for Buyer. (b) Seller has full responsibility for the defense of any claim against Buyer, its agents or customers for alleged infringement of any IP (e.g. patents, copyrights, trade secrets); and will indemnify Buyer against all expenses, losses, royalties, profits, and damages including court costs and attorney fees. Buyer may actively participate through its own counsel at Seller's expense if it so desires. In case the use of said goods or part thereof is enjoined. Seller shall either procure for Buyer the right to continue using said goods or part thereof, or replace the infringing goods or part thereof with a non-infringing equivalent or modify it so it becomes non-infringing. .
15. Drawings: Buyer's review or approval of drawings will be for Seller's convenience and does not relieve Seller of responsibility to meet all requirements of this Order. .
16. Plant Access: Buyer will have access to Seller's facilities performing this Order to review status and progress of production and witness tests and inspections. Such access/review/witnessing does not relieve Seller of any obligations under this Order. .
17. Warranties: (a) Seller expressly warrants that for twenty-four (24) months after delivery to Buyer's facility, all goods and services will (i) conform to plans, drawings, specifications and samples (such plans, etc. are incorporated by reference and made a part hereof); and (ii) be free from defects in design, material and workmanship, and be of merchantable quality and fit for the purposes intended. Seller further expressly warrants that all services will be performed in a competent, professional, efficient and safe manner and will conform to standards in the trade or industry. (b) If any of the goods and/or services are defective or do not conform to the warranties, Buyer at its option and sole discretion (and at Seller's expense) may (i) require Seller to promptly inspect, remove, reinstall, ship and rework or replace/re-perform nonconforming goods and/or services with goods and/or services that conform to all requirements of this Order, (ii) take such actions as may be required to cure all defects and/or bring the goods and/or bring the goods and/or services to conformity with all requirements of this Order, in which event all related costs and expenses (including, but not limited to, material, labor and handling costs and any required re-performance of value added machining or other service) and other reasonable charges shall be for Seller's account, and/or (iii) reject and return all or any portion of such goods and/or services for refund or credit at Buyer's option. All reworked or replaced goods, or part thereof, or re-performed services shall carry warranties on the same terms as set forth above, with the warranty period starting anew after the repair or replacement. All rights and remedies of the Buyer, whether provided by this Order or by law or statute, shall be cumulative and may be exercised singly or concurrently. .
18. Indemnity: Seller will indemnify and hold harmless Buyer, its directors, officers, agents, subcontractors and employees (each, an "Indemnified Party"), from all claims, liabilities, damages, and expenses of any kind (including attorney's fees), incurred by or asserted against an Indemnified Party, in any manner arising out of or relating to Seller's performance or failure to perform its obligations, or any goods or services supplied, under this Order, including claims relating to personal injury (including death) or damage to property. .
19. Modification. These Purchase Order Terms and Conditions, including this Order (i) constitute the sole and entire agreement between Buyer and Seller for this Order, and supersede and cancel all prior negotiations, agreements, commitments and representations between the parties regarding this Order, whether written, oral or implied (e.g., each party agrees that it has not relied on, or been induced by, any representations of the other party not contained herein); and (ii) are governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to any conflict of laws or choice of law rules that would apply the laws of another jurisdiction. The United Nations Convention of Contracts for the International Sale of Goods does not apply. This Agreement may be amended or modified only by a written consent signed by both the Buyer and the Seller.

## **APPENDIX II: SUPPLIER CODE OF CONDUCT**

### ***Compliance with Laws***

All suppliers must fully comply with all applicable national, state, and/or local laws, regulations, and ordinances. In addition, suppliers must be fully compliant with their obligations with respect to any applicable agreement, understanding, or other binding commitment.

### ***Labor Standards and Human Rights***

Litron forbids the use of child and compulsory labor, human trafficking and slavery, unsafe and hazardous working conditions and environments, and any behavior that does not maintain human dignity and respect.

### ***Health & Safety***

Suppliers must provide safe and healthy working environments. Suppliers are required to implement policies that prohibit the use of illegal weapons, harassment in the workplace and the illegal use or possession of alcohol, drugs, and other controlled substances in the workplace.

### ***Equal Employment***

Suppliers must implement hiring practices that prohibit discrimination on the basis of age, culture and language, disability, ethnicity, gender identity, marital or family status, national origin, race or color, religious beliefs, sex, sexual orientation, or any other characteristics protected by law. These principles extend to all employment decisions, including recruiting, hiring, training, promotions, compensation, benefits, transfers and workforce reductions.

### ***Conflicts of Interest***

Suppliers must avoid all transactions or relationships that are or appear to be conflicts of interest.

### ***Bribes and the U.S. Foreign Corrupt Practices Act***

Any bribe or improper payment, whether or not it directly or indirectly benefits Litron, is prohibited. Bribes include: cash, kickbacks or kickback schemes, unexplained rebates, payments for advertising or other disguised allowances or expenses. In addition, all suppliers are required to fully comply with all applicable anti-corruption laws including, without limitation, the U.S. Foreign Corrupt Practices Act (FCPA).

### ***Sustainability and Social Responsibility***

Litron expects its suppliers to execute business practices that preserve and protect the environment, contribute to the social well-being of the communities in which they do business and have operations, and demonstrate accountability and transparency in sustainability performance.

### ***Publicity***

Litron prohibits the public disclosure of its name, logo, likeness, supplier relationships, products, parts, designs or any other non-public information in any press release, prospectus, offering memorandum,

customer list, we site, including, without limitation, product displays at any trade show or supplier facility, without specific prior written authorization.

**Supplier Diversity**

Litron is committed to the inclusion of diverse businesses within the sourcing process and the supply chain. Litron expects all suppliers to support this commitment by deploying strategies and programs to increase sourcing opportunities for diverse businesses, where applicable.

**Confidentiality**

All Litron suppliers are expected to respect Litron’s proprietary and confidential information and must maintain policies that enforce strict compliance with the confidentiality of such information.

<b>Revision</b>	<b>CRF</b>	<b>Description of Change</b>	<b>Requested By</b>	<b>Date</b>
<b>01</b>	<b>887</b>	<b>Initial Release</b>	<b>TD</b>	<b>12/10/12</b>
<b>02</b>	<b>938</b>	<b>Add Supplier Quality Clauses</b>	<b>TD</b>	<b>04/26/13</b>
<b>03</b>	<b>1000</b>	<b>Add section (f) to Q1, DPAS rating flowdown</b>	<b>TD</b>	<b>06/11/13</b>
<b>04</b>	<b>1569</b>	<b>Updated on time delivery rating to 3 days early, 3 days late. Updated Q1(a), removed Q1(c) and renumbered, Added Q1(g), Q2(f) and Q11</b>	<b>TD</b>	<b>12/19/16</b>
<b>05</b>	<b>1655</b>	<b>Added Q5(b-1) for product conformity/safety/ethical behavior flowdown. Updated 3.0 to 3 days early, 5 days late</b>	<b>TD</b>	<b>1/26/18</b>
<b>06</b>	<b>1867</b>	<b>Removed reference to revision of ISO 9001 standard in section 2.0. Updated section 3.0 to include telephone audits.</b>	<b>JM</b>	<b>8/12/19</b>

## APPENDIX III: QUALITY TERMS

Q1 Required Reports and Paperwork – Test and inspection reports as required by the applicable procurement specification must accompany each shipment. For raw material shipments, or supplier supplied material, physical and chemical test report certifications (mill, certification) shall be supplied with each shipment. Test reports shall be legible and include the material designation, specification and revision letter (material must be certified to the latest revision in effect at the time of shipment), results of all specified testing requirements, the mill heat lot number and any other requirements specified on the purchase order.

- (a) Raw Material Point of Certification (i.e. the certification laboratory) shall be a laboratory accredited by one of the following organizations and located within the United States. Captive laboratory results may be accepted in lieu of accreditation
- a. Nadcap
  - b. A2LA
  - c. ASTM
  - d. ISO Guide 25
  - e. ISO 17025
- (b) Certificate of Conformance- A certificate of conformance shall accompany each shipment of material defined in the purchase order. The certificate of conformance shall be legible and at a minimum include the Litron purchase order number, part number and revision, quantity, material lot number (when purchaser supplied material) and the mill heat number when supplier supplied material. When multiple lots numbers or mill heat numbers are used in completing a shipment, parts shall not be mixed and all material lot numbers or mill heat numbers shall be reported. When processing is performed against a work order, parts shall not be mixed and traceability shall be maintained to the work order.
- (c) DFARS Clause 252.225-7014, Preference for Domestic Specialty Metals, Alt 1: Prohibits the prime contractor and all suppliers at every tier from incorporating “specialty metals” (as defined in the clause) into military parts, components and/or end item deliverables unless the specialty metals have been melted in the United States, its outlying areas, or a qualifying country listed in DFARS 225.872-1. Articles manufactured in a qualifying country, regardless of where the specialty metal may have been melted, are not subject to the requirement, but the United States is *not* a qualifying country for this purpose. Suppliers with instructions that they must in turn flow the clause down to their suppliers.
- (d) Fraudulent/Counterfeit Electronic Parts SAE AS5553: The supplier is required to have a program that supports the detection, verification, and prevention of counterfeit parts per SAE AS5553. When this clause appears on the PO, the seller shall supply full chain traceability including copies of Manufacturer (OCM or Mill/Foundry) Certificates of Conformance (CofC) OR provide disclosure in writing that the part/source is not authorized EEE. Disclosure for non-authorized parts must be made prior to delivery. The seller shall retain copies of certificates with lot records for a period consistent with contract requirements. The Manufacturer’s CofC should include the following:
- a. Manufacturer name and address
  - b. Manufacturer and/or buyers full part number and description

- c. Batch identification for the item(s) such as date codes, lot codes, serializations, or other batch identifications
- d. Statement of conformance to applicable government standards
- e. Signature or stamp with title of seller's authorized personnel signing the certificate
- (e) DPAS Rating Applies, see purchase order notes for rating. This is a rated order certified for national defense use, and you are required to follow all the provisions of the Defense Priorities and Allocations System Regulation (15 CFR Part 700).
- (f) ROHS (Restriction of Hazardous Substances) EU Directive 2011/65/EU: ROHS compliance applies. Certificate of compliance required with delivery.
- (g) Conflict minerals: Compliance to the Franklin-Dodd Act HR 4173 Section 1502 is required. Supplier must maintain a policy for control of conflict minerals sourcing and is responsible for submitting the EICC CMRT report to Litron at initial approval and as the EICC makes updates to the report template or new supply sources are added to the supplier's supply chain.

**Q2** Manufactured items: Test and inspection reports as required by the applicable procurement specification must accompany each shipment

- (a) IN PROCESS reports are required. Sample size to be determined by ANSI/ASQC Z1.4 or comparable standard. A cpk of 1.33 min is required for critical dimensions and must be verified by capability studies, otherwise 100% inspection is required.
- (b) FINAL REPORTS: Certificates of Analysis are required. Sample size to be determined by ANSI/ASQC Z1.4 or comparable standard. A cpk of 1.33 min is required for critical dimensions and must be verified by capability studies, otherwise 100% inspection is required.
- (c) FIRST ARTICLE: Inspection is required on part representative of the production process to be used in the manufacture of these parts. A copy of the First Article documentation is to accompany the first shipment of parts. Form AS9102 or equivalent is to be used for this documentation. If 12 months has elapsed since the last shipment of this part number, First Article Inspection is again required (For stocked/standard parts, proof of continuous manufacture is acceptable in lieu of a new FAI). A cpk of 1.33 min is required for all dimensions and must be verified by capability studies.
- (d) STATISTICAL PROCESS CONTROL: SPC is required during the manufacture of the item(s) for which this clause is called out. SPC shall be in accordance with a plan and approved by Litron Quality Assurance.
- (e) SPECIAL PROCESS APPROVAL: Special processes such as heat treating, electroplating, EDM, ECM, plating, etc. require approval by Litron of the process and the supplier of the process prior to performing the special process. The CoC shall include the specification number and revision of all special processing performed. Special processes, once approved, may not be changed without Litron approval of the changes.
- (f) NADCAP PROCESS CERTIFICATION: Special processes require NADCAP certification.

**Q3** Record Retention: Supplier shall retain all records pertaining to material, manufacturing processes, special processes, testing and inspection for 15 years minimum. Supplier must notify Litron prior to destruction of records.

Q4 Non-Conforming Material; Litron is to be notified of any non-conforming material and approved in writing by Litron QA prior to shipment. Suppliers may use their own forms, or request a Supplier Deviation Request (LTN-0209) from Litron QA.

- (a) Disposition “repair” is not allowable on parts when this clause applies.

Q5 Seller Quality System: Supplier must maintain a Quality System that meets, as a minimum, the requirements of ISO 9000. For suppliers with a third party certificate, revocation of the certificate requires immediate notification of Litron Purchasing and/or QA departments.

- (a) Seller is required to maintain a Quality System that meets the requirements of ISO 13485:2003. Verification is required.
- (b) Seller is required to maintain a Quality System that meets the requirements of AS9100. Verification is required.
  - 1. Seller shall establish a communication method that ensures all personnel are aware of their contribution to product/service conformity, product safety, and ethical behavior. This method shall establish a frequency of communication that is appropriate to the organization. Seller shall maintain records of this communication.
- (c) Seller is required to hold NADCAP certification for the applicable process. Verification is required.

Q6 Survey/Audit Rights: Litron and its customers and/or regulatory agencies shall have the right to conduct surveys and perform surveillance of the supplier’s and sub-suppliers’ facilities to evaluate their capability to comply with the requirements necessary to conform to contractual requirements.

Q7 ITAR/EAR: This Purchase Order and all flow down is subject to Export Control Laws as noted below – Please notify Litron if you are unable to comply with these laws.

- (a) *Definition.* Export controlled items, as used in this clause, means items subject to the Export Administration Regulations (EAR) (15 CFR parts 730-774) or the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120-130). The term includes:
  - a. *Defense items, defined in the Arms Export Control Act 22 U.S.C. 2278(j)(4)(A), as defense articles, defense services, and related technical data, and further defined in the ITAR 22 CFR part 120.*
  - b. *Items, defined in the EAR as “commodities, software, and technology,” terms that are also defined in the EAR 15 CFR 772.1*
- (b) The contractor shall comply with all applicable laws and regulations regarding export-controlled items, including, but not limited to, the requirement for Contractors to register with the Department of State in accordance with ITAR. The Contractor shall consult with the Department of State regarding any questions relating to compliance with ITAR and shall consult with the Department of Commerce regarding any questions relating to compliance with the EAR.
- (c) The Contractor’s responsibility to comply with all applicable laws and regulations regarding export-controlled items exists independent of, and is not established or limited by, the information provided by this clause.
- (d) Nothing in the terms of this contract adds to, changes, supersedes, or waives any of the requirements of applicable Federal laws, Executive orders, and regulations, including but not limited to –

- a. The Export Administration Act of 1979, as amended (50 U.S.C. App 2401, et. seq)
- b. The Arms Export Control Act (22 U.S.C. 2751, et seq)
- c. The International Emergency Economic Powers Act (50 U.S.C. 1701, et seq)
- d. The Export Administration Regulations (15 CFR parts 730-774)
- e. The International Traffic in Arms Regulations (22 CFR parts 120-130)
- f. Executive order 13222, as extended
- g. The Contractor shall include the substance of this clause, including this paragraph (e) in all subcontracts.

**Q8 Supplier Written Change Notification:** Supplier must notify Litron of any change in the product and/or process, changes to suppliers of services or raw materials, and changes to manufacturing facility location. Any change must be submitted to Litron QA prior to implementation. Process or product changes must not be implemented without written Litron approval. Supplier must notify Litron when there is a significant facility or organization change such as company name, location, or key personnel. Supplier is expected to flow down this requirement to their supply chain.

**Q9 ESD Control Program:** The device(s) supplied on this order are susceptible to damage from electrostatic discharge. The supplier is required to establish and maintain a documented ESD program per the requirements of MIL-STD1686 or ESD 20.20.

- (a) The device supplied on this order requires ESD packaging

**Q10 Clean Room Requirements:** The device(s) supplied on this order require manufacture and/or processing in a clean environments. Verification is Required.

- (a) Supplier is required to maintain a Class 1000 Cleanroom (ISO Class 6)
- (b) Supplier is required to maintain a Class 10000 Cleanroom (ISO Class 7)
- (c) Supplier is required to maintain a Class 100000 Cleanroom (ISO Class 8)

**Q11 Anti-Human Trafficking Requirements:** Supplier is responsible for maintaining a Human Trafficking Policy and Awareness program policy per FAR clauses 22.1700 and 52.222-50.