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REVISION: D	19650 Pauling – Foothill Ranch, CA 92610-2610 Tel: (949) 460-2100 Fax: (949) 460-2300	REPORT #:
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The latest revision of this document can be found in the online document control system.

REV.	DESCRIPTION OF CHANGE	AUTHOR (Full Name)	DATE RELEASED
NC	New document	Michael Goodyear	12-02-1998
A	Added ozone depleting substances free certification information	CN	12-14-2001
B	Revised to include change in supplier location and updates to supplier quality assurance system	John Tucker Greg Manhart	04-30-2015
C	Complete rewrite	Mike Watters	25-Sep-17
D	- ***Updated title; WAS: Supplier Quality Assurance Requirements Manual (document), Supplier Quality Assurance System Requirements Manual (Agile).*** - ***Updated document category; WAS: Quality Control*** - ***Reorganization of content*** - ***Added certification requirements: ISO 9001 for raw material, NADCAP for OSP, and ISO 17025 for calibration (7.3.2).*** - ***Updated CAR acknowledgment period from 24 to 2 business days (7.9.3).*** - ***Updated CAR plan development period from 10 to 15 business days (7.9.3).*** - ***Added expired record disposition (7.16.3).***	***Jacob Bergstrom***	***28-Feb-24***

Document Category: Quality Assurance

1. **BAL SEAL ENGINEERING:** Bal Seal provides its customers with innovative, custom-engineered sealing, connecting, conducting, and EMI shielding and grounding solutions.

   Bal Seal Engineering's quality policy is to provide its customers with products and services that meet or exceed their expectations. This is demonstrated by a commitment of continuous improvement and a strong emphasis on customer satisfaction and to provide on-time delivery with first-time quality.

2. **PURPOSE:** Bal Seal serves diverse market sectors such as industrial, automotive, aerospace, defense, analytical, energy management, medical devices, and medical electronics. This manual is to inform Bal Seal suppliers of the core requirements regarding supplier quality management systems, processes, and manufacturing process controls required for doing business with Bal Seal.

3. **SCOPE:** This manual applies to all suppliers providing Bal Seal with product realization materials, products, processes, and related services. When applicable, it also applies to sub-tier suppliers. The general requirements outlined herein do not supersede conflicting requirements in the Bal Seal contract, purchase order, or drawing, including applicable engineering specifications and process specifications, or applicable long-term agreement(s). Questions concerning this manual should be directed to the Bal Seal purchasing or quality assurance team.

4. **RESPONSIBILITY**

   4.1. **The supplier** is responsible for compliance to applicable sections of this document.

   4.2. **The Bal Seal Quality Assurance department** is responsible for the maintaining this document.

   4.3. **The Bal Seal Purchasing department** is responsible for communicating the requirements of this document to the supplier.

   4.4. **The Bal Seal Purchasing and Quality Assurance departments** share responsibility for supplier approval, monitoring, performance review, and status changes of suppliers.

5. **DEFINITIONS**

   DCMA – Defense Contract Management Agency

   IQ/OQ/PQ – Installation Qualification, Operational Qualification, Process Qualification. Referenced in ISO 13485, Medical devices -- Quality management systems -- Requirements for regulatory purposes.

   PPAP – Production Part Approval Process. Referenced in IATF 16949, Automotive Quality Management System Standard.

   AQL – Acceptable Quality Level

DMR – Discrepant Material Report

CAR – Corrective Action Request

6. REFERENCE DOCUMENTS

Document	Document Title	Available From
ANSI/NCSL Z540.3	Requirements for the Calibration of Metrology and Test Equipment	www.ansi.org
AS6174	Counterfeit Materiel; Assuring Acquisition of Authentic and Conforming Materiel	www.sae.org, www.asd-stan.org
AS9100	Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations	www.sae.org, www.asd-stan.org
FMEA	Potential Failure Mode & Effects Analysis Manual	www.ansi.org, www.aiag.org
ISO 13485	Quality Management System Requirements (Medical)	www.ansi.org, www.iso.ch
ISO 9001	Quality Management System Requirements (General)	www.ansi.org, www.iso.ch
ISO/IEC 17205	General Requirements for the Competence of Testing and Calibration Laboratories	www.ansi.org, www.iso.ch
IATF 16949	Automotive Quality Management System Standard	www.ansi.org
LE-170	Bal Seal Mutual Non-Disclosure Agreement	Bal Seal Purchasing
LE-188	Bal Seal Terms and Conditions of Purchase	Bal Seal Purchasing
MSA	Measurement System Analysis Manual	www.ansi.org
PPAP	Production Part Approval Process Manual	www.ansi.org
SPC	Statistical Process Control Manual	www.ansi.org

7. SUPPLIER QUALITY MANAGEMENT SYSTEM REQUIREMENTS

7.1. Supplier Conduct

7.1.1. The supplier shall ensure operations are being performed in a manner that is appropriate, as it applies to their ethical, legal, environmental, and social responsibilities.

7.1.2. The supplier must adhere to the laws and regulations in the locality in which they reside. This includes all local, state, and federal laws/regulations in the country of origin.

7.1.3. The supplier must maintain and operate its manufacturing/production facilities and processes in relation to environmental, health and safety in accordance with local, state, and federal laws/regulations in the country of origin.

7.1.4. The supplier shall ensure their employees are aware of these requirements and their contribution to product/service conformity.

7.2. Confidentiality: Reference LE-188.

7.3. Supplier Approval

7.3.1. Bal Seal requires all products and service suppliers to be approved prior to the issuance of contracts/purchase orders. All suppliers shall be approved by Bal Seal, regardless of approvals by its customers or other entities.

7.3.2. QMS systems certified to ISO 9001, ISO/IATF 16949, AS9100, ISO 13485, ISO 17025, NADCAP are preferred and in some instances required by Bal Seal. These requirements do not apply to customer-specified suppliers.

7.3.2.1. Raw material suppliers shall have a minimum of ISO 9001 certification.

7.3.2.2. Plating and passivation suppliers shall have NADCAP certification for the process provided.

7.3.2.3. Calibration suppliers shall be certified to ISO 17025 for the calibration service provided.

Note: OEMs (Original Equipment Manufacturer) providing calibration service to Bal Seal are not required to be certified to ISO 17025. They shall perform calibration against measurement standards that are traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.

7.3.3. The supplier approval process may include the following, as determined by Bal Seal quality assurance:

- Supplier Initial Assessment – Bal Seal may request the supplier to provide a copy of its quality management system certificate and Quality Manual or complete a

self-assessment of its business and quality management system and capabilities (i.e., quality, delivery, technology, cost, and continuous improvement objectives).

- On-Site Assessment Audit – due to product/process complexity or criticality, or nonconformance history, Bal Seal and/or its customers may conduct on-site assessments of a Supplier's product or process capabilities and effectiveness. These assessments could include any QMS process.

7.4. Raw Material Lot Control

7.4.1. Unless otherwise specified in the contract/purchase order, or specifically approved in writing by Bal Seal quality assurance, only one raw material lot can be used per production lot/batch.

7.4.2. The supplier shall ensure, document and furnish positive traceability of product to the raw material certification/test report that represents the raw material from which the products were manufactured. Traceability shall be provided by identifying the raw material heat, lot, batch or melt number from the certification/test report on the product and/or on packaging (when used), or the products segregated and identified.

7.5. Shelf-Life Control

7.5.1. Materials – With each delivery of materials or products that have a limited or specified shelf life, the supplier shall furnish data that shows (a) the cure or manufacture date, (b) expiration date or shelf life, (c) lot or batch number, and when applicable any special handling or storage requirements.

7.5.2. Unless otherwise specified by contract, for all shelf life limited materials (e.g. Elastomeric materials) and products delivered to Bal Seal, the remaining shelf life shall be a minimum of 80% of the total shelf life for the material.

7.6. Conflict Minerals

7.6.1. Bal Seal is committed to ensuring that products sold do not incorporate "conflict minerals" (minerals that are smelted into tin, tantalum, tungsten, and/or gold) sourced from entities that directly or indirectly finance conflict in the Democratic Republic of the Congo or adjoining countries. Bal Seal intends to fully comply with the requirements of Section 1502 of the Dodd-Frank Act in order to support its customers' requirements.

7.6.2. The supplier shall perform sufficient due diligence into its respective supply chains to determine whether products sold to Bal Seal contain tin, tungsten, or gold, and if so, whether and to what extent those metals are sourced from conflict-free smelters.

7.6.3. The supplier shall report to Bal Seal the results of such due diligence on the Conflict Minerals Reporting Template or other agreed format, to enable Bal Seal to comply with its customers' requirements.

7.6.4. The supplier shall commit to being or becoming "conflict-free", so any such metals are sourced only from conflict-free smelters.

7.7. Counterfeit Parts

7.7.1. The supplier shall have a documented process for the avoidance, detection, mitigation, and disposition processes to prevent counterfeit materials, and/or parts from being delivered to Bal Seal. The supplier, as applicable, shall pass down these requirements to their lower tier subcontracts for the delivery of items that will be included in or furnished as materials/parts to Bal Seal.

7.7.2. The supplier shall ensure their Counterfeit Parts/Material Prevention process/procedure includes training of applicable personnel to the requirements within the procedure. The procedure should support the requirements of AS9100 and AS6174.

7.7.3. The supplier shall only purchase products to be delivered or incorporated as goods to Bal Seal directly from the Original Component Manufacturer (OCM)/Original Equipment Manufacturer (OEM), OCM/OEM authorized distributor chain, aftermarket manufacturer, or authorized reseller. These materials/parts shall have verification documentation that are traceable to OCM/OEM; OCM/OEM authorized distributor chain, aftermarket manufacturer, or authorized reseller that identifies the name and location of all the supply chain intermediaries from the part manufacturer to the direct source of the product. If materials/parts can only be acquired from independent distributors or brokers in cases of diminishing material supply (DMS) or obsolescence, written notice shall be provided to the Bal Seal Quality Engineer and Buyer prior to procurement of these goods. After supplier receives written approval by Bal Seal, goods may be subjected to testing and screening process, appropriate to the commodity, using a Bal Seal approved method or third-party laboratory. Records of evidentiary tests and inspections performed that ensure verification of the goods shall be provided to Bal Seal for review and approval by Bal Seal at delivery. Written notice is not required for raw material and standard hardware purchased from independent distributors or brokers, but products must be able to provide commodity level traceability to the OCM/OEM.

7.7.4. Supplier shall provide notification to Bal Seal Quality Engineer and/or Buyer if supplier becomes aware or suspects that it has furnished counterfeit goods within 2 business days. The supplier shall provide to Bal Seal Quality Engineer and/or Buyer, upon request, the supply chain traceability to an original manufacturer or authorized distributor chain that identifies the name and location of all the supply chain intermediaries from the part

manufacturer to the direct source of the product. The supplier shall have a documented process in place to ensure counterfeit goods are contained and do not reenter the supply chain.

7.8. Control and Disposition of Nonconforming Material

7.8.1. The supplier shall establish and implement a documented process to control nonconforming material and product.

7.8.2. The supplier shall not knowingly ship product that deviates from the drawing, specification limits, or design intent without prior written authorization from the Bal Seal Buyer. If such a condition exists, the supplier may petition the Bal Seal Buyer, in writing, to allow shipment of the product under a written nonconformance deviation. If requested by the Bal Seal Buyer, the supplier shall send samples of such nonconforming items to Bal Seal for evaluation.

7.8.3. The cost of shipping, inspection, and testing to determine the potential acceptability of such product will be the supplier's responsibility.

7.8.4. Any parts shipped to Bal Seal that have been approved with deviation shall be clearly identified as such externally on the box, container, or other packaging and on shipping documentation. Inside of each box shall contain a copy of the Bal Seal-approved deviation document.

7.8.5. Bal Seal approval of a deviation is specific to the products for which it has been submitted and approved and shall not to be construed as a permanent engineering change.

7.8.6. The supplier shall begin work immediately on root cause corrective action identification and process improvement to eliminate future occurrence of nonconforming product.

7.8.7. Nonconforming product identified by Bal Seal at its location may be returned to the supplier and dispositioned as mutually agreed to by Bal Seal and the supplier.

7.9. Corrective Action Requests

7.9.1. Bal Seal may issue a request for a corrective action report to the supplier when nonconforming material, components, or assemblies are found. When a formal reply is requested, the supplier shall use the corrective action request form supplied by Bal Seal or its own equivalent format.

7.9.2. When documenting the root cause, the supplier shall include the underlying reasons:

a) why the specific nonconforming condition or incident occurred,
b) why it was not detected by the supplier's quality controls, and
c) why the related process, from a systemic viewpoint, allowed the nonconformance (and potentially others like it) to occur.

7.9.3. The supplier shall respond to the corrective action request as follows:

- Within 2 business days, acknowledge receipt of the CAR, communicate to Bal Seal containment actions taken, and identify all suspect product in-process, in stock, in transit, and potentially at Bal Seal by lot number, and quantity.
- Within 15 business days, the supplier shall submit the corrective action plan indicating the actions to be taken to correct the nonconformity, prevent recurrence of similar nonconformities, and the applicable effectivity dates. If a longer time period is needed, the supplier may request an extension from Bal Seal.

7.10. Change Control of Approved Processes

7.10.1. The supplier shall not change any of their drawings, processes, material sources or procedures that were originally subjected to Bal Seal approval without the written authorization from the Bal Seal Purchasing department. This includes substantial changes to facilities and equipment.

7.10.2. The supplier shall notify Bal Seal in writing (a minimum of 90 days when practical), in advance of a change.

7.10.3. Bal Seal may require a first article inspection report or PPAP for change approval. Bal Seal quality engineering will provide detailed requirements when applicable (see section 8.6).

7.11. Change in Supplier Location

The supplier shall notify Bal Seal in writing (a minimum of 90 days when practical), in advance of any sale, relocation, or transfer of supplier's production or service operations. The supplier shall include the following, as a minimum, in the written notification:

- Purpose of the relocation,
- Address of the new location(s),
- Assessment of actual or potential impact to current POs,
- Risk mitigation plan to ensure compliance to existing requirements,
- Plan defining the identification, storage, protection, retrieval and retention of records,
- Master schedule and timeline of relocation activities

7.12. Bal Seal Designated Source: Where specified by contract, the supplier shall purchase products, materials or services from Bal Seal designated sources. However, the supplier is responsible to ensure that items procured from such sources meet all applicable technical and quality requirements.

7.13. Control of Sub-tier Suppliers

7.13.1. The supplier, as the recipient of the contract, is responsible for meeting all requirements, including work performed by the supplier's sub-tier suppliers (also known as sub-suppliers or subcontract suppliers). When the supplier uses sub-tier suppliers to perform work on products and/or services scheduled for delivery to Bal Seal, the supplier shall include (flow-down) on contracts to its sub-tier sources all of the applicable technical and quality requirements contained in the Bal Seal contract including quality system requirements, regulatory requirements, the use of Bal Seal designated sources, the requirement to document and control 'key characteristics' and/or 'key processes, and to furnish certifications and test reports as required. Bal Seal and its customers reserve the right of entry to sub-tier facilities, subject to proprietary considerations.

7.13.2. Approval per LE-188 is required before any information regulated by the Bal Seal/supplier nondisclosure agreement can be communicated to a sub-tier supplier.

7.14. Preventive Maintenance: The supplier shall identify key process equipment, utilities, environment controls and provide for periodic maintenance. Records of such activities shall be maintained.

7.15. Calibration System

7.15.1. The supplier shall establish and maintain a measurement management system which meets the requirements of either ANSI/NCSL Z540.3 or ISO/IEC 17025.

7.15.2. Measuring equipment shall be calibrated at specified intervals (or prior to use) using measurement standards that are traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.

7.15.3. Measuring equipment shall be identified to enable the calibration status to be determined.

7.15.4. Alternative methods, gauges, or standards may be used at Bal Seal to verify the Supplier’s inspection results. Bal Seal may request the supplier to participate in a correlation study to compare supplier measurement results against results obtained by Bal Seal gauges and methods.

7.16. Record Retention

7.16.1. Records of materials, processes and tests shall be maintained on file for a minimum of 15 years after the last delivery of products and/or services on the contract. Contractual/purchase order requirements may increase this retention period.

7.16.2. Upon request, the supplier shall be capable of retrieving and delivering required records to Bal Seal within forty-eight hours from time of request by Bal Seal.

7.16.3. After the retention period, the supplier may destroy or retain Bal Seal records in accordance with its own procedures.

8. SUPPLIER CONTRACTUAL REQUIREMENTS

8.1. Contract Review

8.1.1. Upon accepting a Bal Seal contract/purchase order, the supplier is responsible for compliance to all contract (e.g., engineering drawing, specification, purchase order, etc.) requirements. All changes will be documented on a purchase order amendment.

8.1.2. All documents, drawings and specifications, regardless of origin, are applicable to the supplier when specified in the contract or documents referenced in the contract, and are required to be used at all levels of the supply chain.

8.1.3. Unless otherwise specified in the contract, the document revision in effect on the date of issue of the contract applies to the contract.

8.1.4. Neither audit, surveillance, inspection nor tests made by Bal Seal, representatives of Bal Seal or its customer(s), at the supplier's facilities, at any sub-tier facilities, or upon receipt at Bal Seal, relieves the supplier of the responsibility to furnish acceptable products or services that conform to all contract requirements; nor does it preclude subsequent rejection by Bal Seal.

8.2. Material Handling

8.2.1. Material shall be handled in such a way as to prevent damage, contamination, corrosion, or any other defect.

8.2.2. Plated or passivated parts shall be handled with Nitrile (non-Latex) gloves.

8.3. Product Inspection

8.3.1. Product inspection requirements, including magnification, may be detailed on the purchase order or engineering documentation.

8.3.2. The supplier is responsible to develop or obtain gages and standards to adequately control its processes and to determine product conformance to specifications. Acceptable gauge minimum accuracy ratio is 4:1. Variable gages and measurements are preferred.

8.3.3. Product and Material Quality – sampling inspection: The supplier is responsible for 100% verified quality for all items delivered to Bal Seal. When the supplier elects to use statistical methods for the acceptance of products or processes, such methods shall comply with the requirements established by DCMA, and in all cases the sample sizes shall be 1.0 or higher unless otherwise specified. The criteria for lot acceptance as zero (i.e., c=0). A copy of the supplier's statistical process control plan shall be furnished to Bal Seal upon request.

8.4. Packaging

8.4.1. The supplier shall adequately plan for packaging designed to prevent product contamination, deterioration or loss and to eliminate shipping damage.

8.4.2. Packaging, packaging materials, handling and shipping of items shall be in accordance with the contract/purchase order, or when not specified, in accordance with best commercial practices to prevent damage, deterioration, and to maintain the quality of the product and/or material while in transit and storage.

8.4.3. To prevent product damage, packaging shall secure the product from moving and rubbing against itself during shipment.

8.5. Certification and Test Reports

8.5.1. CERTIFICATE OF CONFORMANCE: The supplier shall provide a certificate of conformance (or applicable) indicating that the material(s) or service(s) provided against the contract/purchase order meet all applicable requirements. All certifications, reports, and documents shall be legible and reproducible, and shall contain the following, as a minimum:

- Purchase order number
- Part name, number, revision and quantity
- Lot Number(s)
- Applicable specification number(s), with revision level(s)

- Signature and date of an authorized representative
- Cure date (for elastomeric items) Use format “quarter, year” Example: “3Q98”

8.5.2. RAW MATERIAL CERTIFICATIONS: A physical and chemical report from the mill source indicating quantitative values of ingredients and referencing applicable specifications is required.

8.5.3. MERCURY-FREE CERTIFICATION: By providing material under this purchase order requirement, the supplier certifies that all material supplied has not come into contact with, been exposed to, or contains any form of mercury.

8.5.4. OZONE DEPLETING SUBSTANCES-FREE CERTIFICATION: By providing material under this purchase order requirement, the supplier certifies that the materials supplied to Bal Seal comply with the European Parliament Directive (EU) 2015/863 amendment of Directive 2011/65/EU on the restrictions of use of certain hazardous substances.

8.5.5. RoHS CERTIFICATION: By providing material under this purchase order requirement, the supplier certifies that the materials supplied to Bal Seal complies with the restrictions for Lead (Pb), Mercury (Hg), Cadmium (Cd), Hexavalent chromium (Cr6+), Polybrominated biphenyls (PBB), and Polybrominated diphenyl ether (PBDE) as defined by the European Union.

8.6. Production and Process Approval Process

8.6.1. A First Article Inspection (FAI), PPAP process (IATF 16949), or IQ/OQ/PQ (ISO 13485) process may be required to initially qualify a part and/or process for supplier approval.

8.6.2. When required, FAI, PPAP, or IQ/OQ/PQ instructions and format will be supplied by Bal Seal quality engineering.

8.6.3. When a PPAP or IQ/OQ/PQ is required, the supplier shall:

- Develop a control plan by identifying special product and process characteristics that are key to achieving quality. The supplier shall also include those special characteristics designated by Bal Seal in the drawing, specification, or contract. Where specified in the control plan, the supplier is required to apply effective statistical process controls. Instructions and format for control plans will be supplied by Bal Seal quality engineering.
- Develop a visual diagram (flow chart) of the proposed or current process. This diagram shall clearly describe the production process steps and sequence, and meet the specified Bal Seal needs, requirements and expectations.

- Develop a process FMEA in accordance with, and compliant to, Bal Seal-specified requirements. A single process FMEA may be applied to a process manufacturing a family of similar parts or materials if reviewed for commonality by the supplier.
- (If the supplier has product design responsibility) develop a design FMEA in accordance with, and compliant to Bal Seal-specified requirements. A single design FMEA may be applied to a family of similar parts or materials.
- Perform measurement systems analysis (MSA) studies, e.g., gauge repeatability & reproducibility, bias, linearity, stability, for all new or modified gauges, measurement, and test equipment. See AIAG MSA Manual for more information.

9. SUPPLIER PERFORMANCE

9.1. Bal Seal's supplier evaluation system uses several factors to develop an overall supplier performance rating. This rating serves as an objective measure to determine whether Bal Seal expectations are being met.

9.2. At Bal Seal's discretion, the Bal Seal Buyer may determine, that to address the supplier's performance deficiencies, a meeting with the supplier's management is necessary and a supplier documented corrective action and improvement plan is required.

9.3. The supplier is rated on the following criteria. Any category with a rating of equal of less than 80% may require corrective action from the supplier.

9.3.1. SUPPLIER RATING FACTORS

- Number of late shipments
- Number of discrepant material reports issued
- Number of corrective/preventive action requests issued