NOT MEASUREMENT SENSITIVE

MIL-STD-790G
13 September 2011
SUPERSEDING
MIL-STD-790F
1 August 1995

DEPARTMENT OF DEFENSE STANDARD PRACTICE

ESTABLISHED RELIABILITY AND HIGH RELIABLITY
QUALIFIED PRODUCTS LIST (QPL) SYSTEMS FOR
ELECTRICAL, ELECTRONIC, AND FIBER OPTIC
PARTS SPECIFICATIONS



AMSC N/A AREA 59GP

FOREWORD

- 1. This standard is approved for use by all Departments and Agencies of the Department of Defense.
- 2. In implementing the Parts Specification Management for Reliability Report (PSMR-1), issued by the Department of Defense in May 1960, it was determined that a manufacturer must provide evidence of (a) adequate production and test facilities, and (b) sound procedures for process control. This standard was developed to provide guidelines.
- 3. Comments, suggestions, or questions on this document should be addressed to: DLA Land and Maritime, ATTN: VAT, Post Office Box 3990, Columbus, Ohio 43218-3990 or by email resistor@dla.mil. Since contact information can change, you may want to verify the currency of this address information using the ASSIST Online database at https://assist.daps.dla.mil.

CONTENTS

<u>PARAGRAPH</u>		PAGE
	<u>FOREWORD</u>	ii
1. 1.1	SCOPE Scope	1 1
2. 2.1 2.2 2.3	APPLICABLE DOCUMENTS General Non-Government publications Order of precedence	1 1 1
3.	<u>DEFINITIONS</u>	2
4. 4.1 4.2 4.3	GENERAL REQUIREMENTS General Validation Elements	4 4 5 5
5. 5.1 5.1.1 5.1.2 5.1.3 5.1.4 5.1.5 5.2 5.2.1 5.2.2 5.2.3 5.2.4 5.2.4.1 5.2.4.2 5.2.4.3 5.2.5 5.2.5.1 5.2.5	DETAILED REQUIREMENTS General Key personnel and organizations Test facilities Government-Industry Data Exchange Program (GIDEP) alerts Sub-assembly facilities Distributors QPL system elements Training Calibration Proprietary processes and procedures Failure and defect analysis system Failure reporting Failure and defect analysis Failure and defect analysis capabilities and facilities Corrective action Production of prototype parts for evaluation Clean rooms Description of production processes and controls	5 5 5 5 5 5 5 6 6 6 6 6 7 7 7 7 7 7 8 8 8 8 8 8 8 8 8
5.2.8 5.2.9 5.2.10 5.2.11 5.2.12 5.2.12.1 5.2.12.2 5.2.12.3	Acquisition and production control system Statistical process control Acceptance criteria for incoming materials and work in-process Handling and packaging procedures Materials Incoming, in-process, and outgoing inventory control Conforming materials Nonconforming materials	8 9 9 9 9 9

CONTENTS

<u> </u>	PARAGRAPH		PAGE
	5.2.12.4 5.2.13 5.2.14 5.2.15 5.2.16 5.2.17 5.2.18 5.2.18.1 5.2.18.2 5.2.18.3 5.2.19	Material traceability Product traceability Certification of conformance and acquisition traceability Controlled storage area Quality assurance operations Manufacturer's self-assessment system Record retention Records to be maintained Computerized records Altered records Technology Review Board	10 10 10 11 11 11 11 11 11 11
<u> </u>	6. 6.1 6.2 6.3 APPENDIX A	NOTES Intended use Subject term (key word) listing Changes from previous issue	12 12 12 12
	A.1 A.1.1	SCOPE Scope	13 13
	A.2	APPLICABLE DOCUMENTS	13
	A.3 A.3.1 A.3.2 A.3.3 A.3.4 A.3.5 A.3.6 A.3.7	Self-assessment program Self-assessment representatives Deficiencies Follow-up Schedules Self-assessment results Self-assessment requirements	13 13 13 13 13 13 13

APF	PEND)IX	В
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B.1 B.1.1	SCOPE Scope	16 16
B.2	APPLICABLE DOCUMENTS	16
B.3 B.3.1 B.3.1.1 B.3.1.2 B.3.1.3 B.3.2 B.3.3 B.3.4	REQUIREMENTS Technology Review Boards (TRB) levels of responsibilities Purpose of TRB Level 1 TRB Level 2 TRB TRB TRB TRB organizational structure TRB responsibilities	15 16 16 17 17 17 17
TABLES		
B-I	TRB Authority Levels	16
CONCLUE	DING MATERIAL	19

1. SCOPE

1.1 <u>Scope</u>. This standard is for direct reference in established reliability and high reliability electrical, electronic, and fiber optic parts specifications and establishes the criteria for a manufacturer's qualified product system.

2. APPLICABLE DOCUMENTS

- 2.1 <u>General</u>. The documents listed in this section are specified in section 3, 4, and 5 of this standard. This section does not include documents cited in other sections of this standard or recommended for additional information or as examples. While every effort has been made to ensure the completeness of this list, document users are cautioned that they must meet all specified requirements of documents cited in section 3, 4, and 5 of this standard, whether or not they are listed.
- 2.2 <u>Non-Government publications</u>. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those cited in the solicitation or contract.

* TECHAMERICA

EIA-557 - Statistical Process Control Systems.

(Copies of these documents are available online at http://www.techamerica.org/standards or from TechAmerica, 601 Pennsylvania Ave, NW, North Building, Suite 600, Washington, DC 20004.)

INTERNATIONAL ORGANIZATION for STANDARDS (ISO)

	ISO 10012-1	 Equipment, Quality Assurance Requirements for Measuring - Part 1, Meteorological Confirmation System for Measuring Equipment.
*	ISO 14644-1	 Cleanrooms and Associated Controlled Environments – Part 1: Classification of Air Cleanliness.
*	ISO 14644-2	 Cleanrooms and Associated Controlled Environments – Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1.

(Copies of this document are available from http://www.iso.org/ or from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036.)

NATIONAL CONFERENCE OF STANDARDS LABORATORIES (NCSL)

NCSL Z540.3 - Requirements for the Calibration of Measuring and Test Equipment.

(Copies of this document are available from http://www.ncsli.org/ or from the National Conference of Standards Laboratories (NCSL) International, 1800 30th Street, Suite 305, Boulder, CO 80301-1026.)

* 2.3 Order of precedence. Unless otherwise noted herein or in the contract, in the event of a conflict between the text of this document and the references cited herein, the text of this document takes precedence. Nothing in this document, however, supersedes applicable laws and regulations unless a specific exemption has been obtained.

3. DEFINITIONS

- 3.1 <u>Assembly plant</u>. A plant established by a manufacturer or operated by a distributor authorized by the manufacturer to perform specified functions pertaining to the manufacturer's identified qualified products in accordance with specified assembly procedures, test methods, processes, controls, and storage, handling, and packaging techniques.
- * 3.2 <u>Burn-in (pre-conditioning)</u>. Process of subjecting components to conditions (temperature extreme, power input extremes, etc) with the intent to either stabilize performance or significantly reduce latent defects.
 - 3.3 Calibration. A comparison result between a measuring device and a known standard.
- 3.4 <u>Clean rooms</u>. A clean room has a controlled level of contamination that is specified by the number of particles per cubic meter at a specified particle size.
 - 3.5 <u>Corrective action</u>. A documented design, process, procedure, or materials change implemented and validated to correct the cause of failure or design deficiency.
 - 3.6 <u>Criticality</u>. A relative measure of the consequence of a failure mode and its frequency of occurrence.
 - 3.7 <u>Defect analysis</u>. The process of examining technical or management (nontechnical) data, manufacturing techniques, processes, or materials to determine the cause of variations of electrical, mechanical, optical, or physical characteristics outside the established limitations.
 - 3.8 Degradation. A gradual impairment and its inability to perform.
 - 3.9 <u>Demonstrated</u>. That which has been measured by the use of objective evidence gathered under specified conditions.
 - 3.10 <u>Electrical, electronic, and fiber optic parts</u>. Basic circuit elements which cannot be disassembled and still perform their intended function, such as capacitors, connectors, filters, resistors, switches, relays, transformers, crystals, electron tubes, semiconductors, and fiber optic devices.
 - 3.11 <u>Environmental</u>. The aggregate of all external and internal conditions (such as temperature, humidity, radiation, magnetic and electric fields, and shock vibration) either natural or man made, or self-induced, that influences the form, performance, reliability or survival of an item.
 - 3.12 <u>Established reliability</u>. A quantitative maximum failure rate demonstrated under controlled test conditions specified in a specification and usually expressed as percent failures for each thousand hours or cycles of test.
 - 3.13 <u>Failure</u>. The event or inoperable state in which, any item or part of an item does not, or would not, perform as previously specified.
 - 3.14 <u>Failure activating cause</u>. The stresses, or forces, (thermal, electrical shock, vibration, etc.), which induce or activate a failure mechanism.

- 3.15 <u>Failure analysis</u>. The process of examining electrical, electronic, or fiber optic parts to determine the cause of variations of performance characteristics outside of previously established limits with the end result that failure modes, failure mechanisms, and failure activating causes will be identified.
- 3.16 <u>Failure mechanism</u>. The process of degradation, or the chain of events; which results in a particular failure mode.
- 3.17 <u>Failure mode</u>. The abnormality of an electrical, electronic, or fiber optic part's performance which cause the part to be classified as failed.
- 3.18 <u>Failure rate</u>. The total number of failures within an item population that is divided by the total number of life units expended by that population, during a particular measurement interval under stated conditions.
- 3.19 <u>Inspection lot</u>. A group of electrical, electronic or fiber optic parts offered for inspection at one time and in combinations authorized by the applicable specification.
- 3.20 <u>Item</u>. A non-specific term used to denote any product, including system, material parts, subassemblies, sets, or accessories.
- * 3.21 <u>Major change</u>. Any change that alters the form, fit and functions (including design, material, construction, performance, quality, reliability, and interchangeability).
 - 3.22 Manufacturer. The actual producer of said electrical, electronic, or fiber optic parts.
 - 3.23 <u>Production lot</u>. A group of electrical, electronic, fiber optic parts manufactured during the same period from the same basic raw materials processed under the same specifications and procedures, produced with the same type equipment, and identified by the documentation defined in the manufacturer's qualified product system through all significant manufacturing operations, including final assembly operations. Final assembly operations are considered the last major assembly operations such as casing, hermetic sealing, or lead attachment rather than painting or marking.
 - 3.24 Qualification. The entire procedure by which electrical, electronic, and fiber optic parts are processed, examined, and tested to obtain and maintain approval for qualified products listing.
- * 3.25 <u>Qualified Product Database (QPD)</u>. A database of products that have met the qualification requirements stated in the applicable specification, including appropriate product identification and test or qualification reference with the name and plant address of the manufacturer and distributor, as applicable.
- * 3.26 Qualified Product List (QPL). A list of products that have met the qualification requirements stated in the applicable specification, including appropriate product identification and test or qualification reference with the name and plant address of the manufacturer and distributor, as applicable.
 - 3.27 Qualifying activity. The military preparing activity or its government agent delegated to administer the qualification program.

3.28 Quality assurance. Quality assurance is a planned and systematic pattern of all actions necessary to provide adequate confidence that adequate technical requirements are established; products and services conform to established technical requirements; and satisfactory performance is achieved.

3.29 Reliability.

- (1) The duration or probability of failure-free performance under stated conditions.
- (2) The probability that an item can perform its intended function for a specified interval under stated conditions. (For non-redundant items this is equivalent to definition (1). For redundant items this is equivalent to definition of mission reliability.
- 3.30 <u>Screening</u>. A process of removing unsatisfactory items, or those items that is likely to exhibit early failure. Inspection includes visual examination, physical dimension measurement and functional performance measurement under specified environmental conditions.
- 3.31 <u>Sub-assembly facility</u>. A facility approved by a Qualified Manufacturer to perform critical manufacturing steps of a QPL part.
 - 3.32 <u>Self-assessment</u>. The performance of periodic review by the manufacturer's designated personnel to verify that the requirements of this standard are being met.
 - 3.33 <u>System</u>. A composite of equipment and skills and techniques, that is capable of performing or supporting an operational role or both. A complete system includes all equipment, related facilities, material, software, services, and personnel required for its operation and support to the degree that it can considered self-sufficient in its intended operational environment.
 - 3.34 <u>Technology Review Board (TRB)</u>. A board established by the manufacturer that is given authority and responsibility to oversee the MIL-STD-790 qualified product system as described herein. The TRB consists of designated manufacturer's representatives that have the knowledge and expertise to administer the system (see Appendix B).
 - 3.35 <u>Time</u>. The universal measure of duration which an action, process, or condition exists or takes place. The general word "time" will be modified by an additional term when used in reference to operating time, mission time, and test time.
 - 3.36 <u>Traveler</u>. The test production and raw material process routing sheet.
- * 3.37 <u>Value Added Distributor</u>. A distributor that has been approved by a Qualified Manufacturer and the Qualifying Activity to assemble QPL products using piece parts received from the manufacturer. May also be referred to as a Category C distributor.

4. GENERAL REQUIREMENTS

4.1 <u>General</u>. Manufacturers of established reliability and high reliability electrical, electronic and fiber optic components shall demonstrate to the qualifying activity that a system is in place to integrate all design, planning, manufacturing, inspection, and test functions as described herein.

- 4.2 <u>Validation</u>. The qualifying activity is responsible for determining if the manufacturer meets the requirements of this standard. Validation is required as part of the qualification and retention of qualification to the individual product specification. The qualifying activity shall perform a review of the manufacturing facility as part of the validation effort. Revalidations are required to maintain qualification and shall be performed within 24 months of the last review. This validation period may be extended by the qualifying activity if the manufacturer can demonstrate adequate controls of their system through Statistical Process Control (SPC), self-assessment, Technology Review Boards (TRBs), etc.
- 4.3 <u>Elements</u>. The manufacturer shall demonstrate a system for established reliability and high reliability parts that include the specific elements as defined in the detailed requirements of this standard (see section 5).

5. DETAILED REQUIREMENTS

- 5.1 <u>General</u>. The detail requirements for meeting this standard are described in this section. It is not intended that the manufacturer create a military unique system in order to meet these requirements. Manufacturers may use existing internal systems in meeting these requirements provided they are validated by the qualifying activity.
- 5.1.1 <u>Key personnel and organizations</u>. The responsibility and authority of key personnel and organizations associated with the qualified products shall be identified. The manufacturer shall identify changes affecting in key organizations and personnel. The qualifying activity shall be informed of any changes within 30 days after such an occurrence.
- 5.1.2 <u>Test facilities</u>. The manufacturer shall identify the test facilities and equipment used for qualification and conformance inspection of the electrical, electronic, and fiber optic parts.
- * 5.1.3 <u>GIDEP alerts</u>. The manufacturer shall notify the qualifying activity of all pending GIDEP alerts/problem advisories prior to issuance.
- 5.1.4 <u>Sub-assembly facilities</u>. Qualified manufacturers validated to this standard may utilize sub-assembly facilities (contractors) to perform specific manufacturing steps in accordance with the authorized qualified manufacturer's system. The manufacturer is responsible for ensuring these sub-assembly contractors meet the requirements of this standard as applicable. The qualifying activity reserves the right to perform a validation of the sub-assembly contractor. The manufacturer is responsible for ensuring that all parts utilized by the sub-assembly contractor meet all quality standards of the applicable specification(s). The manufacturer shall maintain a list of all sub-assembly contractors, the functions that they are authorized to perform and their unique identification. This list shall be available to the qualifying activity upon request. No additional sub-assembly contractors shall be utilized without proper and prior notification to the qualifying activity. All sub-assembly shall be in locales that are suitable for auditing by DoD employees as determined by the qualifying activity.

- 5.1.5 <u>Distributors</u> Manufacturers validated to this standard may approve authorize distributors to perform additional functions and operations on the qualified products. The manufacturer is responsible for validation of these distributors to the requirements of this standard as applicable. The qualifying activity reserves the right to perform a validation of the distributor. The controls and requirements shall be such as to assure the product sold by distributor is of the same quality and performance as parts supplied directly from the manufacturer. The manufacturer is responsible for ensuring that all products sold through these distributors meet the requirements of the applicable product specifications. The manufacturer shall identify each distributor and the functions that they are authorized to perform according to the following categories:
 - a. Category A distributor. This category of distributor is authorized to store, pack, handle, and distribute qualified products.
 - b. Category B distributor. This category of distributor is authorized to perform additional operations, tests, and inspections in addition to responsibilities of a category A distributor. If the distributor is authorized to mark the parts, a code symbol is to be added to the modified part to identify the distributor (in accordance with agreement with original manufacturer) in addition to the original part marking and lot identification by the manufacturer.
 - c. Category C distributor. This category is a value added distributor that has been approved by a qualified manufacturer and the qualifying activity to assemble QPL products in addition to the responsibilities of a Category B distributor including part marking. Approval includes but is not limited to the following:
 - Distributor shall be audited by the qualified manufacturer to ensure compliance to all applicable specifications. The qualifying activity reserves the right to perform a validation of the distributor.
 - 2. Assembly procedures and routers shall be equivalent to the manufacturer's documents and all changes shall be approved by the qualified manufacturer.
 - 3. The qualified manufacturer shall be responsible for any and all problems associated with QPL products assembled at the Category C distributor.
 - 5.2 <u>QPL system elements</u>. The manufacturer's system shall address, as a minimum, the elements described herein. This system shall be maintained by the manufacturer such that the qualifying activity can verify and validate these elements (e.g., internal documentation and control systems).
 - 5.2.1 <u>Training</u>. The manufacturer shall maintain a training program to cover all phases of their activity involved in producing electrical, electronic, and fiber optic parts. The type and extent of training shall be determined by the manufacturer.
 - 5.2.2 <u>Calibration</u>. Each instrument used to measure or control production process or to measure the acceptability of parts under test shall be calibrated in accordance with NCSL Z540.3, ISO 10012-1, or equivalent system as approved by the qualifying activity.
 - 5.2.3 <u>Proprietary processes and procedures</u>. The qualifying activity shall have access to all areas of the manufacturer's plant for the purpose of verifying implementation of this standard.

- 5.2.4 <u>Failure and defect analysis system</u>. The manufacturer shall maintain a failure and defect analysis system. Failure analysis of parts are required when failures exceed the number allowed by the specification in qualification and conformance inspections or which have failed during field use (either at equipment contractor or military field activities).
- 5.2.4.1 <u>Failure reporting</u>. The manufacturer shall maintain a failure recording and reporting system for parts which have failed during qualification or conformance inspections or while in use in equipment. The system shall provide for at least the following:
 - a. The operating or test conditions under which the part failed, including environmental exposure levels, if known.
 - b. The source from which the failed part was received.
 - c. Verification of the reported condition of the failed part by the manufacturer's personnel responsible for production, inspection, quality, or engineering.
 - d. The length of time the part has been operating if it failed in life testing. Compliance within failure rate levels shall be calculated in accordance with the governing applicable product specification.
 - e. For field failures, review and corrective action (as applicable) shall be within 30 days after receipt of parts and supporting information.
- 5.2.4.2 <u>Failure and defect analysis</u>. The manufacturer shall maintain a system to retain the results of failure and defect analysis. This system shall provide for at least the following:
 - a. The results of analysis.
 - b. The probable failure activating cause when possible.
 - c. Recommended corrective action.
 - d. Include approval by responsible authority.
- 5.2.4.3 <u>Failure and defect analysis capabilities and facilities</u>. The manufacturer shall have, either as part of their facilities or an arrangement with suitable laboratories outside of their facilities, proper capabilities to perform failure and defect analysis.
 - 5.2.5 <u>Corrective action</u>. Where failures or defects are greater than the prescribed limits, the manufacturer shall prepare a recommendation for corrective action. Corrective Action recommendations for performance failures shall include failure mode information when established and shall be supported by verifying information, or a proposed evaluation test plan. Corrective actions on parts covered by the specification shall not be made without approval from the qualifying activity, except those actions which consist only of improvements in control operations. Corrective action affecting control procedures shall not be implemented for production until approved by qualified personnel.
 - 5.2.5.1 <u>Production of prototype parts for evaluation</u>. Prototype parts for change evaluation shall be produced on the controlled production line to the point at which the proposed corrective change must be made; the change shall then be effected; and the changed prototype parts shall then be continued through the balance of the normal series of production operations. Shipment of product incorporating the change shall not occur until approved by the qualifying activity.

- 5.2.6 <u>Clean rooms</u>. When the military product specification includes the requirements of a clean room, airborne particulate class limits shall be defined. The proper class shall be specified by the manufacturer's design activity in the process specification (ISO 14644-1 and ISO 14644-2 may be used as a guideline). The manufacturer shall establish action and absolute control limits (at which point work stops until corrective action is completed) based on historical data and criticality of the process in each particular area.
 - 5.2.7 <u>Description of production processes and controls</u>. The manufacturer shall maintain a system that details the production processes, steps, and controls applied to parts currently produced and proposed for inclusion in this program. Requirements and tolerances shall be specified for all critical environments and utilities which come in contact with the production and test of electrical, electronic, and fiber optic parts. When applicable, the system shall include such items as:
 - a. List of process control equipment and periodic calibrations.
 - b. Control of chemical purity and ionization of water.
 - c. Known composition of all gases and chemicals, including degree and type of contamination, used in the processes and control of fabrication.
 - d. Definition of maximum permissible variations in voltage used in the processes or supplied to the test equipment which may introduce errors or variations in the performance or inaccuracies in test data.
 - e. Definition of clean rooms or other controlled atmospheric requirements.
 - f. Process specifications showing process tolerances.
 - g. Detailed engineering specification requirements covering types of parts.
 - h. Identification of each inspection operation for receiving inspection, inspection during manufacture, inspection of completed parts including related sampling plans, and inspection tolerances.
 - Procedures for forming conformance inspection lots which will comply with part specification criteria.
 - j. Procedure for identification of each production lot through all significant manufacturing operations, including final assembly operations such as casing, hermetic sealing, or lead attachment. Alternately, where this procedure is impractical (e.g., where a part cannot be identified until after final assembly and determination of its performance characteristics), the manufacturer shall as a minimum be able to identify the time period during which the final production operation was performed on each item of product prior to final test. The date or lot code marked on each part shall be identified to a production lot.
 - k. The manufacturer listed must notify the qualifying activity of any major change affecting the design or process of the qualified product.
 - 5.2.8 <u>Acquisition and production control system</u>. The manufacturer shall maintain an acquisition and production control system that identifies pertinent internal documents relating to acquisition and processing of materials, production of parts and methods of product assurance (e.g., name, number, release date, and latest revision).

- 5.2.9 <u>Statistical process control</u>. When specified in the individual component specification, a statistical process control (SPC) program system in accordance with <u>EIA-557</u> shall be established.
- 5.2.10 <u>Acceptance criteria for incoming materials and work in-process</u>. Acceptance criteria shall be identified including type of inspection, the materials group inspected, the sampling and test procedures, the date of completion of inspection, the amount of material tested, acceptance rejection criteria and frequency of inspection.
- 5.2.11 <u>Handling and packaging procedures</u>. Handling procedures shall be established to provide physical protection of material during all sequences of production and inspection. Assembled parts shall be physically protected during testing and conformance inspections. Handling and packaging procedures shall be prepared to cover storage of parts in a controlled storage area, their removal from the area, and their preparation for shipment.

5.2.12 Materials.

- 5.2.12.1 <u>Incoming, in-process, and outgoing inventory control</u>. The methods and procedures shall be identified which are used to control storage and handling of incoming materials, work in-process, and warehoused and outgoing product in order to achieve such factors as age control of limited-life materials, and prevent inadvertent mixing of conforming and nonconforming materials, work, or finished product. Procedures shall be maintained for controlling the receipt of acquired materials and supplies. The procedures shall provide the following:
 - a. Withholding received materials or supplies from use pending completion of the required inspection or tests, or the receipt of necessary reports.
 - Segregation and identification of non-conforming materials and supplies from conforming materials.
 - c. Identification and control of limited-life materials and supplies.
 - Identification and control of raw materials.
 - e. Assurance that the required test reports, certification, etc., have been received.
 - f. Clear identification of materials released from receiving inspection and test to clearly indicate acceptance or rejection status of material pending review action.
- 5.2.12.2 <u>Conforming materials</u>. The manufacturer shall maintain a positive system of identifying the inspection status by means of stamps, tags, routing cards, or other control devices. In controlling the status of materials, the manufacturer shall establish suitable controls to assure that identification of status is applied under the jurisdiction of authorized inspection personnel.
- 5.2.12.3 <u>Nonconforming materials</u>. Nonconforming materials shall be controlled by a positive system of identification to prevent their inadvertent use or intermingling with conforming materials.

- 5.2.12.4 <u>Material traceability</u>. Conforming materials shall be identified upon receipt and, where possible, throughout the production process to the accepted product. Where basis of part production lot identification (e.g., the time period during which certain operations are performed) is used, the accepted product shall be identified to the appropriate production lot, and records of conforming material batches or lots used in each production lot shall be maintained. Completed parts shall be identified to permit positive correlation to the production lot.
- 5.2.13 Product traceability. The traceability system shall be maintained such that the qualifying activity can trace and determine that the qualified product passed the applicable screening, qualification, and conformance inspections as well as be able to trace and determine the exact processes (includes machines, operators, equipment, etc.), piece parts, and raw materials used in the actual manufacture of the qualified product.
- 5.2.14 Certification of conformance and acquisition traceability. Manufacturers or suppliers including all Categories of Distributors (see 5.1.5) who offer QPL devices described by the specifications that this standard represent shall provide written certification, signed by the corporate officer who has management responsibility for the production of the QPL devices, (1) that the QPL devices being supplied have been manufactured and meet the performance defined in the specifications whether or not the actual testing is performed, (2) that the QPL devices are as described on the certificate of conformance which accompanies the shipment, and (3) distributors have handled the QPL devices in accordance with the requirements of their packaging specifications and within this standard. The responsible corporate official may, by documented authorization, designate other responsible individuals to sign the certificate of conformance (such as members of the manufacturer's review system), but, the responsibility for conformity with the facts shall rest with the responsible corporate officer. The certification shall be confirmed by documentation to the Government or to users with Government contractors or subcontractors, regardless of whether the QPL devices are acquired directly from the manufacturer or from another source such as a distributor. When distributors are involved, their acquisition certification shall be in addition to the certificates of conformance and acquisition traceability provided by the manufacturer and previous distributors. The certificate of conformance and acquisition traceability shall include the following information:
 - a. Manufacturer documentation:
 - (1) QPL Manufacturer's name and address.
 - (2) Customer's or distributor's name and address.
 - (3) Acquisition order number.
 - (4) QPL part number.
 - (5) Lot identification codes and latest reinspection date, if applicable.
 - (6) Quantity of devices in shipment from manufacturer.
 - (7) Assembly plant location, if applicable.
 - (8) Statement certifying QPL devices conformance and traceability.
 - (9) Signature and date of transaction.
 - (10) ESD classification, when not marked on the device, if applicable.

- b. Distributor documentation for each distributor (see 5.1.5):
 - (1) Distributor's name and address.
 - (2) Name and address of customer.
 - (3) Manufacturer's name.
 - (4) Quantity of devices in shipment.
 - (5) QPL part number.
 - (6) Certification that this shipment is a part of the shipment covered by the manufacturer's documentation and an attached copy of the manufacturer's original certification.
 - (7) Certification that authorized dealers and distributors has handled the products in accordance with the requirements of each device packaging specification and within this standard.
 - (8) Signature and date of transaction.
- 5.2.15 <u>Controlled storage area</u>. The manufacturers shall describe the procedures and controls which will be used to maintain a separate storage area (e.g., specially marked containers, special cabinets, or stockroom) for parts that have passed the specification conformance inspections. Such an area shall be maintained and no other parts shall be permitted in this area.
- 5.2.16 <u>Quality assurance operations</u>. Quality assurance operations shall be identified as to type, procedures, equipment, judgment and action criteria, records, and frequency of use.
- 5.2.17 <u>Manufacturer's self-assessment system</u>. The manufacturer shall establish a self-assessment system to verify that the requirements of this standard are being met. Appendix A offers guidance for self-assessment system. Self-assessment shall be performed at least annually.
- * 5.2.18 Record retention.
- * 5.2.18.1 Records to be maintained. Records shall be legible and maintained which will adequately describe the processes, materials, inspections, and tests which affect the quality of the device for appropriate amounts of time such that quality concerns and customers are properly supported (e.g. conformance testing records). The records pertaining to production processes, incoming, and in-process inspections should be retained for a minimum of 3 years (7 years for space level) and those pertaining to performance verification retained for a minimum of 5 years (7 years for space level) after performance of the inspections. Records pertaining to alternate methods (with qualifying activity approval), conformance testing shall be retained for 5 years (7 years for space level) after the process or materials affected have been removed from the qualified flow.
- * 5.2.18.2 Computerized records. Computerized records are optional provided they clearly and objectively indicate that all requirements of the specifications have been met. The computerized records for traceability, screening and conformance inspection should be readily accessible and available to Government personnel for review and an appropriate electronic or hard copy provided to the qualifying activity as required. Computerized records, when used, should be maintained with controls sufficient to easily provide the necessary information and traceability, including identification of individual and time of input. The integrity of the system and the data should be maintained.
- * 5.2.18.3 <u>Altered records</u>. Altered records should identify all information necessary to maintain proper traceability and the integrity of the original data and justification for the change.

5.2.19 <u>Technology Review Board (TRB)</u>. The manufacturer may request the approval and use of an internal TRB. Requirements for TRB's are specified in <u>appendix B</u>. Establishment of a TRB at any level is subject to approval/withdrawal by the qualifying activity. The TRB allows manufacturers to assume more responsibility and authority for meeting the requirements of this standard.

6. NOTES

(This section contains information of a general or explanatory nature that may be helpful, but is not mandatory.)

- 6.1 <u>Intended use</u>. This standard specifies general requirements for qualified product systems for established reliability and high reliability electrical, electronic, and fiber optic part specifications.
 - 6.2 Subject term (key word) listing.

Assessment
Calibration
GIDEP
Process control
Production
Qualification
Technology Review Boards
Traceability

6.3 <u>Changes from previous issue</u>. The margins of this standard are marked with asterisks to indicate where changes from the previous issue were made. This was done as a convenience only and the Government assumes no liability whatsoever for any in accuracies in these notations. Bidders and contractors are cautioned to evaluate the requirements of this document based on the entire contact irrespective of the marginal notations and relationship to the last previous issue.

APPENDIX A

SELF-ASSESSMENT SYSTEM

A.1. SCOPE.

- * A.1.1 <u>Scope</u>. This appendix provides guidance for use in the manufacturer's self-assessment system. The intent of this system is to assure continued conformance to specification requirements. This appendix is a mandatory part of this standard. The self-assessment system contained herein is for compliance, other methods of establishing a self-assessment system are allowed with qualifying activity approval.
 - A.2. APPLICABLE DOCUMENTS. This section is not applicable to this appendix.
 - A.3. GENERAL.
 - A.3.1 <u>Self-assessment program</u>. The manufacturer shall have an independent self-assessment system to assess the effectiveness of the manufacturer's quality assurance system. This system shall identify any deficiencies for resolution in the processing, testing, or deviations from specification requirements.
 - A.3.2 <u>Self-Assessment representatives</u>. The manufacturer's quality assurance representative or their designated appointees shall perform all self-assessments. The representatives shall be independent from the areas reviewed.
 - A.3.3 <u>Deficiencies</u>. All deficiencies shall be identified and submitted to the department head for corrective actions. All corrective actions shall be agreed to by the manufacturer's quality department prior to implementation.
 - A.3.4 <u>Follow up</u>. The quality department shall establish a procedure to follow up on all deficiencies to assure the corrective actions have been implemented in a timely manner.
- * A.3.5 <u>Schedules</u>. The original self-assessment frequency shall be established by the manufacturer's quality department but in no case exceed 12 months for each area unless authorized by the qualifying activity. Changes to the frequency of self-assessment shall require approval of the manufacturer's qualifying department.
 - A.3.6 <u>Self-assessment results</u>. The results of the self-assessment shall be made available to the qualifying activity prior to validation. The manufacturer shall make available to the qualifying activity, during validation, all corrective actions taken as a result of the self-assessment.
 - A.3.7 <u>Self-assessment requirements</u>. The following is an explanation of the typical requirements that every manufacturer should meet.
 - a. Manufacturer should identify key personnel and organizations (see 5.1.1).
 - b. Manufacturer should have a system that details the manufacturing flow processes performed, quality control stations, and the internal document control number pertaining to each (see 5.2.7).

APPENDIX A

- c. It should be verified that the manufacturer's manufacturing and quality documentation control system is being adequately maintained. This means tracing document status all the way from responsible authority to its location on the production line (see 5.2.8).
- d. Incoming inspection area should be examined to determine that the conforming and nonconforming materials are segregated. Traceability should be from the finished product traveler to the incoming inspection (see 5.2.12). Adherence to applicable material specifications and standards in section 2 of this specification should be verifiable.
- e. Manufacturing travelers should be checked to determine that they are being filled out and signed off at every step of the production and test stages. A sample review of past travelers is recommended. Significant steps of the process should be included on the traveler (see 5.2.7j). If part of group A is performed in production testing, the manufacturer should be able to produce data for group A tests for each inspection lot.
- f. Logs on voltage and temperature checks in ovens and chambers, life and burn-in start and stop times, etc., should be in place and filled in.
- g. Voltages and temperatures should be checked at least once a week on life test ovens.
- h. Overvoltage and thermal runaway protections on reliability life test chambers should be utilized (see 5.2.7).
- Environmental controls should be maintained and monitored as required in the specification or standard that is applicable.
- j. All instructions (e.g., setting equipment, testing, and handling) should be signed, dated, and part of documentation control system. Operators should follow instructions for procedures (see 5.2.8).
- k. Process control records should be reviewed to verify that they are being utilized and that process corrections are implemented when a need is indicated by the control charts (e.g., X bar and R charts) (see 5.2.9).
- Manufacturer should describe and maintain failure and defect analysis systems which should result in corrective actions to reduce part failures and defects to acceptable level (see 5.2.4).
- m. A sample or production processes and controls should be reviewed to determine that operators are following the steps outlined in the production and test documents (see 5.2.8).
- n. It should be determined that distributors are being controlled to assure that the product sold by the distributor is of the same quality and performance as parts acquired directly from the manufacturer (see 5.1.5).
- o. The calibration system should always be checked (see 5.2.2).
- Compliance to specification test requirements should be clearly shown on internal control documents.

APPENDIX A

- q. The manufacturer should demonstrate the ability to perform the tests required by the specification.
- r. The manufacturer should describe, conduct, and maintain a training program producing qualified parts (see 5.2.1).
- s. Both the original and altered data should be readable. When changes are made the entry should be initialed and all entries should be permanent (ink).

APPENDIX B

ESTABLISHMENT OF TECHNOLOGY REVIEW BOARDS (TRBs)

B.1 SCOPE

B.1.1 <u>Scope</u>. The information contained herein provides for manufacturer selection of a TRB operation at stated levels. This appendix is not a mandatory part of this standard. The information contained herein is intended for guidance only. However, once a TRB option is selected and designated as a requirement, this appendix becomes mandatory, and the information contained herein is intended for compliance, other methods of establishing a TRB are allowed with qualifying activity approval. This appendix established requirements for a TRB system which provides for a phased assignment of responsibility to the TRB for the development of design, procurement, manufacturing, test, reliability, and quality assurance standard procedures. A TRB shall be established as noted in table B-I at either level 1 or 2 which defines the extent of control authorized by the qualifying activity. A prerequisite for a TRB shall be an approved MIL-STD-790 system.

TABLE B-I. TRB authority levels. 1/

TRB authority	TRB level
Process/material changes, traceability (B.3.4a)	1 and 2
Alternate methods/equipment, procedures (B.3.4b)	1 and 2
Evaluation corrective action on quality reliability (B.3.4c)	2
Deletion/alternative tests (B.3.4d)	2

- 1/ Table B-I defines the minimum authority of each TRB level. Actual responsibility and authority will be determined by the qualifying activity.
- B.2 APPLICABLE DOCUMENTS. This section is not applicable to this appendix.

B.3 REQUIREMENTS

- B.3.1 <u>TRB levels or responsibilities</u>. Establishment of a TRB at any level is subject to approval/withdrawal by the qualifying activity at any time. Upon initiation of a TRB, the level of responsibility (see B.3.4) will be assigned by the qualifying activity. The qualifying activity shall provide an overview and determination of the level of authority based upon the experience demonstrated by the TRB. Continual review and monitoring of the TRB operation and procedures will allow the qualifying activity to determine the assignment of the TRB to the appropriate level, 1 or 2. TRB's are not authorized for class S (space level) programs unless specified in the individual class S product specification. In addition, TRB level 2 is not authorized unless specified in the individual product level specification.
- B.3.1.1 <u>Purpose of TRB</u>. The TRB shall assess the impact of proposed changes upon the reliability, form, fit, and function of the product, and oversee review to assure proper implementation of concepts to improve the operational procedures and requirements.

APPENDIX B

- B.3.1.2 <u>Level 1 TRB</u>. This level provides for a mature program and provides authority for changes by a TRB. The qualifying activity will authorize responsibilities as noted in B.3.4 herein.
- B.3.1.3 <u>Level 2 TRB</u>. When authorized by the individual product specification, the level is for TRB's that have matured sufficiently to attain the confidence of the qualifying activity. This level TRB is accorded major authority as designated in B.3.4. TRB level 2 is not authorized unless specified in the individual product level specification.
- B.3.2 <u>TRB</u>. The manufacturer electing to establish a technology review board shall develop the necessary system to govern its operation. The manufacturer shall be responsible for ensuring that the actions of the TRB result in products that meet all applicable specification requirements. In the event of disputes, the referee point shall be the original specification requirement as defined by the preparing/qualifying activity. As a minimum, these procedures shall address the following:
 - Record retention.
 - b. Minimum organizational membership by function.
 - c. Responsibilities.
 - d. System for recovery of data used in TRB decisions.
 - e. TRB operating structure.
 - f. Decision making/approval procedures.
 - g. MIL-STD-790 oversight.
- B.3.3 TRB organizational structure. The following functions, as a minimum, shall be considered for the manufacturer's TRB: design and construction, material procurement, manufacturing, test, reliability, and quality assurance. Other personnel with decision making responsibilities affecting the product, its processes, or its production facility may participate as required. The manufacturer shall identify those organizations that must be represented on the TRB. A responsible technical representative within each of these organizations shall be identified to the qualifying activity. Any changes to either permanent participating organizations or their corresponding technical representatives must be reported, within 30 days, to the qualifying activity.

APPENDIX B

- B.3.4 <u>TRB responsibilities</u>. The TRB authority may extend to review and oversight of the manufacturer's entire process. Under no circumstances shall the establishment of a TRB relieve the manufacturer of the responsibility to report nonconformance to specification requirements to the qualifying activity. The life test requirements of the individual product specification are not within the spectrum of authority or responsibilities of the TRB. The TRB may be responsible for the following as authorized by the qualifying activity:
 - a. Managing and approving design/construction process/material confirmation and change control activities including traceability.
 - Approving alternative equipment/methods/procedures that modify, delete, or substitute for existing equipment methods/procedures detailed in MIL-STD-790 (other than those required by the individual product specification).
 - c. When performance or reliability of shipped components, including tests, is called into question, the TRB shall provide quick evaluation, approve appropriate corrective action, and provide prompt notification of all problems to the qualifying activity.
 - d. Approving alternative methods that modify, substitute for, or delete existing tests required by the product specification (e.g., tests within groups A, B, C, etc.).

Preparing activity:

(Project 59GP-2008-001)

DLA - CC

Custodians:

Army - CR

Navy - EC

Air Force - 85

DLA - CC

NASA -NA

Review activities:

Army - AR, MI

Navy - AS, CG, MC, OS, SH

Air Force - 19, 99

DLA - DH

Other - NRO

NOTE: The activities listed above were interested in this document as of the date of this document. Since organizations and responsibilities can change, you should verify the currency of the information above using the ASSIST Online database at https://assist.daps.dla.mil.