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MIL-STD-790E NOTICE 1 27 Jul 1990

#### MILITARY STANDARD

#### PRODUCT ASSURANCE PROGRAM FOR ELECTRONIC AND FIBER OPTIC PARTS SPECIFICATIONS

TO ALL HOLDERS OF MIL-STD-790E:

1. THE FOLLOWING PAGES OF MIL-STD-790E HAVE BEEN REVISED AND SUPERSEDE THE PAGES LISTED:

NEW PAGE	DATE	SUPERSEDED PAGE	DATE
Cover page		Cover page	15 December 1989
ii <sup>'</sup>	15 December 1989	11	REPRINTED WITHOUT CHANGE
111		111	15 December 1989
iv		iv	15 December 1989
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2. RETAIN THIS NOTICE AND INSERT BEFORE TABLE OF CONTENTS.

3. Holders of MIL-STD-790E will verify that page changes and additions indicated above have been entered. This notice page will be retained as a check sheet. This issuance, together with appended pages, is a separate publication. Each notice is to be retained by stocking points until the military standard is completely revised or canceled.

4. The margins of this notice are marked with vertical bars to indicate where changes (additions, modifications, corrections, deletions) from the previous notice were made. This was done as a convenience only and the Government assumes no liability whatsoever for any inaccuracies in these notations. Bidders and contractors are cautioned to evaluate the requirements of this document based on the entire content irrespective of the marginal notations and relationship to the last previous notice.

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# CONCLUDING MATERIAL

Custodians: Army - ER Navy - EC Air Force - 85

Review activities: Army - AR, CR, MI Navy - AS, OS, SH Air Force - 11, 17, 19, 99 DLA - DH

User activities: Navy - CG, MC Preparing activity: Navy - EC

Agent: DLA - ES

# (Project RELI-0062)

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MIL-STD-790E 15 DEC 1989 SUPERSEDING DoD-STD-347 27 MAR 1985 MIL-STD-790D 30 MAY 1986

# MILITARY STANDARD

PRODUCT ASSURANCE PROGRAM FOR ELECTRONIC AND FIBER OPTIC PARTS SPECIFICATIONS



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Supersedes cover page of MIL-STD-790E

#### MIL-STD-790E

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#### FOREWORD

1. This military standard is approved for use by all Departments and Agencies of the Department of Defense.

2. Beneficial comments (recommendations, additions, deletions) and any pertinent data which may be of use in improving this document should be addressed to: Commander, Defense Electronics Supply Center, ATTN: DESC-ES, 1507 Wilmington Pike, Dayton, OH 45444-5276, by using the self-addressed Standardization Document Improvement Proposal (DD Form 1426) appearing at the end of this document or by letter.

3. 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. During the preparation and coordination of the product assurance specifications, the need for guidelines to assure uniform evaluation of manufacturers' product assurance programs was recognized. This standard was developed to provide such guidelines.

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4. The attention of foreign manufacturers, or manufacturers with off-shore facilities is drawn to DOD-4120.3-M for acceptability under the International Standards Agreement.

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# 1. SCOPE

1.1 <u>Purpose</u>. This standard is for direct reference in electronic and fiber optic parts product assurance specifications and establishes the criteria for electronic and fiber optic parts product assurance program which are to be met by manufacturers qualifying electronic parts to the specifications.

- 1.2 Application. This standard is applicable when:
  - a. Referenced in Established Reliability (ER) specifications where attainment of specified failure rate levels is required. It is also applicable for other product specifications where the assurance of homogeneity of parts requires control of production facilities, materials, and processes.
  - b. The qualifying activity evaluates and approves the program plan as a prerequisite for qualified approval.

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#### 2. APPLICABLE DOCUMENTS

2.1 Government documents.

2.1.1 Specifications, standards, and handbooks. The following specifications, standards, and handbooks form a part of this document to the extent specified herein. Unless otherwise specified, the issues of these documents are those listed in the issue of the Department of Defense Index of Specifications and Standards (DODISS) and supplement thereto, cited in the solicitation (see 6.2).

STANDARDS

FEDERAL

**FED-STD-209** 

Clean Room and Work Station Requirements, Controlled Environment.

MILITARY

NIL-STD-721 - Definitions of Terms for Reliability, Maintainability.

MIL-STD-45662 - Calibration Systems Requirements.

(Unless otherwise indicated, copies of federal and military specifications, standards, and handbooks are available from the Naval Publications and Forms Center, (ATTN: NPUDS), 5801 Tabor Avenue, Philadelphia, PA 19120-5099.)

2.1.2 Other Government documents, drawings, and publications. The following other Government documents, drawings, and publications form a part of this document to the extent specified herein. Unless otherwise specified, the issues are those cited in the solicitation.

DOD 4120.3M - Defense Standardization and Specification Program Policies, Procedures and Instructions.

2.2 Non-Government publications. The following documents form a part of this document to the extent specified herein. Unless otherwise specified, the issues of the documents which are DoD adopted are those listed in the issue of the DODISS cited in the soliciation. Unless otherwise specified, the issues of documents not listed in the DODISS are the issues of the documents cited in the solicitation (see 6.2).

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

ANSI/EIA - 557 Statistical Process Control Systems.

(Application for copies should be adressed to the American National Standards Institute, 1430 Broadway, New York, NY 10018-3008.)

2.3 Order of precedence. 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.

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# 3. DEFINITIONS

3.1 <u>Definitions</u>. The definitions of all product assurance terms used herein are as provided in MIL-STD-721, with the exception and addition of the following:

- a. <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.
- b. Audit checklist. A form listing specific items which are to be audited.
- c. <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.
- d. <u>Distributor, category A</u>. An organization contractually authorized by a manufacturer to store, repack, and distribute completely finished parts. These parts shall have been inspected by the manufacturer to all of the applicable requirements of the specification.
- e. <u>Distributor, category B</u>. An organization contractually authorized by a manufacturer to perform one or more final operations on uncompleted parts. These parts shall have been inspected by the manufacturer to all of the applicable requirements of the specification prior to shipment to the distributor.
- f. Distributor, category C. An organization contractually authorized by a manufacturer to perform one or more assembly operations on uncompleted parts which shall be inspected by the distributor to all the requirements of the specification. Category C distributors shall be considered as an assembly plant of the manufacturer (see 3.1a), and shall be treated as such on the QPL.
- g. <u>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, semiconductor, and fiber optic devices.
- h. <u>Established reliability</u>. A quantitative maximum failure rate demonstrated under controlled test conditions specified in a military specification and usually expressed as percent failures for each thousand hours of test.
- i. <u>Failure activating cause</u>. The stresses or forces, thermal, electrical shock, vibration, etc., which induce or activate a failure mechanism.
- j. <u>Failure analysis</u>. The process of examining 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.
- k. <u>Failure mechanism</u>. The process of degradation or chain of events which results in a particular failure mode.
- 1. -Failure mode. The abnormality of an electronic or fiber optic parts performance which causes the part to be classified as failed.

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- m. <u>Inspection lot</u>. A group of electronic or fiber optic parts offered for inspection at one time and in combinations authorized by the applicable specification.
- n. Manufacturer. The actual producer of electronic or fiber optic parts.
- o. <u>Production lot</u>. A group of electronic or 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 product assurance program through all significant manufacturing operations, including final assembly operations. Final assembly operations shall be considered the last major assembly operations such as casing, hermetic sealing, or lead attachment rather than painting or marking.
- p. <u>Product assurance</u>. The management and technical integration by the product activities essential in maintaining the reliability of the design, production, testing, records etc., in regards to a product line.
- q. <u>Qualification</u>. The entire procedure by which electronic and fiber optic parts are processed, examined, and tested to obtain and maintain approval for listing on a qualified products list (QPL).
- r. <u>Qualifying activity</u>. The military preparing activity or its government agent delegated to administer the qualification program.
- s. 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.
- t. <u>Quality control operations</u>. The regulatory processes during manufacture through which actual quality performance is measured and compared with standards and the difference is acted upon.
- u. <u>Sub-assembly facility</u>. A facility owned by the manufacturer qualifying a product and authorized, by both the manufacturer and the qualifying activity, to perform manufacturing steps in accordance with processing procedures contained in the program plan.
- v. <u>Self-audit</u>. The performance of periodic survey by the device manufacturer's designated personnel to evaluate compliance to military specifications.
- w. Traveler. The production and raw material process routing sheet.

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#### 4. GENERAL REQUIREMENTS

4.1 Product assurance program.

4.1.1 <u>General</u>. The product assurance program shall integrate all designing, planning, manufacturing, inspecting, and testing functions related to the manufacture and distribution of electronic and fiber optic parts. The program shall be tailored to the type of part and the peculiarities of the manufacturer's over-all method of operation, but as a minimum, comply with the applicable requirements specified in section 5 and appendixes A and B.

#### 4.1.2 Program plan.

4.1.2.1 <u>Basic plan</u>. The manufacturer shall document a product assurance program plan in a manner adequate to demonstrate compliance with section 5 of this standard or intent to  $\cos_{\mu\nu}$ ly prior to receipt of qualification approval. When the program plan indicates intent to comply, the documentation shall include an implementation schedule. One program plan shall be required by a single manufacturing facility. The program plan shall include the manufacturer's interpretation of how each requirement of this standard shall be implemented. The program plan, after acceptance by the qualifying activity, shall constitute the requirements to be met by the manufacturer insofar as they relate to the product assurance program.

4.1.2.2 <u>Supplemental plans</u>. If more than one electronic or fiber optic part is to be qualified, supplements to the basic program plan (including subdivisions or deviations) shall be prepared. Where distributors, either categories A, B, or C, are authorized by the manufacturer to market the parts (see 5.1.6), a supplemental plan shall be prepared which describes in detail the entire function performed by the distributor, the controls invoked by the manufacturer and the methods of implementing and monitoring these controls. The controls and requirements shall be such as to assure the product sold by the distributor is of the same quality and performance as parts acquired directly from the manufacturer. The manufacturer shall be responsible for imposing all requirements consistent with this standard on distributors and shall be responsible for all of the manufacturers parts sold by the distributor which do not meet specification requirements. The manufacturer shall identify each authorized distributor and the function each distributor is authorized to perform. Supplemental plans shall contain the following information:

- a. Category A distributor: The storage, packing, handling, and distribution requirements complying with 5.2.11 and 5.2.14 shall be described.
- b. Category B distributor: The following shall be described:
  - (1) The operations, tests, and inspections the distributor is authorized to perform.
  - (2) Controls to assure that only inspected or tested and qualified parts are marked or processed by the distributor.
  - (3) Selection and inspection of sample units from each of the authorized distributors by the manufacturer in accordance with the applicable specification periodic inspection requirements.
  - (4) Compliance by the authorized distributor with all requirements of section 5, except 5.1.3, 5.1.4, and 5.2.4b.
  - (5) Procedures for submission of failed parts and failure reports to the manufacturer.

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- (6) When the distributor is authorized to mark the part, a code symbol is to be added to the modified part. This shall be developed in conjunction with the original part manufacturer's identification so that the organization making the modification can be identified. The original part manufacturer's identification shall be included to indicate the manufacturer responsible for product failure analysis, corrective action, and lot identification.
- c. Category C distributor: The following shall be described:
  - (1) Requirements imposed on the distributor's assembly plant by the manufacturer as a prerequisite for authorization.
  - (2) The operations, tests, and inspections the authorized distributor's assembly plant shall perform.
  - (3) Controls to assure that qualified parts marked or processed by the distributor's assembly plant are inspected and to meet applicable specification requirements.
  - (4) Procedures for incorporating distributor's assembly plant inspection data with that of the manufacturers.
  - (5) Compliance by the authorized distributor's assembly plant with all requirements of section 5, except 5.1.3, 5.1.4, and 5.2.4b.
  - (6) Procedures for submission of failed parts and failure reports to the manufacturer.
  - (7) When the distributor's assembly plant is authorized to mark the part, a code symbol shall be added to the modified part. This shall be developed in conjunction with the original part manufacturer's identification so that the organization making the modification can be identified. The original part manufacturer's identification shall be included to indicate the manufacturer responsible for product failure analysis, corrective action, and lot identification.

### 4.1.3 Program review and acceptance.

4.1.3.1 Review. The manufacturer shall prepare program documentation as required by this standard and demonstrate to the qualifying activity that the program is being administered in accordance with the documentation, prior to qualification and thereafter. The qualifying activity shall audit the manufacturer's compliance with the program prepared to the requirements of this standard. Reaudits may be extended to a 24-month period at the discretion of the qualifying activity provided compliance with program requirements has been satisfactorily demonstrated. Any audit of the manufacturer's subsidiaries, authorized distributors, and authorized distributor's assembly plants shall be performed through and in conjunction with the manufacturer only. (The program plan shall indicate that agreements exist between the manufacturer and distributors or distributor's assembly plants authorizing such audits.)

4.1.3.2 <u>Acceptance</u>. The qualifying activity is responsible for determining if the manufacturer's product assurance program meets the requirements of this standard. The product assurance program, once accepted, must be agreed to with the qualifying activity, as stated in the plan, to retain qualification.

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5.2.5.1 Production of prototype parts for evaluation. 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. Changes incorporated in the prototype parts shall be effected in a manner so as not to change production parts or processes until the prototype parts are made and tested, and the change accepted by the qualifying activity.

5.2.6 <u>Clean room</u>. Where process controls include the requirements of a clean room, design and operation of the clean room shall be based on Federal Standard 209. The proper class shall be specified by the manufacturer's design activity in the process specification.

5.2.7 Description of production processes and controls. The manufacturer shall prepare and maintain a detailed description of 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 electronic and fiber optic parts. All documentation and its interrelationships shall be identified in flowchart form. When applicable, documentation shall include such items as:

- a. List of process control equipment and records of 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 specific 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.
- i. Procedures for forming quality 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.

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k. In accordance with DOD 4120.3-M, the source listed on the QPL must notify the qualifying activity of any change affecting the design or process of the qualified product. Availability of test procedures and reports to the qualifying activity will minimize the necessity to require requalification tests.

5.2.8 Acquisition and production control documentation. The manufacturer shall identify by name, number, release date, and latest revision date all documents used in the acquisition and processing of materials, production of parts, and methods of product assurance. This documentation shall include purchase, process, and test specifications, internal procedures, and controls for the application of such documents. These records shall be kept for at least 5 years.

5.2.9 <u>Process control</u>. Records shall cover the implementation of devices such as control charts (e.g., X bar and R charts) or other means of indication of the degree of control achieved in the production process. Records shall also indicate the action taken when each out-of-control condition is observed, and the disposition of nonconforming products processed during the period of out-of-control operation. Records associated with nonconforming products shall be kept for a minimum of 3 years. When specified in the individual component military specification, a formal statistical process control (SPC) program in accordance with ANSI/EIA-557 shall be established.

5.2.10 Inspection of incoming materials and work in-process. Inspection operations shall be documented as to the 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 quality 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 Incoming, in process, and outgoing inventory control. The methods and procedures shall be documented 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. Each area shall maintain identity of work in-process to facilitate access by Government source inspectors. Procedures shall be prepared and 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.
- b. Segregation and identification of nonconforming materials and supplies from conforming materials.
- c. Identification and control of limited-life materials and supplies.

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- Specification revision and dates must be current at the time of audit. 1. This information need not be placed on the flowchart. However, this information must be made available to the verification team during the audit.
- 2. This flowchart is not complete and is used as an example to show the type of information which shall be included. Different symbols can be utilized if defined.

FIGURE 1. Typical process flowchart.

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- d. 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 another 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 quality 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 <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 reliability assured production specification quality conformance inspections. Such an area shall be maintained and no other parts shall be permitted in this area.

5.2.15 <u>Quality control operations</u>. Quality control operations shall be documented as to type, procedures, records, and frequency of use.

5.2.16 <u>Quality assurance operations</u>. Quality assurance operations shall be documented as to type, procedures, equipment, judgment and action criteria, records, and frequency of use.

5.2.17 <u>Manufacturing flowchart</u>. The flowchart for all devices shall reflect the complete manufacturing processes being used at the time and shall show all manufacturing, inspection, testing and quality verification points, and the point where all materials or subassemblies enter the flow. The chart will identify all documents pertaining to the production processes, quality control points, and production controls which were used. The documents will be identified by name and number (see figure 1).

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5.2.18 <u>Manufacturer's internal audit activities</u>. The manufacturer's internal audit activity shall be included in the program plan in accordance with appendix A. This plan shall identify key review areas, their frequency of audit, and the corrective action system to be employed when variations from approved procedures or specification requirements are identified. For class "S", space level components (not to be confused with ER failure rate level "S"), appendix B requirements shall apply in addition to appendix A.

5.2.19 <u>Subassembly facility</u>. Self-audit programs for subassembly facilities shall be approved by the qualifying activity and shall be imposed by the manufacturer.

5.2.20 <u>Production line audits</u>. Qualifying activities shall ensure that the conformance of the process flow and control documentation for each production line in a manufacturer's facility are checked by auditing, at least biannually. This does not preclude the performing of reaudits in accordance with 4.1.3.1 herein.

5.2.21 <u>Class "S" space level components (NOTE: Not to be confused with ER</u> <u>failure rate level "S"</u>). For class S, space level components, the manufacturer <u>shall implement the procedures and requirements of appendix B in addition to the</u> other program requirements of this standard.

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#### 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>. The information outlined in this section is intended to be explanatory and does not represent direct requirements of the standard.

6.2 <u>Documentation</u>. With regard to the documentation required by section 5, it should be noted that only documentation required by 5.1.1, 5.1.2, 5.1.3, 5.1.4, and 5.1.5 must be submitted to the qualifying activity.

6.2.1 Organizational structure. While the qualifying activity cannot approve an organizational structure, it is essential that the qualifying activity continually be aware of the relationship of the organizations responsible for the management of the product assurance program.

6.2.2 <u>Facilities</u>. The applicability of the procedures documented under 5.2 should be identified to the production areas and inspection or test facilities. This may be accomplished by a very simple floor layout plan or similar documentation.

6.3 Subject term (key word) listing.

Audit Calibration GIDEP Process control Production Qualification Traceability

6.4 <u>Changes from previous issue</u>. Marginal notations are not used in this revision to identify changes with respect to the previous issue due to the extensiveness of the changes.

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#### APPENDIX A

#### SELF-AUDIT REQUIREMENTS

#### 10. SCOPE

10.1 <u>Scope</u>. This appendix contains details for implementation of the minimum requirements to be used in the manufacturer's self-audit program. The intent of this self-audit program is to assure continued conformance to military specification requirements. This appendix is a mandatory part of the standard. The information contained herein is intended for compliance.

20. APPLICABLE DOCUMENTS. This section is not applicable to this appendix.

30. GENERAL

30.1 <u>Self-audit program</u>. The manufacturer shall have an independent self-audit program under the direction of the quality assurance department to assess the effectiveness of the manufacturer's quality assurance system. The self-audit shall identify any deficiencies for resolution in the processing, testing, or deviations from specification requirements.

30.2 <u>Self-audit representatives</u>. The manufacturer's quality assurance representative or his designated appointees shall perform all self-audits. The designated auditors shall be independent from the areas audited. If an independent auditor is not available or impractical, then another individual should be assigned to participate in the audit or review the results with the auditor from the area. The auditors shall be trained in the area to be audited, in the applicable military specification requirement and provided with an appropriate checklist for annotating deficiencies. Prior to the audit, the assigned auditor shall review the previous checklist to assure corrective actions have been implemented and are sufficient enough to correct the deficiencies.

30.3 <u>Audit deficiencies</u>. All audit deficiencies shall be documented on the appropriate checklist and a copy submitted to the department head for corrective actions. All corrective actions shall be agreed to by the manufacturer's quality department prior to implementation.

30.4 <u>Audit follow up</u>. All audit reports will be filed and monitored by the quality department. The quality department shall establish a procedure to followup on all audit deficiencies to assure the corrective actions have been implemented in a timely manner.

30.5 <u>Audit schedules</u>. The original audit frequency shall be established by the quality department but in no case exceed 6 months for each area unless authorized by the qualifying activity. Changes to the frequency of audit shall require approval of the quality department.

30.6 <u>Self-audit report</u>. The self-audit report shall be submitted to the qualifying activity for review prior to the qualification audit or reaudit. Manufacturer shall keep the self-audit report on file for a minimum of 3 years. The manufacturer shall make available to the qualifying activity, during reaudits, all corrective actions taken as a result of the self-audit. The qualifying activity will require the modification of the frequency of the self-audit or require additional testing based on the data from the self-audit.

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30.7 <u>Self-audit requirements</u>. The audit shall include, but not be limited to, all of the items on the checklist in table I. The results of any additional items that are assessed shall be added to the checklist for record purposes. The following is an explanation of the minimal requirements that every manufacturer must meet.

- a. Manufacturer must have a diagram of their organizational structure, which includes the relationship between key organizations. This chart shall clearly define the responsibility and authority for both policy and action (see 5.1.1).
- b. Manufacturer must have a manufacturing flow chart that contains every process performed, every quality control station, and the internal document control number pertaining to each (see 5.2.7).
- c. It must 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 shall be examined to determine that the conforming and nonconforming materials are segregated. Traceability must be from the finished product traveler to the incoming inspection reports (see 5.2.12). Adherence to applicable material specifications and standards in section 2 of the military specification shall be verifiable.
- e. Manufacturing travelers must 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 necessary to verify they have been doing it all along. Make sure that all significant steps of the process are included on the traveler (see 5.2.7j). If part of group A is performed in production testing, the manufacturer is required to produce data of all 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., must be in place and filled in.
- g. Voltages and temperatures must 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 5.2.7d).
- i. Environmental controls shall be maintained and monitored as required in the military specification or standard that is applicable.
- j. All instructions (e.g., setting equipment, testing, and handling) must be signed, dated, and part of documentation control system. Operators must follow instructions for procedures (see 5.2.8).
- k. Process control records will 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).
- 1. Manufacturer must verify that records indicate what actions are to be taken when out-of-control conditions are observed. Records must also show the disposition of nonconforming products (see 5.2.9).

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# APPENDIX B

#### PROCEDURES FOR THE PRODUCT AND QUALITY AUDIT FOR CLASS S, SPACE LEVEL COMPONENTS

### 10. SCOPE

10.1 Scope. This appendix provides detailed instructions to the manufacturer and audit team for the auditing of manufacturing facilities for high reliability parts designated for space environment applications. These instructions are to be applied by the audit team in assessing the capability of a manufacturer to produce a consistent baseline QPL device. The information contained herein is intended for compliance when specified in the applicable part or component specification.

20. APPLICABLE DOCUMENTS. This section is not applicable to this appendix.

**30. INSTRUCTIONS** 

30.1 <u>Baseline documentation</u>. The manufacturer shall complete the baseline document and submit the required information to the qualifying activity prior to scheduling the Product and Quality Audit. The accepted baseline shall be confirmed at the time of the initial survey. Proprietary information necessary to critical processes in the baseline shall be signed and dated by the auditor at the time of the Internal Audit and confirmed as unchanged with each subsequent audit. Documents considered proprietary shall be identified to the qualifying activity. These shall be stamp certified by the auditor but remain on the manufacturer's site as the baseline for subsequent audits. Each manufacturer shall provide a detailed process flow chart which shall include, as a minimum:

- a. All significant process steps and measurement and inspection points by descriptive name, document number, revision letter, and revision date.
- b. All raw materials, interim, and finished part quality control points; incoming inspection, storage and processing steps by descriptive name, document number, revision letter, revision date, and location in the processing sequence.
- c. The identification of all critical (significant to end product properties) manufacturing and inspection steps.
- d. The most significant physical properties to be controlled at each process step (pressure, temperature, humidity, etc.) and the control tolerance required to maintain process control along with other forms of control charts.

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30.1.1 Baseline supplements. The manufacturer shall complete and submit the following documents to the qualifying activity prior to scheduling the product and quality audit and a baseline revision history prior to each subsequent audit.

- a. Part marking, environmental, packaging, and date requirements, part numbers, design information, critical materials list, manufacturing instructions summary, Q. A. manual, and calibration manual.
- b. A summary list of all documents pertaining to the testing of military parts, including their type of storage and storage location (i.e., acceptance test records stored on personal computer (PC) disk in test laboratory, building 3). An example of each document and key to explaining any coded information contained in each document.
- c. Lot control plan, traceability plan, training plan for QC personnel, acceptance test plan (group A), qualification retention test plan (groups B and C), verification of MIL-STD-790 requirements, equipment calibration, maintenance records, reporting plan, and destructive test plan (if any).

30.1.2 Changes to baseline. The audit team shall compare the latest baseline document to the previous baseline document to assure all changes have been submitted to the qualifying activity and have been approved.

- a. Minor changes. Any subsequent departure from the approved flowchart (i.e., additions or deletions) or changes to the revision status of those processes or inspections are allowed, provided they do not violate the changes prohibited by section 30.1.2.b (major changes). The component specification shall identify the major areas. These minor changes shall be described in general terms and submitted to the qualifying activity for acceptance and also to the audit team during subsequent audits. This action shall result in an update of the baseline document.
- b. <u>Major changes</u>. No changes (i.e., substitutions, additions, deletions or modifications) shall be allowed in major areas without prior review and approval of the qualifying activity. Partial or total product requalification may be required as determined by the qualifying activity in those areas identified as major areas for control (see 30.3).

30.2 Audits. An initial audit shall be performed by the audit team reporting to the qualifying activity. Reaudits may be extended to a 24-month period at the discretion of the qualifying activity, provided compliance with the program requirements has been satisfactorily demonstrated. The audit shall include, but not be limited to, all of the items on the checklist (plus MIL-STD-790) and any GIDEP ALERTS issued against the manufacturer at the facility of interest as deemed necessary by the qualifying activity. The results of any additional items that are assessed shall be added to the checklist for record purposes.

Supersedes page 24 of MIL-STD-790E.