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MILITARY STANDARD

PRODUCT ASSURANCE PROGRAM REQUIREMENTS FOR FIBER OPTIC COMPONENTS

FSC 60GP

DEPARTMENT OF DEFENSE
Washington, DC 20301

Product Assurance Program Requirements
For Fiber Optic Components

DoD-STD-347

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: US Army Communications-Electronics Command, ATTN: DRSEL-ED-TO, Fort Monmouth, NJ 07703, by using the self-addressed Standardization Document Improvement Proposal (DD Form 1426) appearing at the end of this document or by letter.

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1. SCOPE

1. Scope. This standard is for direct reference in fiber optic specifications and establishes the product assurance program requirements which serve as the basis that manufacturers qualifying fiber optic devices must meet.

2. Application. This standard is applicable when:

a. Referenced in specifications where product assurance of fiber optic parts require control of production facilities, materials, and processes.

b. The qualifying activity evaluates and accepts the program plan (developed by the manufacturer) and monitors the manufacturer's conduct of that program.

2. REFERENCED DOCUMENTS

2.1 Government documents. The following documents of the issue in effect on date of invitation for bids or request for proposal, form a part of this standard to the extent specified herein:

STANDARDS

MILITARY

MIL-STD-721	-	Definitions of Effectiveness Terms for Reliability, Maintainability, Human Factors, and Safety.
MIL-STD-45662	-	Calibration Systems Requirements.

FEDERAL

FED-STD-209	-	Clean Room and Work Station Requirements, Controlled Environment.

(Copies of specifications, standards, handbooks, drawings, and publications required by manufacturers in connection with specified acquisition functions should be obtained from the contracting activity or as directed by the contracting officer.)

3. DEFINITIONS

3.1 Product assurance terms. 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. Assembly plant. 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, controls and storage handling and packaging techniques.

b. Audit checklist. A form listing specific items which are to be audited.

c. Defect analysis. The process of examining technical or management (nontechnical) data, manufacturing techniques, or materials to determine the cause of variations of optical, electrical, mechanical, or physical characteristics outside the limitations established at any manufacturing checkpoint.

d. Distributor, category A. An organization contractually authorized by a manufacturer to store, repack, and distribute completely finished parts which have been inspected by the manufacturer to all of the requirements of the applicable specification.

e. Distributor, category B. An organization contractually authorized by a manufacturer to perform one or more final operations on uncompleted parts which have been inspected by the manufacturer to all of the requirements of the applicable specifications.

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 applicable 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 qualified products list (QPL).

g. Failure activating cause. The stresses or forces, such as shock or vibration, which induce or activate a failure mechanism.

h. Failure analysis. The process of examining fiber optic components to determine the cause of variations of performance characteristics outside the previously established limits with the end result that failure modes, failure mechanisms, and failure activating causes will be identified.

i. Failure mechanism. The process of degradation or chain of events which results in a particular failure mode.

j. Failure mode. The abnormality of a fiber optic component's performance which causes the part to be classified as failed.

k. Inspection lot. A group of fiber optic components offered for inspection at one time and in combinations authorized by the applicable specification.

l. Manufacturer. The actual producer of fiber optic components.

m. Production lot. A group of fiber optic components manufactured during the same period from the same basic raw materials processed, under the same specifications and procedures, produced with the same equipment, and identified by the documentation defined in the manufacturer's product assurance program through all significant manufacturing operations, including final assembly operations.

n. Qualification. The entire procedure by which fiber optic components are examined and tested to obtain and maintain approval at specified failure rate levels, and then identified on the qualified products list.

o. Qualifying activity. The military activity or its agent delegated to administer the qualification program.

p. Self-audit. The performance of periodic survey by the device manufacturer's designated personnel to evaluate compliance to military specifications.

q. Traveller. The production and raw material process routing sheet.

4. GENERAL REQUIREMENTS

4.1 Product assurance program.

4.1.1 General. The product assurance program shall integrate all designing, processing, manufacturing, inspecting, and testing functions related to the manufacture and distribution of quality fiber optic components. 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 requirements specified in section 5 herein. Failure to comply with the entirety of the document can be reason for removal from the applicable QPL.

4.1.2 Program plan.

4.1.2.1 Basic plan. The manufacturer shall establish, implement, and maintain a product assurance program in accordance with section 5 of this standard in order to become a qualified manufacturer of fiber optic devices. The manufacturer's product assurance program shall demonstrate and assure that design, manufacture, inspection, and testing of fiber optic devices are adequate to assure compliance with the applicable requirements and quality standards of the applicable specification. 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 Supplemental plans. If more than one fiber optic component part is to be qualified, supplements to the basic program plan (including subdivisions or deviations) shall be prepared by the manufacturer. Where distributors, either category A, B, or C, are authorized by the manufacturer to market quality fiber optic components (see 5.1.6), a supplemental plan shall be prepared by the manufacturer 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 assure the product sold by the distributor is of the same quality and performance as parts procured directly from the manufacturer. The manufacturer shall be responsible for implementing all requirements on distributors and shall be responsible for all of the manufacturer's applicable fiber optic components 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, and distribution requirements complying with 5.2.12 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 qualified and inspected parts are 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 inspections requirements.

(4) Compliance by the authorized distributor with all requirements of section 5, except 5.1.3, 5.1.4, and 5.2.4.

(5) Procedures for submission of failed parts and failure reports to the manufacturer.

(6) When the distributor is authorized to mark the part, a code symbol is to be added to the modified part. 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 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. 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 shall demonstrate to the qualifying activity that the program is being administered in accordance with the documentation, prior to qualification and annually thereafter. The qualifying activity shall audit the manufacturer's compliance to the program prepared to the requirements of this standard and reaudit biannually to determine compliance with the specification and program plan.

4.1.3.2 Acceptance. 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 maintained at a level of control acceptable to the qualifying activity to retain qualification.

4.2 JAN and J marking. The United States Government has adopted, and is exercising legitimate control over, the certification marks "JAN" and "J", respectively, to indicate fiber optic equipment, procured by, or manufactured for use by, or for the Government in accordance with standard Government specifications. Accordingly, fiber optic components procured to, and meeting all of the criteria specified herein and in applicable detail specifications shall bear the certification mark "JAN", except that components too small to bear the certification mark "JAN" shall bear the letter "J". The "JAN" or "J" shall be placed immediately before the type number except that if such location would place a hardship on the manufacturer in connection with such marking, the "JAN" or "J" may be located on the first line above or below the type designation. Fiber optic components furnished under contracts or orders which either permit or require deviation from the conditions or requirements specified herein and in applicable detail specifications shall not bear "JAN" or "J". In the event a fiber optic component fails to meet the requirements of this specification and the applicable detail specifications, the manufacturer shall remove the "JAN" or the "J" from the sample tested and also from all components represented by the sample. The United States Government has obtained certificate of Registration No. 504, 860 for the certification mark "JAN".

5. DETAILED REQUIREMENTS

5.1 Documentation submission. The product assurance program documentation specified in 5.1.1, 5.1.2, and 5.1.6 shall be submitted to the qualifying activity as a prerequisite for qualification. All documentation specified herein shall be a continuing requirement for retention of qualification approval.

5.1.1 Organizational structure. The responsibility and authority assigned to each organization for product assurance shall be defined and documented to include the following:

a. A chart, in functional block-diagram form, showing the relationship of key organizational blocks. The organization responsible for product assurance management shall have a direct line of communication with the top management of the manufacturing facility. (In particular, the chart shall identify the organizational segment responsible to management for overall product assurance, and shall clearly define the responsibility and authority for both policy and action. The chart shall show the relationship between line and service organizations, and staff and policy organizations responsible for product assurance.)

b. A statement delineating lines of authority and responsibility.

5.1.1.1 Organizational structure changes. Any changes affecting the product assurance organizational structure shall be reflected in the corresponding documentation and forwarded to the qualifying activity within 30 days after such an occurrence.

5.1.2 Test facilities. The manufacturer shall identify the test facilities and tabulate a list of equipment used for qualification and quality conformance inspection.

5.1.3 Failure analysis reports. A summary of written reports based on the required program covering analysis of failures other than those reported by equipment contractors shall be submitted to the qualifying activity on a 6-month basis. For field failures, such action shall be taken within 30 days after receipt of parts and supporting data. The analysis of parts which fail while in the possession of an equipment contractor shall be by agreement between the manufacturer and the equipment contractor. At the request of the qualifying activity, a detailed failure analysis report shall be submitted to the qualifying activity regarding a particular failure. Any pending GIDEP Alerts on qualified parts must be reported to the qualifying activity prior to issuance.

5.1.4 Corrective action evaluation test procedures and reports. The manufacturer shall submit corrective action evaluation test procedures and test results where corrective actions have been initiated (see 5.1.5). The procedure and responsibility for decisions regarding the necessity for corrective action as a result of failure or defect analysis, and for evaluation and approval of proposed corrective actions, shall be documented. If the procedure for evaluation and approval of changes proposed for other reasons, such as cost reduction or product improvement differs from the above, it shall also be documented. All test results, conclusions, and recommendations shall be submitted to the qualifying activity within 10 working days after completion of the evaluation. The qualifying activity shall notify the manufacturer of acceptance or issue disqualification procedures within 10 days.

5.1.4.1 Preparation of evaluation test procedure. The manufacturer shall specify environmental, electrical, mechanical, numerical, and optical studies to be used in evaluating the adequacy of proposed corrective action. The test procedure shall also be designed to reveal any undesirable side effects which may occur as a result of the proposed changes in procedures, manufacturing methods, or controls. The test procedure shall be submitted to the qualifying activity concurrently with the evaluation test report.

5.1.5 Corrective action implementation. The manufacturer shall forward the following information when the proposed corrective action has been accepted by the qualifying activity:

a. The initial documentation and all changes with the date on which each corrective action becomes effective for devices to be submitted for quality conformance inspection.

b. The identification of the affected documents including the effective revison coding.

c. Identification of the first production and/or quality conformance inspection lot number incorporating the corrective action.

5.1.6 Distributor organizations. The manufacturers shall identify each authorized distributor or distributor's assembly plant, the function each organization is authorized to perform, and the authorized address at which the functions are performed. Any change in functions, or the addition or deletion of a distributor or a distributor's assembly plant, shall be reported to the qualifying activity within 10 days after such an occurrence.

5.2 Program implementation. Documentation specified herein shall be retained in the manufacturer's plant and shall be made available at the manufacturer's plant upon request by the qualifying or procuring activity. Documentation shall be dated and shall substantiate that the product assurance program, as defined by the manufacturer, has been implemented and is effectively being maintained.

5.2.1 Training. The manufacturer shall describe, conduct, and maintain a quality-oriented training program to cover all phases of his activity involved in producing quality fiber optic components. The type and extent of training shall be determined by the manufacturer, and shall be related to, and consistent with, the failure rate level for which qualification is sought. Each individual shall be retested and/or retrained at the end of a designated period or when personnel performance indicates poor proficiency. Personnel shall not be used in critical processes or inspections until the required level of proficiency has been demonstrated. The training program should include a continual work and workmanship training program for personnel involved with part design, production, inspection, handling, and testing should be provided to improve the quality and homogeneity of the part.

5.2.1.1 Training records. Records shall be maintained to indicate the type of training presented, the dates when training was presented, and the groups represented in the training sessions.

5.2.2 Calibration. Each instrument used to measure or control production process or to measure the acceptability of parts under test shall be calibrated in accordance with MIL-STD-45662. In addition, the following shall apply:

a. Calibration intervals shall be established upon analysis of documented repair and calibration data. Calibration intervals for plant standards shall not exceed 1 year except in those cases where an extended period has been obtained and concurred upon by the qualifying activity.

b. A scheduling system shall be maintained to assure that calibration is accomplished according to a predetermined schedule, and that instruments due for calibration are removed for service on or before the calibration due date.

c. Records shall cover the scheduled calibrated intervals as determined for each equipment item, the dates of completion of actual calibration, identification of the group performing the calibration, and certification of the compliance of the equipment with documented requirements after calibration.

5.2.3 Proprietary processes and procedures. Proprietary processes and procedures shall be documented to include the name, number, release date, and latest revision date. However, the documents need not be submitted to the qualifying activity for review; but upon specific request, the manufacturer's designated official shall certify to the qualifying activity that the proprietary operations are defined and controls are specified.

5.2.4 Failure and defect analysis programs. The manufacturer shall describe and maintain failure and defect analysis programs which should result in corrective action to reduce part failure and defects to an acceptable level. Procedures for such analyses shall include the following:

a. Defect analysis of in-process material or parts when records indicate a critical process is not within the manufacturer's prescribed limits.

b. Failure analysis of parts when failures exceed the number allowed in qualification and quality conformance inspections or which have failed during field use. If subsequent to identification of a failure mechanism, similar failures occur on a series of parts which are attributed to the same mechanism, analysis is required as a minimum of the first two parts.

5.2.4.1 Failure reporting. The manufacturer shall describe and maintain a failure recording and reporting system for parts which have failed during qualification or quality conformance inspections, or while in use of 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 or engineering.

d. The procedure for informing the qualifying activity of analysis results.

5.2.4.2 Failure and defect analysis records. The manufacturer shall establish a form to record the results of failure and defect analysis. Records shall be maintained which substantiate the failure and defect analysis performed and shall provide for at least the following:

a. The results of analysis.

b. The probable failure activating cause when possible.

c. Recommended corrective action, if any.

Failure analysis records shall be retained in files located in a central facility for a minimum of three years following the last similar failure. Defect analysis records shall be held for the period determined by the manufacturer.

5.2.5 Corrective plan of action. Where failures or defects are greater than the prescribed limits, the manufacturer shall prepare a plan or recommendation for corrective action. Corrective action recommendations for the performance failures shall include failure mode information when established and shall be supported by verifying data, 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 procedures. Corrective action affecting control procedures shall not be implemented for production until approved by qualified personnel responsible for the engineering, quality control, and reliability functions of the manufacturer.

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 of processes until the prototype parts are made and tested, and the change accepted by the qualifying activity.

5.2.6 Clean rooms. 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 quality fiber optic components. All documentation and its interrelationships shall be identified in flow chart form. Documentation shall include when applicable 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 electrical power 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, and inspection of completed parts including related sampling plans, and inspection tolerances.

i. Procedures for forming product assurance inspection lots which will comply with the fiber optic component 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.

5.2.8 Procurement and production control documentation. The manufacturer shall identify by name, number, release date, and latest revision date all documents used in the procurement and processing of materials, production of parts, and methods of product assurance. This documentation shall include purchase, process and test specifications, interval procedures, and controls for the application of such documents. These records shall be kept for at least (three) 3 years.

5.2.9 Process control. Records shall cover the implementation of devices such as control charts (e.g., X 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 product processed during the period of out-of-control operation.

5.2.10 Inspection of incoming materials and utilities, and of 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 use.

5.2.11 Handling and packaging procedures. Handling procedures shall be established to provide physical protection of material during all sequences of production and inspection. Assembled fiber optic components shall be physically protected during testing and quality conformance inspections. Handling and packaging procedures shall be prepared to cover storage of fiber optic components 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. Procedures shall be prepared and maintained for controlling the receipt of procured 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.

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 Conforming materials. 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 Nonconforming materials. 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 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.

5.2.13 Controlled storage area. 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 applicable specification quality conformance inspections.

5.2.14 Product assurance operations. Product assurance operations shall be documented.

5.2.15 Manufacturing flow chart. The flow chart 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 procurement and inspection of materials, the production processes, the production environments and production controls which were used. The documents will be identified by name, number, and revision in effect at the time of manufacture or changes approved thereafter.

5.2.16 Manufacturer's internal audit activities. The manufacturer's internal audit activity shall be included in the program plan (see Appendix A and B). 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.

5.2.17 Subcontractor surveillance. Self-audit program shall be imposed on subcontractors by the manufacturer.

6. NOTES

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

6.2 Documentation. With regard to the documentation required by section 5, it should be noted that only that 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 Facilities. 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. A complete list of facilities required to conduct qualification inspections should meet the requirements of the provisions for qualification defined in DoD 4120.3-M.

6.2.3 Reports. To discharge its responsibility in maintaining the integrity of the QPL, the qualifying activity must be cognizant of problems related to qualified products.

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

Custodians:
Army - CR
Navy - AS
Air Force - 85

Review activities:
Air Force - 11, 13, 14, 17, 70, 71, 80, 82, 84, 90, 99
DLA - ES

User activities:
Navy - SH, OS

Agent:
DLA - ES

Preparing activity:
Army - CR

(Project 6OGP-0104)

APPENDIX A

Self-audit requirements

A10. SCOPE

A10.1 Scope. 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.

A20. REFERENCED DOCUMENTS. This section is not applicable to this appendix.

A30. GENERAL

A30.1 Self-audit program. The manufacturer shall establish 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.

A30.2 Self-audit representatives. The quality assurance representative or his designated appointees shall perform all self-audits. The designated auditors shall be independent from the area audit if an independent auditor is not available or impractical; then, as a minimum, 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.

A30.3 Audit deficiencies. 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 Assurance (QA) department prior to implementation.

A30.4 Audit-follow-up. All audit reports will be filed and monitored by the QA department. The QA department shall establish a procedure to follow-up on all audit deficiencies to assure the corrective actions have been implemented in a timely manner.

A30.5 Audit schedules. The original audit frequency shall be established by the QA department but in no case exceed 1 year for each area, unless authorized by the qualifying activity. Changes to the frequency of audit due to consistently above or below average performance on the self-audit shall require approval of the QA department.

A30.6 Self-audit areas. The self-audit will be performed to Appendix B.

A30.7 Self-audit checklist. The audit checklist shall be prepared by the QA department and maintained under document control. The checklist shall be provided to the auditor prior to initiation of each self-audit. The checklist shall assure that the quality assurance systems is adequate and followed by all personnel in each area.

A30.8 Qualifying activity. The manufacturer shall submit to the qualifying activity for review and approval, any deficiencies, and any deficiency that has been repeated within the specified time period. The qualifying activity may modify the frequency of the self-audit or require additional testing based on the data from the self-audit.

A30.9 Traveller. The traveller shall show the sequence of operations performed and include as a minimum, tests, sampling number, supervisor and operators initials or stamp. Tests that are timed shall show the time in, time out and devices that passed or failed. Each traveller shall have a number for traceability. If more than one lot traveller is used they shall be traceable to each other. The traveller shall be kept with military test data for a period not less than three (3) years.

APPENDIX B

Minimum Requirements for the Product and Quality Self-Audit

B10. SCOPE

B10.1 Scope. This appendix re-emphasizes the basic precepts underlying the requirements of DOD-STD-347 and its application in administering self-audit programs by providing an audit requirements checklist. This appendix is a mandatory part of the standard. The information contained herein is intended for compliance.

B20. REFERENCED DOCUMENTS. This section is not applicable to this appendix.

B30. GENERAL

B30.1 Self-Audit requirements. 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 5.2.15).

c. It must be verified that the manufacturer's manufacturing and QC documentation control system is being adequately maintained. This means tracing document status all the way from production engineering to its location on the production line (see 5.2.8).

d. Incoming inspection area shall be examined to determine that the conforming and non-conforming materials are segregated. Traceability for raw materials shall from incoming inspection to finished product. Adherence to applicable material specifications and standards in section 2 of the military specification shall be documented (see 5.2.12.1).

e. Manufacturing travellers 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 travellers is necessary to verify they have been doing it all along. In addition, any whiteouts, changes in lot size, etc., must be challenged. Make sure that all steps of the process are included on the traveller.

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 test chambers must be utilized.

i. Environmental controls shall be maintained and monitored as required in the military specification or standard that is applicable.

j. Informal instructions for setting equipment, testing, handling, etc., are not allowed. Operators must be checking the applicable controlled instruction for procedures to follow.

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 (eg., X bar and R charts) (see 5.2.9).

APPENDIX B

l. 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 products produced during the out-of-control period (see 5.2.9).

m. Manufacturer shall describe and maintain failure and defect analysis programs which should result in corrective actions to reduce part failures and defects to acceptable level (see 5.2.4). A summary of written reports based on the required program covering analysis of failures other than those reported by equipment manufacturers shall be submitted to the qualifying activity on a six-month basis. For field failures such action shall be taken within 30 days after receipt of parts and supporting data (see 5.1.3). The manufacturer shall submit corrective action evaluation test procedures and test results where corrective actions have been initiated (see 5.1.4).

n. Description of production processes and controls must be sampled to determine that operators are indeed following the steps outlined in the documents.

o. It must be determined that distributors are being controlled to assure that product sold by the distributor is of the same quality and performance as parts procured directly from the manufacturer (see 4.1.2.2).

p. The calibration system must always be checked (see 5.2.2).

q. When a manufacturer translates the specification requirements onto an internal control document, he must have a cross reference to the applicable requirement paragraph in the specification to which he is qualified.

r. The manufacturer must be required to demonstrate his ability to perform the tests required by the specification. During the demonstration, the auditor should verify that the equipment is producing a readable output.

s. The manufacturer shall describe, conduct, and maintain a reliability-oriented training program to cover all phases of his activity involved in producing reliability assured production parts (see 5.2.1). Training records shall be maintained to indicate the type of training presented, the dates when training was presented, and the groups represented in the training sessions (see 5.2.1.1).

B30.2 Self audit report. Self audit report shall be available for review by the government auditor during qualification reaudit. Manufacturer shall keep self-audit report on file for a minimum of 3 years.

TABLE I. Audit requirements check list.

Requirement	Sat	Unsat	Comments
a. Diagram of organizational structure			
b. Manufacturing flow chart contains: 1. Every process performed 2. Every quality control station 3. Internal document control number pertaining to each	XX	XX	
c. Maintain document control system			
d. Incoming inspection 1. Segregation conforming and non-conforming material 2. Traceability 3. Adherence to material specifications	XX	XX	
e. Travellers 1. Contains all steps of manufacturing process 2. Being filled out and signed off 3. No whiteouts	XX	XX	
f. Logs on voltage and temperature checks in ovens and chambers			
g. Voltages and temperatures checked at least once a week on life test			
h. Overvoltage and thermal runaway protectors			
i. Environmental control			
j. Operating instructions 1. Operators must use controlled document for procedures 2. No informal instructions	XX	XX	
k. Review process control records			
l. Records must show actions to be taken during out-of control conditions			

TABLE I. Audit requirements check list - Continued.

Requirement	Sat	Unsat	Comments
m. Failure and defect analysis programs 1. Must have documented program 2. Written report submitted every six months 3. Submit corrective action evaluation	XX	XX	
n. Check that operators are following controlled documents			
o. Distributors are being controlled			
p. Calibration system checked			
q. Cross-reference requirement paragraph onto internal control document			
r. Ability to perform required tests			
s. Training 1. Training program for production personnel 2. Training records maintained	XX	XX	
t. Optical requirements	XX	XX	

Signature of QC Manager_____Date_____

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3a. NAME OF SUBMITTING ORGANIZATION	4. TYPE OF ORGANIZATION *(Mark one)*
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b. ADDRESS *(Street, City, State, ZIP Code)*	☐ USER
	☐ MANUFACTURER
	☐ OTHER *(Specify)*: _____

5. PROBLEM AREAS

a. Paragraph Number and Wording:

b. Recommended Wording:

c. Reason/Rationale for Recommendation:

6. REMARKS

7a. NAME OF SUBMITTER *(Last, First, MI)* – Optional	b. WORK TELEPHONE NUMBER *(Include Area Code)* – Optional
c. MAILING ADDRESS *(Street, City, State, ZIP Code)* – Optional	8. DATE OF SUBMISSION *(YYMMDD)*

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