MINIMUM QUALITY SYSTEM REQUIREMENTS

ESCC Basic Specification No. 24600

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space components
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DOCUMENTATION CHANGE NOTICE

Rev. Letter	Rev. Date	CHANGE Reference / Item	Approved DCR No.
		This Issue supersedes Issue 2 and incorporates all modifications defined in the following DCRs :-	
		P1. Cover page	None
		P2. DCN	None
		P4. Para. 2.1. : ESA/SCC No. 24900 added	23792
		P6. Para. 6.8 : Second clause added	23792

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1. PURPOSE

The purpose of this specification is to define the minimum requirements for a Quality System to be fulfilled by a Manufacturer of electrical, electro-mechanical or electronic components for Space application to ESA/SCC requirements.

2. APPLICABLE DOCUMENTS

The order of precedence of the applicable documents is all ESA/SCC specifications (primary references listed herein), the International Standards referenced herein and lastly other referenced specifications.

2.1 ESA/SCC Specifications

: The applicable Generic or Generics.
20100 : Requirements for Qualification of Standard Electronic Components for Space Application.
20600 : Preservation, Packaging and Dispatch of SCC Electronic Components.
21300 : Terms, Definitions, Abbreviations, Symbols and Units.
21500 : Calibration System Requirements.
22700 : Requirements and Guidelines for the "Process Identification Document".
22800 : ESA/SCC Nonconformance Control System.
24300 : Requirements for the Capability Approval of Electronic Component Technologies for Space Application.
24900 : Minimum Requirements for Controlling Environmental Contamination of Components.

2.2 International Standards

ISO 9001 Quality systems - Model for quality assurance in design, development, production, installation and servicing
ISO 8402 Quality management and quality assurance - Vocabulary

3. TERMS AND DEFINITIONS

For the purposes of this specification, the terms and definitions defined in ESA/SCC Basic Specification No. 21300 and ISO 8402 apply.

Prescription A directive within this specification which supplements, modifies or replaces a particular requirement of ISO 9001 when so required for conformance to the ESA/SCC System.

Customer The term used in ISO 9001 and synonymous with Orderer in the ESA/SCC System.

Supplier The term used in ISO 9001 and synonymous with Manufacturer in the ESA/SCC System.

4. INTRODUCTION

For recognition under the ESA/SCC System as a manufacturer of components suitable for Space Application a Manufacturer must undergo a comprehensive assessment. This establishes the ability of the Manufacturer to meet the ESA/SCC requirements and results in the qualification of the Manufacturer for one or more components or of a capability approval of a technology domain. A fundamental requirement for such a Manufacturer is the existence of a comprehensive Quality System within the overall organisation. As part of an overall assessment ESA/SCC will assess by review and audit the effectiveness of the Quality System and its conformance to the minimum requirements specified in this document.

5. QUALITY SYSTEM

The Manufacturer shall establish a Quality System which meets the requirements of the ESA/SCC System. These requirements are those of the International Standard ISO 9001, amended where necessary, by the prescriptions defined herein.

6. QUALITY SYSTEM REQUIREMENTS

The requirements of paragraph 4 of ISO 9001 Second Edition 1994-07-01 shall be met by a Manufacturer of ESA/SCC qualified components, subject to the following prescriptions. (The ISO 9001 paragraph references are given in parentheses.)

6.1 MANAGEMENT REPRESENTATIVE (4.1.2.3)

The Manufacturer shall appoint a Chief Inspector who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of this specification are implemented and maintained. The Chief Inspector shall act as the Manufacturer's point of contact for all matters relating to quality for ESA/SCC and for Orderers of ESA/SCC components. The Chief Inspector shall be proposed by the Manufacturer and shall be acceptable to ESA/SCC. The Manufacturer may also propose up to a maximum of two deputies for the Chief Inspector who shall be acceptable to ESA/SCC and may act in the Chief Inspector's absence. The Chief Inspector may or may not be the management representative required by ISO 9001.

6.2 MANAGEMENT REVIEW (4.1.3)

The management review shall encompass both the requirements of the ESA/SCC System and the requirements of ISO 9001.

6.3 QUALITY SYSTEM (4.2.1 & 4.2.2)

The Quality Manual shall clearly identify as an objective the conformance of the documented quality system to the requirements of this specification. Quality system procedures shall be in appropriate conformance to the requirements of this specification.

6.4 DESIGN CONTROL (4.4)

For ESA/SCC Qualification the Manufacturer will not be required to meet the requirements for Design Control. The Manufacturer will be required to demonstrate that the product conforms to the requirements specified in ESA/SCC Basic Specification No. 20100 with regard to selection for qualification.

For ESA/SCC Capability Approval the Manufacturer may be required to meet the Design Control requirements for the Capability Domain as required by ESA/SCC Basic Specification No. 24300.

6.5 DOCUMENT AND DATA CONTROL (4.5)

Document Control procedures shall apply to all documents that relate to the suppliers Quality System and to the manufacture of an ESA/SCC component. Change control procedures shall require adequate engineering and product assurance evaluation and review of changes before their approval and implementation.

Control methods shall include the generation of a Process Identification Document in accordance with ESA/SCC Basic Specification No. 22700 including the identification of pertinent issued and frozen documents. The requirement for ESA/SCC to approve any changes to an approved and issued P.I.D. or to the documents listed therein, in accordance with ESA/SCC Basic Specification No. 22700, shall be formally documented in the change control procedure(s).

Incorporation of changes into the P.I.D. or into any document listed therein must be such that earlier Issues/Revisions of a document are either archived or can be otherwise reconstructed without loss of integrity.

6.6 CONTROL OF CUSTOMER-SUPPLIED PRODUCT (4.7)

This requirement is not applicable to the manufacture of ESA/SCC components.

6.7 PRODUCT IDENTIFICATION AND TRACEABILITY (4.8)

ESA/SCC product shall be identifiable at all stages of manufacture and test. Lot traceability shall be maintained through all processes and to the operators and process equipment used. Traceability of test data, test equipment and test operators shall be similarly maintained. Where individual component serialisation is specified, traceability shall be to the individual component serial number.

6.8 PROCESS CONTROL (4.9)

Documentary requirements shall be supplemented by the requirements for a Process Identification Document in accordance with ESA/SCC Basic Specification No. 22700.

A suitable working environment shall be established in accordance with the requirements of ESA/SCC Basic Specification No. 24900. This shall apply equally to the working environment for inspection and test.

6.9 RECEIVING INSPECTION AND TESTING (4.10.2.3)

No ESA/SCC component shall be delivered by the Manufacturer that contains materials or piece parts which have not been successfully subjected to the receiving inspection and testing specified in the PID.

6.10 IN-PROCESS INSPECTION AND TESTING (4.10.3)

No ESA/SCC component shall be delivered by the Manufacturer that has not been subjected to the in-process inspection and testing specified in the P.I.D.

6.11 FINAL INSPECTION AND TESTING (4.10.4)

No ESA/SCC component shall be delivered by the Manufacturer until :

- The required ESA/SCC lot acceptance testing has been satisfactorily completed.
- Any pertinent ESA/SCC non-conformance has been closed.
- The data documentation package is complete.
- The certificate of conformity is signed by the Chief Inspector or his/her deputy.

6.12 CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT (4.11)

The requirements of ESA/SCC Basic Specification No. 21500 shall apply additionally. The control measures shall apply equally to process monitoring and control equipment where the results of adjustments and settings are not directly verifiable by measurements or inspections performed upon the product.

6.13 INSPECTION AND TEST STATUS (4.12)

No ESA/SCC component shall be released under a concession. The status of any non-conforming ESA/SCC component shall be clearly identified at all times.

6.14 CONTROL OF NONCONFORMING PRODUCT (4.13)

The Manufacturer shall ensure that his non-conformance procedures invoke the requirements of ESA/SCC Basic Specification No. 22800 for any non-conformance to an ESA/SCC requirement. Once invoked the requirements of 22800 shall replace the Manufacturer's internal procedures.

6.15 REVIEW AND DISPOSITION OF NONCONFORMING PRODUCT (4.13.2)

The Manufacturer shall not perform rework which is not documented in the agreed P.I.D. unless directed to do so by an ESA/SCC MRB.

ESA/SCC qualified components may not be produced under a concession. A concession from the Orderer shall be considered a regrading for an alternative application.

Regrading for an alternative application or rejection or scrapping shall be associated with the obliteration or removal of all of the ESA/SCC marking.

6.16 CORRECTIVE AND PREVENTIVE ACTION (4.14)

The Manufacturer shall ensure that in the event of a non-conformance the associated corrective and preventive actions are appropriate to preventing future recurrences of the problem on the same and other qualified components.

As part of a system for corrective actions the Manufacturer shall establish an appropriate failure analysis capability. This shall include documented procedures for the systematic application of failure analysis techniques and the generation of failure analysis reports. Such reports shall be subject to review and be a basis for the definition of appropriate corrective and preventive actions. The failure analysis capability may include the use of appropriate external facilities.

6.17 PACKAGING (4.15.4)

The requirements of ESA/SCC Basic Specification No. 20600 shall apply additionally.

6.18 QUALITY RECORDS (4.16)

Quality records shall be retained for a minimum period of three years.

Quality records for ESA/SCC components shall be traceable to component lots and for Level 'B' components and lot acceptance samples, to the individually serialised component.

6.19 INTERNAL QUALITY AUDITS (4.17)

The system of internal quality audits shall provide for periodic and systematic reaudit. A process to specify the nominal frequency of audits shall be defined and documented.

6.20 TRAINING (4.18)

Personnel used for the manufacture, test and inspection of ESA/SCC qualified components shall be assessed as to their suitability prior to utilisation by the Manufacturer. A record of this assessment shall be maintained and unsuitably qualified/experienced personnel shall not be utilised without appropriate training and successful assessment.

The training of personnel shall include a periodic reassessment. Retraining shall result when necessary.