MINIMUM QUALITY MANAGEMENT SYSTEM

REQUIREMENTS

ESCC Basic Specification No. 24600

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1. PURPOSE

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

2. APPLICABLE DOCUMENTS

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

2.1 ESCC SPECIFICATIONS

	The applicable Generic or Generics
20100:	Requirements for the Qualification of Standard Electronic Components for Space Application.
20600:	Preservation, Packaging and Despatch of ESCC Electronic Components.
21300:	Terms, Definitions, Abbreviations, Symbols and Units
21500:	Calibration System Requirements.
22700:	Requirements and Guidelines for the Process Identification Document (PID).
22800:	ESCC Non-conformance Control System.
24300:	Requirements for the Capability Approval of Electronic Component Technologies for Space Application.
24900:	Minimum Requirements for Controlling Environmental Contamination of Components.
25400:	Requirements for the Technology Flow Qualification of Electronic Components for Space Application.

2.2 INTERNATIONAL STANDARDS

ISO 9001:2000	Quality management systems - Requirements
ISO 9000:2000	Quality management systems - Fundamentals and vocabulary

3. TERMS AND DEFINITIONS

For the purposes of this specification, the terms and definitions defined in ESCC Basic Specification No. 21300 and ISO 9000:2000 apply.

3.1 DEFINITIONS

Prescription	A directive within this specification which supplements, modifies or replaces a particular requirement of ISO 9001:2000 when so required for conformance to the ESCC System.
Customer	The term used in ISO 9001:2000 and synonymous with Orderer in the ESCC System.

Organization	The term used in ISO 9001:2000 and synonymous with Manufacturer in the ESCC System.
Supplier	The term used in ISO 9001:2000 and synonymous with Sub-Contractor (a supplier to the Manufacturer of either a service, or materials or piece parts) in the ESCC System.

3.2 ABBREVIATIONS

ESCC	European Space Component Coordination
NRB	Non-conformance Review Board
PID	Process Identification Document
TRB	Technology Review Board

4. INTRODUCTION

For recognition under the ESCC 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 ESCC requirements and results in:

– the qualification of the Manufacturer for one or more components, or
– a capability approval of the Manufacturer for a technology domain, or
– the technology flow qualification of the manufacturer for a manufacturing line.

A fundamental requirement for such a Manufacturer is the existence of a comprehensive Quality Management System within the overall company organisation.

As part of an initial evaluation, ESCC will assess by review and audit the effectiveness of the Quality Management System and its conformance to the minimum requirements specified in this document. Subsequently the effectiveness and conformance will be assessed by continuing oversight and a periodic reassessment linked to the formal maintenance of the qualification or approval.

5. QUALITY MANAGEMENT SYSTEM

The Manufacturer shall establish a Quality Management System which meets the requirements of the ESCC System. These requirements are those of the International Standard ISO 9001:2000, amended where necessary, by the prescriptions defined herein.

6. QUALITY MANAGEMENT SYSTEM REQUIREMENTS

The requirements of paragraph 4 to 8 of ISO 9001:2000, third edition, 2000-12-15 shall be met by a Manufacturer of ESCC qualified components, subject to the following prescriptions. (The ISO 9001:2000 paragraph references are given in parentheses.)

6.1 QUALITY MANAGEMENT SYSTEM, GENERAL REQUIREMENTS (4.1)

For ESCC Qualified Technology Flows, the manufacturer shall establish a TRB to control, stabilise, monitor and improve each qualified Technology Flow throughout its entire life cycle as described in ESCC 25400.

In the frame of a Technology Flow Qualification, a sub-contractor control program shall also be established to ensure that all outsourced activities are controlled to the same levels as the

Manufacturer's own activities.

6.2 QUALITY MANAGEMENT SYSTEM, DOCUMENTATION REQUIREMENTS (4.2.1 & 4.2.2)

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

6.3 CONTROL OF DOCUMENTS (4.2.3)

Document Control procedures shall apply to all documents that relate to the suppliers Quality Management System and to the manufacture of an ESCC 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 ESCC 22700 including the identification of pertinent issued and frozen documents. The requirement for ESCC to approve any changes to an approved and issued PID or to the documents listed therein, in accordance with ESCC 22700, shall be formally documented in the change control procedure(s).

Incorporation of changes into the PID 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.

6.4 CONTROL OF RECORDS (4.2.4)

Quality records shall be retained for a minimum period of five years. Quality records for ESCC components shall be traceable to component lots and, where serialisation is required, to the individually serialised component. A record of all components found to be defective shall be maintained.

6.5 MANAGEMENT REPRESENTATIVE (5.5.2)

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 ESCC and for Orderers of ESCC components. The Chief Inspector shall be proposed by the Manufacturer and shall be acceptable to the ESCC Executive. The Manufacturer may also propose up to a maximum of two deputies for the Chief Inspector who shall be acceptable to the ESCC Executive and may act in the Chief Inspector's absence. The Chief Inspector may or may not be the management representative required by ISO 9001:2000.

In the case of Technology Flow Qualification, as defined in ESCC 25400, the Chief Inspector shall be a member of the TRB.

6.6 INTERNAL COMMUNICATION (5.5.3)

The Manufacturer shall task the Chief Inspector with ensuring that the internal communication processes established adequately address any specific quality management provisions applicable solely to ESCC component manufacture.

6.7 MANAGEMENT REVIEW (5.6.1)

The management review shall encompass both the requirements of the ESCC System and the requirements of ISO 9001:2000.

6.8 COMPETENCE, AWARENESS AND TRAINING (6.2.2)

Personnel used for the manufacture, test and inspection of ESCC 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.

6.9 INFRASTRUCTURE AND WORK ENVIRONMENT (6.3 & 6.4)

A suitable working environment for ESCC component manufacture shall be established and maintained in accordance with the requirements of ESCC 24900. This shall apply equally to the working environment for inspection and test.

6.10 CUSTOMER-RELATED PROCESSES (7.2)

The Quality Management Programme of an ESCC Qualified Technology Flow shall define a system for converting all external requirements for new ESCC QML listed component types into in-house requirements as defined in ESCC 25400.

6.11 DESIGN AND DEVELOPMENT (7.3)

Qualification per ESCC 20100

The design of the component to be qualified is considered to be established and in consequence the Manufacturer will not be required to demonstrate full conformance to the requirements for design and development. The Manufacturer will be required to:

– demonstrate that the component conforms to the requirements specified in ESCC 20100 with regard to selection for qualification.
– demonstrate that the requirements for design and development, pertinent to improving the existing design during Evaluation, to fully adapt it to Space Application, are sufficient.

Capability Approval per ESCC 24300

The Manufacturer will be required to meet the design and development requirements for the Capability Domain, as required by ESCC 24300.

Technology Flow Qualification per ESCC 25400

The Manufacturer will be required to meet the design and development requirements for the manufacturing line subject to the Technology Flow Qualification, as required by ESCC 25400.

6.12 VERIFICATION OF PURCHASED PRODUCT (7.4.3)

No ESCC component shall be delivered by the Manufacturer that contains materials or piece parts which have not been successfully subjected to:

– the inspections by the supplier specified in the purchase order.
– the receiving inspection and testing specified in the PID.

6.13 VALIDATION OF PROCESSES, CONTROL OF PRODUCTION AND SERVICE PROVISION (7.5.1 & 7.5.2)

Documentary requirements shall be supplemented by the requirements for a Process Identification Document in accordance with ESCC 22700.

6.14 IDENTIFICATION AND TRACEABILITY (7.5.3)

ESCC 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.

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

6.15 CUSTOMER PROPERTY (7.5.4)

This requirement is not applicable to the manufacture of ESCC components.

6.16 PRESERVATION OF PRODUCT (7.5.5)

The requirements of ESCC 20600 shall apply additionally.

6.17 CONTROL OF MONITORING AND MEASURING DEVICES (7.6)

The requirements of ESCC 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.

6.18 INTERNAL AUDITS, MONITORING AND MEASUREMENT OF PROCESSES (8.2.2)

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.

6.19 MONITORING AND MEASUREMENT OF PRODUCT (8.2.4)

No ESCC component shall be delivered by the Manufacturer that has not been subjected to the in-process inspection and testing specified in the PID.

No ESCC component shall be delivered by the Manufacturer until:

– The applicable ESCC periodic and/or lot acceptance testing has been satisfactorily completed.
– Any pertinent ESCC 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.

For ESCC Qualified Technology Flows, a Statistical Process Control Programme shall be established and documented in a Process Capability and Reliability Assessment Plan as defined in ESCC 25400.

6.20 CONTROL OF NON-CONFORMING PRODUCT (8.3)

The Manufacturer shall ensure that his non-conformance procedures invoke the requirements of ESCC 22800 for any non-conformance to an ESCC requirement. Once invoked the requirements of 22800 shall replace the Manufacturer’s internal procedures.

The Manufacturer shall not perform rework which is not documented in the agreed PID unless directed to do so by an ESCC NRB.

ESCC qualified components may not be produced under a concession. A concession from the Orderer shall be considered as 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 ESCC marking.

6.21 CONTINUAL IMPROVEMENT (8.5.1)

For each ESCC Qualified Technology Flow, a Quality Improvement Program, as defined in ESCC 25400, shall be established.

6.22 CORRECTIVE AND PREVENTIVE ACTIONS (8.5.2 & 8.5.3)

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.