COMPONENT MANUFACTURER EVALUATION

ESCC Basic Specification No. 20200

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DOCUMENTATION CHANGE NOTICE

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1 PURPOSE

The purpose of this specification is to define the requirements for an evaluation of a Manufacturer of electrical, electronic, or electromechanical (EEE) components as part of the Evaluation Phase of either an ESCC Qualification in accordance with ESCC 20100, or an ESCC Capability Approval in accordance with ESCC 24300, or an ESCC Technology Flow Qualification in accordance with ESCC 25400.

2 SCOPE

This specification provides:

- the requirements a manufacturer has to fulfil in order to be successfully evaluated;
- the outline of the evaluation methodology to be followed;
- the description of the ESCC auditing methodology employed as the major evaluation tool.

(The ESCC auditing methodology described is equally applicable to ESCC audits performed outside the scope of an Evaluation Phase.)

3 RELATED DOCUMENTS

3.1 APPLICABLE DOCUMENTS

The following ESCC Specifications form part of, and shall be read in conjunction with, this specification. The relevant issues shall be those in effect on the date of commencement of the evaluation of the Manufacturer.

ESCC 20100	Requirements for Qualification of Standard Electronic Components for Space Application.
ESCC 21300	Terms, Definitions, Abbreviations, Symbols and Units.
ESCC 22600	Requirements for the Evaluation of Standard Electronic Components for Space Application.
ESCC 22700	Requirements and Guidelines for the Process Identification Document.
ESCC 24300	Requirements for the Capability Approval of Electronic Component Technologies for Space Application.
ESCC 24600	Minimum Quality Management System Requirements.
ESCC 25400	Requirements for the Technology Flow Qualification of Electronic Components for Space Application

The applicable Checklists (Basic Specifications) can be found listed in section 9.

3.2 REFERENCE DOCUMENTS

The following International Standards are applicable to the extent specified herein. The relevant issues shall be those in effect on the date of commencement of the evaluation of the Manufacturer.

ISO 9000	Quality management systems - Fundamentals and vocabulary
ISO 9001	Quality management systems - Requirements
ISO 19011	Guidelines for quality and/or environmental management systems auditing

4 TERMS, DEFINITIONS, ABBREVIATIONS, SYMBOLS AND UNITS

4.1 DEFINITIONS

For the purposes of this specification, the terms and definitions defined in ESCC 21300 and ISO 9000 shall apply. In addition, the following shall apply:

Quality System Audit	A systematic review to determine whether quality activities and related results comply with the planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve the Manufacturer's declared quality objectives as well as the minimum quality management system requirements of ESCC 24600.
Manufacturing Line Audit	A systematic review of the manufacturing line on which ESCC components are, or are to be, manufactured in accordance with a PID fulfilling the requirements of ESCC 22700. To thus determine whether manufacturing arrangements, quality activities and related results comply with the planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve the Manufacturer's declared objectives.
Questionnaire	A set of questions on a form, submitted to a manufacturer in order to allow the manufacturer to check and declare his conformance with a given quality management system model.
Checklist	A list of items to be referred to and to be verified in order to establish conformance with given requirements.
Finding	Objective evidence that a control feature of the quality programme or manufacturing process is not implemented in accordance with internal or ESCC requirements.
Observation	An observed control feature of the quality programme or manufacturing process which is a cause for concern. A condition that may become a "Finding".
Comment	A comment to an observed control feature of the quality programme or manufacturing process which is neither a Finding nor an Observation.

4.2 ABBREVIATIONS

EEE	Electrical, Electronic and Electro-mechanical
ESCC	European Space Components Coordination
ESCIES	European Space Components Information Exchange System
Executive	ESCC Executive
PID	Process Identification Document

5 INTRODUCTION

The purpose of the evaluation of a Manufacturer is to assess the capability and the adequacy of the organisation, plant and facilities and to ascertain the Manufacturer's ability to supply EEE components to the appropriate ESCC specifications.

The Manufacturer Evaluation is managed by the Executive. The main assessment comprises one or more formal audits conducted by an ESCC audit team appointed by the Executive Manager.

ESA, as the ESCC Certification Body, has acceptance responsibility for the final results of the overall ESCC Evaluation Phase which is comprised of the Manufacturer Evaluation and the Component Evaluation.

6 ACCESS AND PROPRIETARY INFORMATION

The Manufacturer shall allow the ESCC audit team access to all appropriate working areas and provide access to personnel and facilities sufficient for the accomplishment of the evaluation.

The ESCC audit team and in turn the Executive and ESA are responsible for ensuring that all proprietary information obtained in the course of the evaluation is not disclosed to any other party without the express written permission of the Manufacturer. Reports arising from the evaluation shall be treated as strictly confidential between the manufacturer, the Executive and ESA. (It should be noted that the Executive and hence the ESCC audit team is provided for by resources drawn from both ESA and national space agencies.)

7 REQUIREMENTS ON A MANUFACTURER

For a successful evaluation the Manufacturer is required to be able to demonstrate conformance to the ESCC requirements:

- For a quality management system the Manufacturer must meet the requirements of ESCC 24600 and the applicable specifications referenced therein.
- For the manufacturing line the Manufacturer must apply the appropriate quality management system requirements to the line and be able to demonstrate a systematic ability to manufacture the required ESCC components in accordance with an approved PID to the requirements of the applicable ESCC Generic and Detail specifications.

NOTES

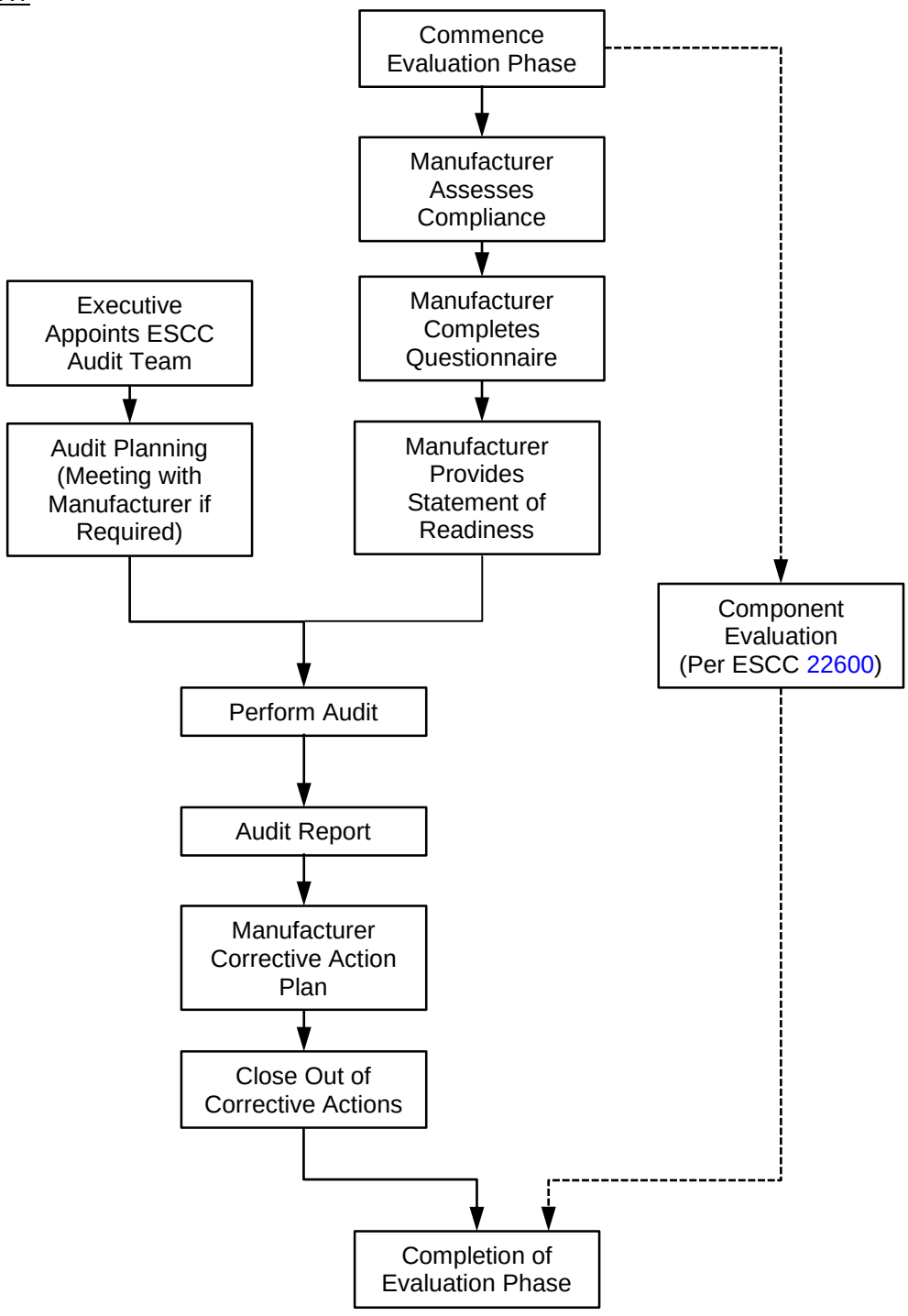
1. ESCC 24600 presupposes a quality management system based on ISO 9001. Third party certification to ISO 9001 is not a prerequisite.
2. The Manufacturer must achieve such conformance within the Evaluation Phase of an ESCC qualification, capability approval, or technology flow qualification.
3. At the outset of an Evaluation Phase, the Manufacturer is required to make a self-assessment of the degree of existing conformance and to initiate appropriate measures to achieve total conformance.

8 EVALUATION PROCEDURE

The evaluation procedure is illustrated in the flow chart of Para. 8.1. It comprises the gathering of background information, the establishment of a degree of readiness and the performance of one or more audits of the quality management system and manufacturing line.

In addition to the procedural details defined herein, an audit shall be performed generally in accordance with the guidelines of ISO 19011.

8.1 FLOW CHART



8.2 AUDIT TEAM

An ESCC audit team will be established by the Executive Manager consisting of one or more auditors supported, where necessary, by technical experts. An Audit Team Leader will be appointed. (A single auditor is de facto the Audit Team Leader.) The Audit Team Leader is responsible for the planning, execution, reporting and closeout of the audit.

The selection of auditors, the team leader and technical experts and the establishment of their respective roles and responsibilities shall generally comply with the guidelines of ISO Publication No. 19011.

8.3 AUDIT OBSERVERS

When deemed to be appropriate in the frame of an ESCC Evaluation, audit observers may be proposed, either by the ESCC Executive, or by the Manufacturer:

- An observer shall be present only if agreed to by the party to whom they are proposed.
- An observer shall be bound by the same requirements for confidentiality as agreed between the ESCC Executive and the Manufacturer.
- An observer may not participate in or influence the conduct of the audit.
- An observer shall only be in receipt of the audit report and any subsequent correspondence leading up to audit close out with the mutual agreement of the ESCC Executive and the Manufacturer.

8.4 AUDIT PREPARATION

The Audit Team Leader shall plan the audit with the Manufacturer by appropriate communications and meetings to achieve the following objectives:

- An agreed audit plan with audit dates. The plan is to include audit scope and objectives, provision for opening and closing meetings, a schedule indicating the main topics to be audited and the assignment of auditors to audit tasks. The plan shall also define the working language for the performance of the audit.
- Review by the auditors of appropriate Manufacturer documentation (e.g. quality manual, PID, previous audit reports etc.) prior to the audit.
- Acceptance by the Audit Team Leader of any declared shortcomings or non-conformances from the Manufacturer prior to the audit in so far as they affect the utility and timing of the audit. (An audit shall be postponed when known shortcomings are too numerous or of a critical nature.)
- Identification of the Manufacturer’s key personnel to host the audit.
- Acceptance by the Manufacturer of the ESCC audit team personnel.
- Identification and mutual acceptance of any person proposed to observe the audit.
- Completion of the Audit Questionnaire (available on the ESCIES web site) by the Manufacturer and its review by the auditors prior to the audit.
- Submission by the Manufacturer of the Statement of Readiness (available on the ESCIES web site) prior to the audit.

The Manufacturer shall plan appropriately for the audit so as to ensure that:

- A review of the ESCC requirements has been completed and any significant known areas of non-compliance are identified in conjunction with the submission of the Statement of Readiness.
- The facilities and areas to be audited will be appropriately operational with a normal complement of personnel and accessible by the auditors against the agreed audit schedule.
- An appropriate meeting room is available to the audit team for the opening and closing meetings as well as for review of documents and for any closed audit team discussions.
- The Chief Inspector or other designated management personnel are available for the closing meeting to receive the summary of the audit results.

8.5 AUDIT CONDUCT

The audit, whether a quality management system, or a manufacturing line, or a combined audit, shall be conducted in the following manner:

- An opening meeting to introduce the audit team and audit hosts, to confirm the audit plan, to outline the purpose and scope of the audit and to agree any changes to the audit schedule or other practical details.
- Performance of the audit with the aid of the appropriate ESCC Checklist by review of documentation and records, observation of work and inspection practices and by the questioning of appropriate personnel. All concerns, whether Findings or Observations, within the audit scope, shall be communicated verbally at the time to the audit host and/or the supervisory staff for the function concerned.
- On completion of the audit activities the audit team shall meet in closed session to prepare an executive summary of the audit results. This summary shall identify the major areas of concern arising from the audit.
- A closing meeting to present the executive summary of the audit results to the Manufacturer and to agree a time scale for the completion of the audit report and the subsequent generation, if required, of a corrective action plan.

8.6 AUDIT REPORTING

The Audit Team Leader is responsible for the preparation and distribution of an audit report, in English, reflecting the results obtained by the audit team. The report shall include inter alia and generally in the following sequence:

- A distribution list, agreed with the Manufacturer, to include the audit team members, the Manufacturer's Chief Inspector or other designated person or persons, and the responsible Executive personnel managing the controlling activity.
- A statement of confidentiality.
- Identification of the main audit participants, i.e. the hosts and the Audit Team Leader and team members.
- A list of the principal reference documents (Quality Manual, PID etc.).
- The purpose and scope of the audit.
- The definitions of Finding, Observation and Comment.
- A sequential listing of all Findings, Observations and Comments. Where applicable, precise objective evidence shall be recorded together with references to the applicable requirement(s) and relevant document(s).
- An executive summary giving the main concerns and whether the audit was satisfactory or unsatisfactory. In general any Finding equates to an "unsatisfactory audit" and initiates a corresponding requirement for corrective action.
- A recommendation, with reference to the purpose of the audit, as to whether the audit results may affect the Manufacturer's ability to properly continue the overall activity, e.g. the Evaluation Phase, until appropriate corrective actions are completed.
- When necessary, a request for a corrective action plan addressing Findings and Observations.
- Acknowledgements.
- Appendices to include relevant details of the audit planning/execution and the Statement of
- Readiness. Where useful, a completed checklist shall also be appended.

The audit report shall be submitted within a period agreed between the Manufacturer and the Audit Team Leader.

8.6.1 Statement of Confidentiality

The statement of confidentiality to be included in an ESCC Audit Report shall state that:

This ESCC audit report is considered to be confidential between the ESCC Executive, as represented in the audit by staff from ... (ESA and/or, where applicable, a national space agency), and ... (the Manufacturer). Its contents shall not be divulged to any other party without written consent by both parties. The report may be tabled by the Executive to the Certification Body, ESA, in the event that this is requested during the review of any application for qualification or qualification maintenance and corresponding ESCC QPL/QML listing.

8.7 CORRECTIVE ACTIONS

When requested to do so, the Manufacturer shall prepare and submit a corrective action plan within an agreed period from receipt of the audit report. The plan shall address each Finding with one or more corrective actions and shall discuss each Observation with corrective actions where appropriate. The plan shall identify responsible personnel and set due dates for each action. The Audit Team Leader shall review the corrective action plan and accept it when it is considered to adequately address the audit results.

The Audit Team Leader is responsible for the monitoring of the close out of the corrective actions. Verification may appropriately be achieved by communications, review of revised documents, specific meetings or by a re-audit. On successful completion of the corrective action plan the Audit Team Leader shall provide the Manufacturer with a notification of the audit close out.

8.8 AUDIT RECORDS

The Audit Team Leader is responsible for the delivery to the Executive Manager of an audit file on close out of the audit. The audit file is to contain, as a minimum:

- The audit report.
- The corrective action plan.
- Evidence of close out of the individual actions.
- Copies of appropriate correspondence.
- The formal notification of audit close out provided to the manufacturer.

9 ADDITIONAL DOCUMENTATION

9.1 ANCILLARY SPECIFICATIONS

The following supplementary specifications have been issued:

2023000	Checklist for Capacitors Manufacturer and Line Survey.
2023102	Checklist for Waveguide Devices Manufacturer and Line Survey.
2023400	Checklist for Connectors Manufacturer and Line Survey.
2023501	Checklist for Quartz Crystals Manufacturer and Line Survey.
2023502	Checklist for Surface Acoustic Wave (SAW) Devices Manufacturer and Line Survey.
2023600	Checklist for Relays Manufacturer and Line Survey.
2024000	Checklist for Resistors Manufacturer and Line Survey.
2025000	Checklist for Semiconductors Manufacturer and Line Survey.
2029000	Checklist for Monolithic Microcircuit Manufacturer and Line Survey.

NOTES

1. For Photosensitive Charge Coupled Devices and Active Pixel Sensors with Hermetic and Non-Hermetic Packages (ESCC Generic Specification No. 9020), no individual ancillary specification (i.e. Manufacturer Evaluation Checklist) exists. ESCC 2029000 should be used to the extent applicable.

9.2 FORMS AND TEMPLATES

Inter alia, the following can be found in the ESCC Forms section of ESCIES (https://escies.org):

- Audit Questionnaire
- Statement of Readiness