european space agency
agence spatiale européenne

Pages 1 to 23

COMPONENT MANUFACTURER EVALUATION

ESA/SCC Basic Specification No. 20200

space components
coordination group

Issue/Rev.	Date	Approved by	
		SCCG Chairman	ESA Director General or his Deputy
Issue 3	March 1996		
Revision 'A'	February 2002		

DOCUMENTATION CHANGE NOTICE

Rev. Letter	Rev. Date	Reference	CHANGE Item	Approved DCR No.
		This Issue supersedes Issue 2 and incorporates all modifications defined in DCR 21094.		
'A'	Feb. '02	P1. Cover Page P2. DCN Appendix A, P8.	: : : Manufacturer Questionnaire: ISO 9001 Reference 4.16, change "3 years" to "5 years"	None None 221635

TABLE OF CONTENTS

1. PURPOSE

The purpose of this specification is to define the requirements for an evaluation of a Manufacturer of electrical, electromechanical or electronic (EEE) components as part of the Evaluation Phase of an ESA/SCC Qualification in accordance with ESA/SCC Basic Specification No. 20100 or an ESA/SCC Capability Approval in accordance with ESA/SCC Basic Specification No. 24300. The specification also provides the outline for the evaluation methodology to be followed and defines a standardised approach to an ESA/SCC audit.

2. APPLICABLE DOCUMENTS

The following documents form part of, and shall be read in conjunction with, this specification. 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. The relevant issues shall be those in effect at the date of performing the Evaluation.

2.1 ESA/SCC Specifications

No. 20100, Requirements for Qualification of Standard Electronic Components for Space Application.
No. 21300, Terms, Definitions, Abbreviations, Symbols and Units.
No. 22600, Requirements for the Evaluation of Standard Electronic Components for Space Application.
No. 22700, Requirements and Guidelines for the "Process Identification Document".
No. 24300, Requirements for the Capability Approval of Electronic Component Technologies for Space Application.
No.24600, Minimum Quality System Requirements.

The applicable Checklists (Basic Specifications) can be found listed in Para. 8.

2.2 International Standards

ISO Publication No. 8402	Quality Management and Quality Assurance - Vocabulary.
ISO Publication No. 10011-1	Guidelines for Auditing Quality Systems - Part 1: Auditing.
ISO Publication No. 10011-2	Guidelines for Auditing Quality Systems - Part 2: Qualification Criteria for Quality Systems Auditors.

3. TERMS AND DEFINITIONS

For the purposes of this specification, the terms and definitions defined in ESA/SCC Basic Specification No. 21300 and ISO Publication No. 8402 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 system requirements of ESA/SCC Basic Specification No. 24600.
Manufacturing Line Audit	A systematic review of the manufacturing line on which ESA/SCC components are, or are to be, manufactured in accordance with a PID fulfilling the requirements of ESA/SCC Basic Specification No. 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 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 ESA/SCC 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. 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 ESA/SCC specifications.

The Manufacturer evaluation is managed by ESA and/or a National Space Agency (NSA). The main assessment comprises one or more formal audits conducted by an ESA/SCC audit team appointed by the managing agency. ESA has acceptance responsibility for the final results of the ESA/SCC evaluation.

5. ACCESS AND PROPRIETARY INFORMATION

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

ESA and/or the NSA 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 and the Agencies involved.

6. REQUIREMENTS ON A MANUFACTURER

For a successful evaluation the Manufacturer is required to be able to demonstrate conformance to the ESA/SCC requirements :

- For a quality system the Manufacturer must meet the requirements of ESA/SCC Basic Specification No. 24600 and the specifications referenced therein.
- For the manufacturing line the Manufacturer must apply the appropriate quality system requirements to the line and be able to demonstrate a systematic ability to manufacture the required ESA/SCC components in accordance with an approved PID to the requirements of the applicable ESA/SCC Generic and Detail specifications.

The Manufacturer must achieve conformance within the Evaluation Phase of an ESA/SCC qualification or capability approval.

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.

7. EVALUATION PROCEDURE

The evaluation procedure is illustrated in the flow chart of Figure I. 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 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 Publication No. 10011-1.

7.1 AUDIT TEAM

An audit team will be established by ESA/SCC with an audit team leader (Lead Auditor) responsible for the planning, execution, reporting and closeout of the audit. Roles and responsibilities of auditors shall comply with Sub-Clause 4.2.1. of ISO Publication No. 10011-1 and auditors shall be selected with due regard to the recommendations of ISO Publication No. 10011-2.

7.2 AUDIT PREPARATION

The Lead Auditor 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 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.
- Completion of the audit Questionnaire of Appendix A by the Manufacturer and its review by the auditors prior to the audit.
- Review by the auditors of appropriate Manufacturer documentation (e.g. quality manual, P.I.D. etc.) prior to the audit.
- Submission by the Manufacturer of the Statement of Readiness of Appendix B prior to the audit.
- Acceptance by the Lead Auditor 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 ESA/SCC audit team personnel.

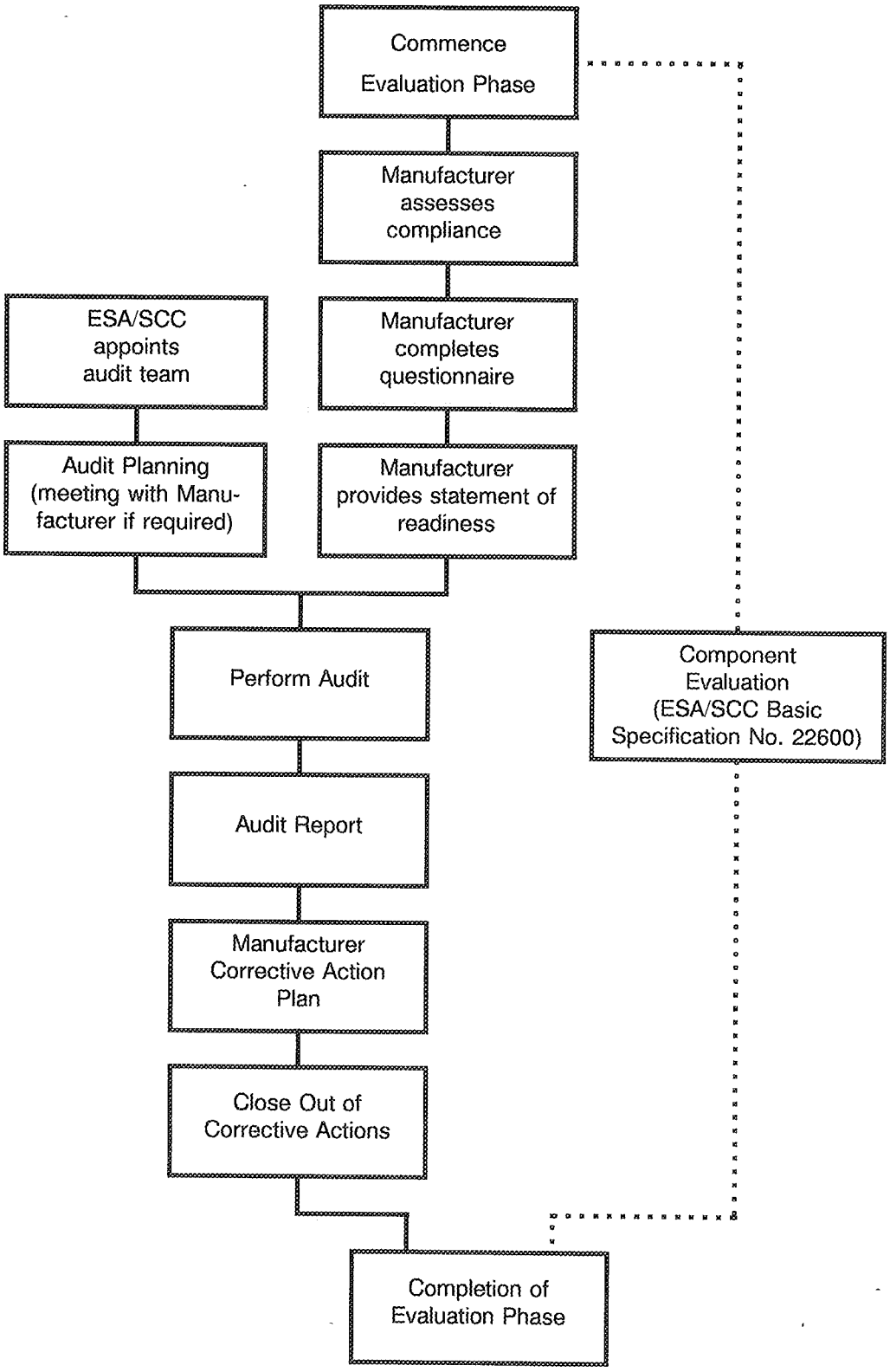
The Manufacturer shall plan appropriately for the audit so as to ensure that :

- A review of the ESA/SCC requirements has been completed and any significant known areas of non-conformance are identified in conjunction with the submission of the Statement of Readiness of Appendix B.
- 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.

7.3 AUDIT CONDUCT

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

FIGURE I : MANUFACTURER EVALUATION PROCEDURE



- An opening meeting to introduce the audit team and audit hosts, 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 ESA/SCC 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, 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.

7.4 AUDIT REPORTING

The Lead Auditor 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 :

- A statement of confidentiality generally in accordance with the model of Appendix 3.
- A distribution list, agreed with the Manufacturer, to include the audit team members, the Manufacturer's Chief Inspector or other designated person, and the responsible ESA and/or NSA personnel managing the controlling activity.
- The purpose and scope of the audit.
- The definitions of Finding, Observation and Comment.
- 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.
- A sequential listing of all Findings, Observations and Comments. Where applicable precise objective evidence shall be recorded together with references to the relevant requirements document.
- When necessary, a request for a corrective action plan addressing Findings and Observations.
- Acknowledgements.
- Appendices to include relevant details of the audit planning/execution, personnel involved 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 Lead Auditor.

7.5 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 due dates against each action.

The Lead Auditor shall review the corrective action plan and accept it when it is considered to adequately address the audit results. The Lead Auditor 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 Lead Auditor shall provide the Manufacturer with a notification of the audit close out.

7.6 AUDIT RECORDS

The Lead Auditor is responsible for the delivery to ESA/SCC 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.

8. 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.

(Pages 10 to 20)

APPENDIX A

MANUFACTURER QUESTIONNAIRE

This questionnaire is designed to serve two purposes, namely, to provide background information to an ESA/SCC audit team and to aid the Manufacturer in assessing basic compliance with ESA/SCC requirements before a formal audit. The questionnaire content should be used by a Manufacturer as a reference when completing the Statement of Readiness of Appendix B.

Completed questionnaires together with supporting documents (company quality manual, company and product brochures, draft P.I.D. etc.) should be submitted to the Lead Auditor in accordance with Para. 7.2.

COMPONENT MANUFACTURER EVALUATION

MANUFACTURER QUESTIONNAIRE

Manufacturer Name :
Address :
Telephone : **FAX :**
Chief Inspector * Name : **Title :** **Telephone :** **FAX :** **email :** (* If no ESA/SCC Chief Inspector then name of primary contact for ESA/SCC audit team.)
Component(s) to be qualified :

(In completing this questionnaire please attach additional sheets as required.)

ISO 9001 Reference	Topic	Response
N/A	**GENERAL INFORMATION** **Names of Key Personnel :** (A company organisation chart may be attached.)	
	Name of the Group of Companies with which the Manufacturer is affiliated, if any :	
	Number of Employees **Total for Group :** **Total for Manufacturer :** **Total for Manufacturing site to be Qualified :**	
	For the site provide a breakdown of numbers by function (e.g. Design, Engineering, QA, QC, Test etc.)	Function — Number
	Plant Area:	Total : Manufacturing . Cleanroom :
	Quality System References and period of validity (external certifications e.g. ISO 9001):	
	Principal customers (identifying Space or other high-rel business) :	

ISO 9001 Reference	Topic	Yes	No	N/A	Comments
4.1	**MANAGEMENT RESPONSIBILITY** Has the Manufacturer's executive management defined its quality policy, objectives and commitment?				
	Has the quality policy been documented by management, and is it known and followed at all levels of the organisation?				
	Is the Management representative for quality management reporting on the performance of the quality system to the Manufacturer's management?				
	Does a system exist for the regular supply of quality report summaries to management?				
	Is the executive management reviewing the quality system at defined intervals to ensure its continuing suitability and effectiveness in satisfying the requirements of ISO 9001 and ESA/SCC Basic Specification No. 24600?				
	Are results and actions from management reviews of the quality system performance recorded and followed?				
	Are defined quality functions provided with adequate resources, including the assignment of trained personnel?				
	Have the responsibilities of all personnel who manage, perform and verify work affecting quality been defined?				
	Has an ESA/SCC Chief Inspector been appointed with defined authority and responsibility for ensuring that ESA/SCC requirements are met and maintained?				
4.2	**QUALITY SYSTEM** Is there an established, documented and maintained quality system?				

ISO 9001 Reference	Topic	Yes	No	N/A	Comments
	Is there a quality manual?				
	Does the quality manual include or reference the quality system procedures and outline the structure of the quality system documentation?				
	Are specific quality plans prepared, as appropriate, to meet the specified requirements for products, projects or contracts?				
	Is there a specific quality plan for Space grade component manufacture?				
	Are the documented quality procedures in agreement with the requirements of ISO 9001, ESA/SCC specifications and the Manufacturer's stated quality policy?				
4.3	**CONTRACT REVIEW** Are documented procedures available describing the review of tenders, contracts and orders which define the internal processes and responsibilities as well as the interfaces with the customer?				
4 4	**DESIGN CONTROL** **(Applicable to ESA/SCC capability approval)** Have procedures been established and responsibilities assigned for the control of development and verification activities at the product design stage, and are they maintained and fulfilled?				
	Are design and development activities planned?				
	When different groups are involved in the design process, is the flow and nature of documented information between them defined and its content regularly reviewed?				
	Are design input requirements identified, documented and is their adequacy against customer and regulatory requirements reviewed?				

ISO 9001 Reference	Topic	Yes	No	N/A	Comments
	Are design output requirements documented in such a way that they can be verified and validated against design input requirements?				
	Are design changes and modifications identified, documented, reviewed and approved by authorised personnel before their implementation?				
4.5	**DOCUMENT AND DATA CONTROL** Are internal or external documents and data that relate to requirements of ISO 9001 and ESA/SCC specifications under control?				
	Is there a master list of applicable documents?				
	Are documents and data related to requirements of ISO 9001 and ESA/SCC specifications reviewed and approved by authorised personnel prior to issue?				
4.6	**PURCHASING** Are there documented and maintained procedures to ensure that purchased product conforms to specified requirements?				
	Are subcontractors evaluated and selected on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements?				
4.8	**PRODUCT IDENTIFICATION AND TRACEABILITY** Can the product be identified from drawings, specifications and documents during all stages of production and delivery where such identification is required?				
4.9	**PROCESS CONTROL** Are processes that directly affect quality during production identified?				

ISO 9001 Reference	Topic	Yes	No	N/A	Comments
	Are production and assembly processes carried out under controlled conditions?				
	Are environmental and cleanliness conditions defined and maintained where necessary?				
	Are requirements for Process Control supplemented by a Process Identification Document compliant with ESA/SCC Basic Specification No. 22700?				
4.10	**INSPECTION AND TESTING** Are procedures maintained for inspection and testing activities in order to verify that the specified requirements for the product are met?				
	Have provisions been made with respect to responsibilities and procedures for receiving inspection and testing and are they implemented?				
	Are the required inspection and testing and associated records defined?				
	Are the defined ESA/SCC inspection, testing and data requirements documented in working level documents?				
4.11	**CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT** Is all test, inspection and measuring equipment (including test software), used to demonstrate the conformance of product to the specified requirements, under strict control for performance, calibration, maintenance and traceability?				
	Are measuring equipment and standards calibrated at periodic intervals considering their stability, purpose or degree of usage? *Note: ESA/SCC allows a maximum interval time of one year*				

ISO 9001 Reference	Topic	Yes	No	N/A	Comments
	Is there a comprehensive and complete set of records documenting the accuracy, calibration method, precision and history of measuring equipment and standards?				
	Is a review of the technical requirements of the contract performed in order to ensure that measuring equipment and standards have the accuracy, stability and range for the intended application?				
	Are you compliant with the requirements of ESA/SCC Basic Specification No. 21500?				
4.12	**INSPECTION AND TEST STATUS** Have arrangements been made for identifying the inspection and test status of product and are they maintained?				
	Do inspection and test status records clearly distinguish between conforming and non conforming product?				
4.13	**CONTROL OF NON CONFORMING PRODUCT** Have provisions been made for the identification of nonconforming product, the documentation of nonconformities, the review of nonconformities, the segregation of nonconforming product, wherever practicable, and the notification of the relevant functions?				
	Are responsibility and authority for the disposition of nonconforming product specified, documented and maintained?				
	Is any non-conformance to an ESA/SCC requirement controlled in accordance with ESA/SCC Basic Specification No. 22800? Is this documented?				

ISO 9001 Reference	Topic	Yes	No	N/A	Comments
4.14	**CORRECTIVE AND PREVENTIVE ACTION** Are quality records, service reports, and other customer feedback, such as non-conformances reports, used to actively determine where corrective actions may be necessary?				
	Has the manufacturer established an appropriate failure analysis capability?				
	Is a failure analysis procedure available and maintained?				
	Is there a maintained procedure for implementing corrective and preventive action?				
4.15	**HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY** Do written procedures exist for handling, storage, packaging and delivery?				
	Are they maintaining the quality of the product up to its delivery?				
	Are the requirements of ESA/SCC Basic Specification No. 20600 fulfilled?				
4.16	**QUALITY RECORDS** Do you have procedures defining identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records?				
	Are records maintained for a minimum of 5 years?				
4.17	**INTERNAL QUALITY AUDITS** Do you have a maintained procedure for planning and implementing internal quality audits?				
	Are internal audits conducted against the requirements of ISO 9001 and ESA/SCC specifications?				

ISO 9001 Reference	Topic	Yes	No	N/A	Comments
	Are the implementation and effectiveness of corrective actions resulting from a quality audit verified and documented?				
4.18	**TRAINING** Are procedures maintained for identifying training needs and provide for the training of all personnel performing activities affecting quality?				
	Are personnel assigned to the manufacture, test and inspection of ESA/SCC components qualified and assessed on the basis of appropriate education, training and experience as required?				
4.20	**STATISTICAL TECHNIQUES** Do you identify the appropriate statistical techniques to assure process capabilities and final product quality?				
N/A	**MANUFACTURING LINE** Are ESA/SCC components to be manufactured on ; - the standard manufacturing line? - a special line? - part standard / part special?				
	Are cleanrooms and/or clean workstations utilised?				
	Are all manufacturing operations for ESA/SCC components to be performed in house?				
	If not are suitable sub-contractors identified and assessed?				
	Are any special in process controls identified? If so, what are they?				
	Does a PID exist? - or - Does a draft PID exist?				

ISO 9001 Reference	Topic	Yes	No	N/A	Comments
	If there is no PID does a preliminary process flow chart exist for the ESA/SCC flow?				
	Are all screening, qualification and lot acceptance tests to be performed in house?				
	If not are suitable sub-contractors identified and assessed?				
	Are all necessary jigs and fixtures available for the manufacture and test of ESA/SCC components?				
	Are specific personnel identified for manufacture, inspection and test of ESA/SCC components?				
	Are personnel identified for ESA/SCC manufacture, inspection and test appropriately trained?				
	Are ESA/SCC traceability requirements fulfilled by the lot travellers?				
	Are environmental and contamination control measures appropriate in the manufacturing line for ESA/SCC components?				
	What recent manufacturing line audits (internal or external) have been performed and with what results?				
	Are any shortcomings of the manufacturing line, not covered by the above questions, which may affect ESA/SCC component manufacture identified?				

(Pages 21 to 22)

APPENDIX B

STATEMENT OF READINESS

ESA/SCC Audit
Statement of Readiness

To :

Attention :

With reference to the ESA/SCC Qualification/Capability Approval† of :

† Delete as appropriate.

We have reviewed our quality assurance system† and manufacturing line† against the requirements of the ESA/SCC System and declare that we consider the requirements are met. Further we declare that we are ready and prepared to receive an ESA/SCC Audit Team for the purpose of verifying our declared compliance to the ESA/SCC requirements.

† Delete as appropriate.

Comments, declared non-conformances etc. (attach extra pages as necessary)

From :

Signature : _____

Chief Inspector / Q.A. Manager

Name : _____

(FAX)

Date (dd--mm--yy) : _____

APPENDIX C

STATEMENT OF CONFIDENTIALITY

An ESA/SCC Audit Report shall contain a statement of confidentiality equivalent to the following :

Statement of Confidentiality

This audit report is considered to be confidential between *Manufacturer name*, ESA and *NSA name* and its contents shall not be divulged to any other party without mutual written consent. A synopsis may be tabled to the ESA/SCC Qualification Board in the event that this is required by the Qualification Board in the review of any application for Capability Approval, Qualification or Maintenance thereof.