COMPONENT MANUFACTURER EVALUATION

MANUFACTURER QUESTIONNAIRE

Manufacturer Name:
Address:
Telephone: FAX:
Chief Inspector * Name: Title: Telephone: Fax: Email: *if no ESCC Chief Inspector then name of primary contact for ESCC audit team
Components to be qualified:

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

Manufacturer Questionnaire

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 site provide a breakdown of numbers by function (e.g. Design, Engineering, QA, Test, etc.)	Function Number
	Plant Area:	Total: Manufacturing: Cleanroom:
	Quality System References and period of validity (external certification e.g. ISO 9001)	
	Principal customers (identifying Space or other High-Rel business)	

Manufacturer Questionnaire

ISO 9001:2008 reference	Topic	Y	N	N/A	Comments
§ 4	**QUALITY MANAGEMENT SYSTEM**				
	Is there an established, documented and maintained quality management system?				
	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, ESCC specifications and the Manufacturer's stated quality policy?				
	Are internal or external documents and the data that relate to requirements of ISO 9001 and ESCC specifications under control?				
	Is there a master list of applicable documents?				
	Are documents and data related to requirements of ISO 9001 and ESCC specifications reviewed and approved by authorized personnel prior to issue?				
	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?				

Manufacturer Questionnaire

ISO 9001:2008 reference	Topic	Y	N	N/A	Comments
§ 5	**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 organization?				
	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 reports 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 ESCC 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 ESCC Chief Inspector been appointed with defined authority and responsibility for ensuring that ESCC requirements are met and maintained?				

ISO 9001:2008 reference	Topic	Y	N	N/A	Comments
§ 6	**RESOURCE MANAGEMENT**				
	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 ESCC components qualified and assessed on the basis of appropriate education, training and experience as required?				
§ 7	**PRODUCT REALISATION**				
§ 7.2 Customer-related processes	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?				
§ 7.3 Design and Development (**)	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?				
§ 7.3 (**)	Are design and development activities planned?				
§ 7.3 (**)	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?				
§ 7.3 (**)	Are design input requirements identified, documented and is their adequacy against customer and regulatory requirements reviewed?				
§ 7.3 (**)	Are design output requirements documented in such a way that they can be verified and validated against design input requirements?				
§ 7.3 (**)	Are design changes and modifications identified, documented, reviewed and approved by authorised personnel before their implementation?				
(** Applicable to ESCC Capability Approval)					

Manufacturer Questionnaire

ISO 9001:2008 reference	Topic	Y	N	N/A	Comments
§ 7.4 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?				
§ 7.5 Production and service provision	Can the product be identified from drawings, specifications and documents during all stages of production and delivery where such identification is required?				
	Are processes that directly affect quality during production identified?				
	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 (PID) compliant with ESCC 22700?				
	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?				
	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 ESCC 20600 fulfilled?				

ISO 9001:2008 reference	Topic	Y	N	N/A	Comments
§ 7.6 Control of monitoring and measuring devices	In 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 equipments and standards calibrated at periodic intervals considering their stability purpose or degree of usage?				
	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 equipments and standards have the accuracy, stability and range for the intended application?				
	Are you compliant with the requirements of ESCC 21500?				
§ 8	**MEASUREMENT, ANALYSIS AND IMPROVEMENT**				
§ 8.2 Monitoring and measurement	Do you have a maintained procedure for planning and implementing internal quality audits?				
	Are internal audits conducted against the requirements of ISO 9001 and ESCC specifications?				
	Are the implementation and effectiveness of corrective actions resulting from a quality audit verified and documented?				
	Have provisions been made with respect to responsibilities and procedures for receiving inspection and testing and are they implemented?				
	Are procedures maintained for inspection and testing activities in order to verify that the specified requirements for the product are met?				

ISO 9001:2008 reference	Topic	Y	N	N/A	Comments
	Are the required inspection and testing and associated records defined?				
	Are the defined ESCC inspection, testing and data requirements documented in working level documents?				
§ 8.3 Control of non-conforming product	Have provisions been made for the identification of non-conforming product, the documentation and review of nonconformities, the segregation of non-conforming products, wherever applicable, ad the notification of the relevant functions?				
	Are responsibility and authority for the disposition of non-conforming product specified, documented and maintained?				
	Is any non-conformance to an ESCC requirement controlled in accordance with ESCC 22800? Is this documented?				
§ 8.4 Analysis of data	Do you identify the appropriate statistical techniques to assure process capabilities and final product quality?				
§ 8.5 Improvement	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 actions?				

Manufacturer Questionnaire

ISO 9001:2008 reference	Topic	Y	N	N/A	Comments
N/A	**MANUFACTURING LINE / PROCESS**				
	Are ESCC components to be manufactured on: - The standard manufacturing line? - A special line? - Part standard/ part special?				
	Are cleanrooms and/or clean workstations utilised?				
	Are there storage facilities for raw materials, piece parts, semi-finished components and finished components?				
	Are environmental and contamination control measures in accordance with ESCC 24900?				
	Are all manufacturing operations for ESCC 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?				
	If there is no PID, does a preliminary process flow chart exist for the ESCC 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 ESCC components?				
	Are specific personnel identified for manufacture, inspection and test of ESCC components?				
	Are personnel identified for ESCC manufacture, inspection and test appropriately trained?				

ISO 9001:2008 reference	Topic	Y	N	N/A	Comments
N/A	**MANUFACTURING LINE / PROCESS**				
	Are ESCC traceability requirements fulfilled by the lot travelers?				
	Are materials, processes and finishes such that finished components do not contain hazardous materials or residues (e.g. Be2O, Cd, Li, Mg, Hg, Zn, radioactive materials etc.)?				
	Are the finished components free from any pure tin (or less than 3% of Pb in case of SnPb alloy) used as a finish on the terminations, leads and external surfaces of components and packages?				
	Are materials, processes and finishes such that finished components do not contain materials or residues which are unstable or fail to meet the ESCC outgassing requirements per ECSS-ST-Q-70-02?				

ISO 9001:2008 reference	Topic	Y	N	N/A	Comments
N/A	**MANUFACTURING LINE / PROCESS**				
	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 ESCC component manufacture identified?				