‘Commercial In Confidence’

PCS Supplier General Requirements

PUR-SOPS-003
Issue: **15**

Precision Control Systems
Value stream or function

☒ Cambridge
☒ Cheltenham
☐ Manhattan (Kansas)

Owner: **Quality Assurance**
BMS change number: BMS713-22
Date: 26 April 2023

ULTRA | PCS

Amendment record sheet

Issue	Summary description of change	BMS change form	Date

15	Total re-write of PUR-SOPS-003 to incorporate relevant requirements of DC0069 Supply Chain Quality Requirements
	
	This edition has been re-formatted with a clause structure aligned to the structure of ISO9001:2015 and aligning language with AS9100D. The intent of the format change is to aid systematic review and use of these requirements. Many updates to content have been made and a full review is recommended. Examples of changes include:
	- Eliminate redundant data and clarifies requirements
	- Section 1.3: Highlights Key requirements including notification of escapes within 24 hours and supplier notification of changes.
	- Section 2: Defines requirement types and requirement applicability and references other supplements.
	- Section 2: Highlights requirements for
	  ○ APQP
	  ○ Control of Special Process
	- 4.4: Notify Major 3rd party audit findings.
	- 7.2: 2 Yearly eyesight testing
	- 7.5.3: Record retention requirements for Production records reduced to 25 Years. Design records remain Indefinite.
	- 8.2.3: No delivery of PMA parts without agreement, (See section 3 for definitions).
	- 8.4.1: Defines quality approvals required in supply chain
	- 8.4.2: Defines rules for free issued materials; explains the certificates required for electronic components.
	- 8.4.3 and 8.5.1: Requirements for distributors providing drawn parts (Provider flow-down and First Article Reports)
	- 8.5.1: Introduces requirements for ULTRA owned tooling; Introduces Special Process sub-tier reporting requirements
	- 8.5.3: Rules for ITAR design data.
	- 8.5.4: Demonstrating ESD control to international standards
	- 8.6: Explains required content in delivery documents
	- 8.7: Requires NC items deemed scrap rendered unusable within 30 days
	- 10.2 Expectations for responding to non-conformity raised by ULTRA
		BMS713-22	26/April/2023

Security

The recipient is warned that this document should be handled in accordance with the Security Classification indicated throughout.

TABLE OF CONTENTS

FORWARD

Ultra PCS (Precision Control Systems) relies on the excellence and expertise of its suppliers to help it meet the requirements of the Aviation and Defense Electronics industry. ULTRA designs and manufactures safety critical units fitted directly to Aircraft. Any part supplied could play a safety critical role in the functioning of an Aircraft.

ULTRAs policy is to use suppliers with a Quality Management System that is at minimum compliant to ISO9001 latest revision. This document uses a similar numbering system but contains several important additions. These include the relevant requirements of:

- Authorities that regulate ULTRA

- Customers of ULTRA

- ULTRA's own AS/EN9100 compliant Business Management System.

This document has been written to enable flow down of relevant requirements to Ultra's supply chain and providers. The document has been divided into General and Additional requirements and is based on the structure of ISO9001:2015 / AS9100:2016 - where section numbers appear to jump, this is to ensure requirements alignment integrity. The intention is to ease understanding of the document and make it simpler to show compliance to these requirements.

The terms 'organisation' and 'providers' have been used interchangeably throughout this document to mean provider of parts and services to ULTRA.

1 CRITICAL INFORMATION

1.1 Scope of Document

This document specifies the minimum criteria, which organisations providing products and services (Providers) to Ultra PCS shall satisfy. This document applies to all Organisations that buy, sell, store, design, make, modify or process a Relevant Item.

This document is normally referenced as part of a purchase order, statement of work, contractual requirement or other inter-organisational agreement. This is in addition to any specific requirements detailed on the purchase order Terms and Conditions, procurement specifications, Supplier agreement, drawings etc. **This document is currently intended for use by providers receiving purchase orders from the ULTRA's UK sites.**

1.2 Policy

A thorough review shall be made of this document by the organisation and arrangements made to ensure compliance before commencing work for ULTRA. Non-adherence to this document could lead to the organisation being in breach of contract and as a result the organisation may be disqualified as an approved provider.

1.3 *Key Requirements*

a) **AUDITS AND VISITS:** The organisation may be required to support regular quality audits (typically at 1-3-year intervals) and business reviews as appropriate.

b) **RIGHTS OF ACCESS:** Ultra PCS, its Customers and relevant regulatory bodies shall have right of access to the organisation's premises records and QMS documentation, and to those of their Suppliers in order to verify compliance to purchase orders and their related requirements. This requirement shall continue for the life of any System in which a Relevant Item is used.

c) **PERMITS / CONCESSIONS:** Product not conforming to the relevant design data shall not be delivered unless the organization holds a copy of an approved ULTRA concession or permit signed by ULTRA Quality Department. Reference shall be made to the concession/permit on any certification accompanying the goods.

d) **NOTICE OF ESCAPE:** ULTRA must be informed immediately (not to exceed 24 hours or the next business day) of suspect nonconforming product shipped regardless of destination.

e) **CHANGES TO MATERIAL OR DESIGN:** The organisation agrees not to make any change in materials or design details which would affect the Relevant Item or any component part thereof with regard to: (A) Part number identification; (B) Physical or functional interchangeability; (C) Repair and overhaul procedures and processes and material changes which affect the product or service without prior written approval of ULTRA, and without revising the part numbers and the originals of all drawings or data.

f) **OTHER CHANGES:** Changes by the organisation or their supply chain affecting Product characteristics, specification, original source, inspection / test, certification or delivery must be notified to ULTRA prior to implementation. Where an Ultra drawing or technical specification exists for the item supplied then other process and organisational changes must be notified to, and accepted by, ULTRA prior to embodiment, as defined in ULTRA Supplier Notification of Change Form ODT-0076. Where such changes involve relocation, or transfer of Seller's primary manufacturing operations ULTRA must be notified in writing at least 90 days in advance.

g) SUPPLY CHAIN FLOW-DOWN: These key requirements, all other appropriate requirements of this document and any other data referenced or implied in ULTRA's purchasing information shall be flowed down at all applicable levels of the supply chain.

2 REQUIREMENT FORMAT AND APPLICABILITY

All requirements relating to laboratory testing and calibration requirements appear in DC0069 Supplement L – "Supply Chain Quality Requirements for THIRD-PARTY TEST LABORATORIES AND CALIBRATION LABORATORIES", available on request.

Ultra flows down additional product specific QMS flow-down through the Purchasing Documentation applicable to a product. In such cases Ultra's general approach is to capture these in a supplementary document normally in the format "PUR-SOPS…". These will be updated from time to time and normally appear on the applicable Purchase Order and are available on request.

Key requirements section of this document (1.3) applies to ALL Providers of Products and Services.

Applicability of the other requirements in this document is based on the type of product being provided and explained in Table 1 below.

Table 1 – Types of Requirement

Description	Definition	Type
All Parts	Applies to all products and services provided	A
Build to Print	Applies where products and services are specified by ULTRA without any design activity by the Provider, e.g. where items are manufactured to Ultra drawings.	B
Commercially available	Applies where products and services are commercially available and defined by organisations other than ULTRA. (Standard catalogue parts)	C
Designed for Ultra	Applies where products have been specifically designed to meet Ultra's specified requirements.	D
Special Processes	Organisations that provide one or more of the defined special processes in the processing and manufacturing of parts required for delivery to ULTRA PCS.	S

The numbering of titles generally follows ISO9001 as supplemented in AS9100.

3 TERMS AND DEFINITIONS

The following terms are used in this document:

Term	Meaning
AUTHORISED / FRANCHISED DISTRIBUTION	Authorised / Franchised distribution is considered as transactions conducted by a distributor distributing product within terms of a contractual agreement with the original component, fixing or fastener manufacturer. For purposes of this document an organisation is only recognised as authorised / franchised if objective evidence of authorisation / franchise is available.
CALIBRATION LABORATORY	Providers which report on the comparison of a measuring equipment of unknown accuracy to another measuring equipment of known accuracy.
CofC	Certificate of Conformity
COSHH	Control of Substances Hazardous to Health: COSHH is the law that requires employers to control substances that are hazardous to health and includes nanomaterials.
DESIGN DATA	Data that define a product, including drawings, requirements specifications, procedures, test specifications, materials specifications and process control criteria.
DIGITAL PRODUCT DEFINITION	Digital data files that disclose, directly or by reference, the physical or functional requirements, including data files that disclose the design or acceptance criteria of a product. E.g. PCB gerber data referenced by a drawing.
EASA	European Aviation Safety Agency
ECM	Electronic or Engineering Co-ordination Memo
FAI	First Article Inspection
KEY CHARACTERISTIC	An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation
MRB	Material Review Board
PFMEA	Process Failure Modes and Effects Analysis
PMA	Federal Aviation Authority Parts Manufacturer Approval. PMA is a combined design and production approval for modified and replacement articles. It allows a

	manufacturer to produce and sell these articles for installation on type certificated aircraft products. Refer to FAA regulations for further information
NAA	National Airworthiness Authority
NDT	Non-destructive testing
OUTSOURCED PROCESS	A Process that the organisation needs for its quality management system and which the organisation chooses to have performed by an external party. ***Examples of Outsourced Processes include testing services, calibration services and design services***
ORGANISATION / PROVIDER	Any organisation that provides a product or service to another organisation. A Provider may be a totally independent organisation from the party which it is supplying or may be a part of the same parent organisation where that part is not subject to the same quality management system.
PURCHASING DOCUMENT	Documents associated with the purchase of a product or service, e.g. Purchase Order, Contract or Side Letter
QMS	Quality Management System
RELEVANT ITEM	Any product or service which has the potential, either directly or indirectly, to affect the conformity to requirements of a deliverable supplied by ULTRA to a customer. This may include any material, part, component, assembly, system, subsystem, hardware, software, test instrument or process provided by a Provider.
RISK	An undesirable situation or circumstance that has both a likelihood of occurring and potentially negative consequence
SPC	Statistical Process Control
SPECIAL PROCESSES	These are defined in section 8.5.1.2
SPECIAL REQUIREMENT	Those requirements identified by the customer or determined by the organisation which have high risks to being achieved, thus requiring their inclusion in the risk management process
SUB-CONTRACTOR	A type of Provider performing any Outsourced Process. This category is also applicable for organisations which provide a Relevant Item which is defined by Design Data provided by ULTRA to the organisation for the purpose
SUPPLIER	A Type of Provider

THIRD-PARTY TEST LABORATORY	An ORGANISATION which provides test services to fulfil a statement of work and / or purchase order issued by ULTRA to the laboratory
UKAS	United Kingdom Accreditation Service (http://www.ukas.com/)
ULTRA	Ultra Precision Control Systems
ULTRA DESIGN DATA	Design Data issued by ULTRA

Ref	Requirement	T
4	**CONTEXT OF THE ORGANISATION**	**T**
4.4	**Quality Management System and its Processes**	T
4.4.010	This document employs, as a foundation, ISO Quality Standard ISO9001 and is supplemented by additional ULTRA requirements as defined herein. Requirement text is suffixed by a 3-digit number to distinguish it from titles and to allow individual requirements to have their own reference designator. E.g. - 1.1 = Title (T) - 1.1.010 = A requirement within section 1.1 - 2.1.1 = Title (T) - 2.1.1.010 = A requirement within section 2.1.1 *NOTE: ULTRA also encourages organisations to obtain appropriate certification to the AS9100 family of standards and the NADCAP scheme for special processes.*	A
4.4.015	Where the organisation holds approvals to AS9100 or NADCAP they shall be applied to the work carried out for Ultra unless otherwise agreed and documented.	A
4.4.020	Unless otherwise agreed with ULTRA and documented, the organisation shall: · Ensure compliance with this document and ISO9001. · Implement and maintain a QMS which is certified to ISO 9001 by a recognised and accredited 3rd party. · Inform ULTRA of changes in approval certification status, scope, certifying body and any Major 3rd party audit findings. · Ensure that ULTRA is provided with a current copy of their ISO9001 / AS9100 certificate initially and upon re-certification. · Provide a compliance matrix or similar evidence of compliance against the applicable requirements of this document if requested by ULTRA.	A

4.4.030	The organisation shall obtain written approval from ULTRA Quality Department before proceeding with any work if the organisation does not possess or ceases to possess an applicable QMS certification. The organisation's QMS approval remains valid provided that: - The scope of approval covers the relevant items being provided. - 3rd partys audit reports are provided on request to ULTRA. - Where AS9100is held it is approved on the IAQG OASIS database with viewing rights granted if requested. - Where ISO9001 is held, certification is from a body accredited by member of the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) for Quality Management Systems, e.g. UKAS or ANAB. Note: Key requirements (see 1.3) apply in the event of suspension of or lapse in certification.	A
4.4.040	**Counterfeit Avoidance Policy** Organisations shall develop implement and maintain a counterfeit parts control plan that documents the processes used for risk mitigation, disposition and reporting of counterfeit parts. The plan should be compliant with industry standard AS-5553 **or AS-6174 as applicable for electronic or material goods,** latest issue.	B+D
5	**LEADERSHIP**	**T**
5.1	**Leadership and commitment**	**T**
5.1.010	ULTRA is an approved organisation working under Aviation Regulations. In performing work for ULTRA, the organisation must ensure compliance with ULTRA's requirements and applicable regulations and ensure conformity to approved Design Data.	A
5.1.2	**Customer focus**	**T**

5.1.2.010	The organisation shall measure product conformity and on time delivery performance and take appropriate action if planned results are not or will not be achieved. Top management and / or their representative shall ensure that responsibility and authority is defined for ensuring: a) Conformity to requirements of the products and services supplied. b) That the organisation's response to any investigation is properly coordinated and documented. c) Coordination is maintained with ULTRA and that ULTRA are provided with all necessary documentation in support of the product or services being provided. d) Notification of changes to ULTRA (See 1.3).	B+D
6	**PLANNING**	**T**
6.010	NOTE: ULTRA has no additional requirements for clause 6 beyond those in ISO9001.	A
7	**SUPPORT**	**T**
7.1	**Resources**	**T**
7.1.5	**Monitoring and measuring resources**	**T**
7.1.5.010	The organisation shall maintain a register that includes at minimum the equipment used to determine conformity of product to ULTRA Design Data. This includes but is not limited to: Test hardware; Test software; Test Equipment; and devices used to record inspection data. The Organisation shall maintain calibration of the equipment, ensuring conformance to the applicable requirements and procedures. These requirements also apply to devices or equipment at the Organisation that are supplied, owned or calibrated by ULTRA.	B+D
7.1.5.020	The organisation shall ensure that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out at their own sites or on their behalf at other sites.	B+D
7.2	**Competence**	**T**

7.2.010	Personnel conducting NDT, or the final visual inspection of an ULTRA Product Characteristic or Dimension shall: Perform a vision assessment (eye examination) on commencement of employment and at two (2) yearly intervals to ensure visual acuity.	B+D
7.3	**Awareness**	T
7.3.010	Ethics Policy: Each Organisation providing product to ULTRA is required to maintain the highest standard of professional competence and integrity appropriate to their role. At all times Organisations should comply with the letter and spirit of the law and maintain fair dealings with their suppliers, customers, visitors and other employees. ULTRA PCS believes that employment should be freely chosen and therefore expects suppliers must refrain from using any form of forced, involuntary or debt bonded labour. ULTRA PCS is opposed to the use of any form of child labour or practices that inhibit the development of children. Suppliers must comply with all child labour laws and shall not employ anyone under the age of 15, or where it is higher, the mandatory school leaving age in the local country.	A
7.3.020	Personnel using ULTRA Design Data for any process that affects product conformity with requirements shall be made aware that items they process may be safety critical items and it is critical that components supplied to ULTRA conform to the intended design. ULTRA provides products to the aerospace, defence, medical, railroad, agricultural, truck, and other markets. In many applications, failure of our product can lead to catastrophic events and potential injury or death.	B+D
7.5	**Documented Information**	T
7.5.010	When specifically requested the organisation shall make specified quality data and/or approved design data available in the English language.	A
7.5.3	**Control of Documented Information**	**T**
7.5.010	The organisation shall ensure that personnel have access to and awareness to those documents necessary to perform their role in compliance with the organisation's QMS and this document.	A

7.5.3.020	Relevant ULTRA data and documents shall be preserved and controlled as external documents, with their status being clearly identified. This includes: - Quality requirement documents (E.g. this document). - Product requirements documents (E.g. Document Lists, Drawings, Specifications, Items lists.) - Other requirements documents pertaining to product and service realisation.	A
7.5.3.030	The organisation shall maintain, and have available on a timely basis, quality records traceable to the conformance of product/part numbers delivered. The organisation shall make such records available to regulatory authorities and ULTRA and the authorised representatives of ULTRA's customers. Such records at minimum include: - ULTRA Purchasing information and evidence of acknowledgement - Outgoing CofCs - Inspection and test records including test data - Traceable evidence of manufacturing sequence and completion of operations (e.g. route cards) - Evidence of traceability of materials and Outsourced Processes - CofCs for all materials, products, parts, and special processes used. (See 8.5.1.3) - Evidence of qualifications, training and that any eyesight requirements have been met for personnel performing NDT, special process and visual inspection.	B+D
7.5.3.040	All design records must be kept indefinitely unless otherwise agreed. All other records are to be kept and maintained for a minimum of 25 years from their date of origin. Written approval shall be obtained from ULTRA's Head of Quality prior to disposal of records. Records shall be made available to ULTRA or to the applicable regulatory bodies.	B+D

7.5.3.050	If the organisation wishes to meet record retention requirements by maintaining any records at their external providers, arrangements must be controlled and documented and periodically verified in accordance with this document.	B+D
7.5.3.060	Changes to Documents The organisation shall coordinate with ULTRA over any changes to documents that potentially affect conformity to ULTRA's requirements, e.g. changes in issue level of external standards or specifications. The organisation shall obtain approval from ULTRA prior to implementation of such changes. The organisation should obtain a purchase order amendment if a change in issue level or other detail is required. **Changes to agreed manufacturing processes with ULTRA shall not be made without the prior approval and permission of ULTRA QA department.** **Notification of changes to ULTRA (See 1.3).**	A
7.5.3.070	Corrections to work instructions or documents must be recorded, dated and traceable to the originator (e.g., signature, stamp, etc.) in ink or other permanent marking method with the original data being legible and retrievable after the change.	B+D
8	**OPERATION**	**T**
8.1	**Operational planning and control**	**T**
8.1.010	The Organisation shall plan and control the temporary or permanent transfer of work (e.g. from one facility to another, from their facility to a supplier or from one supplier to another) and ensure the applicable requirements (E.g. approval of changes) continue to be met including Supplier Notification of Change process (Ref 1.3) **ULTRA must be notified of these activities at least 90 days in advance of implementation. A plan for Last Article Inspections (LAI) and First Article Inspections (FAI) shall be agreed with ULTRA to ensure the conformity of products during and after the move. It is critical that changes and validation activities by the organisation are planned so as not to impact the delivery of goods to ULTRA and the end customer.**	B+D

8.1.020	Quality Plans ULTRA may require the organisation to provide and maintain, a Quality Plan that describes all processes applicable including any outsourced processes. Such plans typically include: - Process by which changes notified from ULTRA will be incorporated. - Description of the Configuration Management system used for ULTRA products - How traceability requirements will be met. - Definition of training and skill levels for key staff. - Product Failure Mode Effect Analysis (PFMEA) and Control Plans for manufacturing processes as appropriate. Where there is a requirement for ongoing maintenance of a product (e.g. repairs to products returned from Service) plans shall make provision for this, including the segregation of production and service product. NOTE 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realisation and measurement, analysis and improvement.	B+D
8.1.030	The Organisation may be required to use statistical techniques in accordance with AS9103 to prove conformity of products and to demonstrate control of processes affecting key characteristics.	B+D
8.1.1	**Operational Risk Management**	**T**
8.1.1.010	The organisation shall plan and manage product realisation in a structured and controlled manner to meet requirements at risk levels acceptable to ULTRA.	B+D
8.1.1.020	The Organisation shall identify and manage risks to the achievement of quality and delivery requirements. Any risks potentially affecting the quality or conformity of delivered product shall be notified in writing to ULTRA.	B+D
8.1.1.030	The following specific risks shall be assessed and managed where applicable:	B+D
8.1.1.031	- Entrapment or non-removal of fluids harmful to the product. (E.g. acid flux);	B+D
8.1.1.032	- Transcription or translation errors or omissions during the creation of supplier manufacturing and purchasing data from ULTRA data;	B+D

8.1.1.033	- Purchase of misrepresented or counterfeit parts or materials. (NOTE: Any parts identified as potentially counterfeit shall be identified and quarantined in accordance with section 8.7. The organisation shall initiate appropriate containment action and report the event to ULTRA in accordance with section 8.7.)	B+D
8.1.2	**Configuration Management**	**T**
8.1.2.010	The Organisation shall establish, document and maintain a management process which is appropriate for the product and allows all characteristics of a supplied product to be defined by a build standard traceable to component / material level and to all relevant ULTRA Design Data.	B+D
8.2	**Requirements for products and services**	**T**
8.2.1	**Customer Communication**	**T**
8.2.1.010	Most product supplied to ULTRA is used in Aerospace and Defence applications. If the organisation determines that additional requirements may apply to the product or software other than those already specified, then the Organisation shall inform ULTRA.	A
8.2.1.020	Notification of Changes Requirements for change notification and agreement are defined in section 1.3 and the notification of change form (OCP-0038). The organisation shall review this form and ensure that all such changes are submitted in accordance with the process outlined by the form and that changes requiring ULTRA's agreement are held pending such agreement.	B+D
8.2.1.030	ULTRA acceptances of changes shall be maintained as a quality record by the organisation.	B+D
8.2.1.040	If Design, Production, Inspection, Procurement data, or other data defining ULTRA requirements is received from a source other than ULTRA Procurement, then the organisation shall ensure the applicable ULTRA Procurement Contact is aware.	B+D
8.5.1.050	If an Organisation wishes to make changes relating to any data that has previously been approved by ULTRA, the Organisation shall obtain written approval from ULTRA prior to implementation.	B+D
8.2.3	**Review of requirement related to the product**	**T**

8.2.3.110	Before commencing work for ULTRA, the organisation shall review this document and any additional requirements specified in the purchase order or statement of work to determine how they will satisfy these requirements. The organisation shall ensure that they can meet the exact stated requirements including all drawings, items lists, digital product definition and statements of work and specifications at the issue levels quoted. The organisation is responsible for obtaining and reviewing current copies of any document or specifications referenced. Any queries on drawings, specifications and technical instructions shall be notified in writing to the ULTRA Purchasing Department and resolved prior to commencement of supply	A
8.2.3.115	**Product Inspection Standards:** All delivered part inspection standards shall be agreed with ULTRA prior to the delivery of product unless specified with Contract, PO, Drawing, Specification or Industry standard document. Examples of acceptable inspections standard agreements are shown below: • Amended Contract, PO, Drawing, Specification requirements • Approved Inspection Method sheets • Approved Quality / Inspection Control Plan	A
8.2.3.120	Unless specifically waived in writing, all provisions of this document also apply to prototype or sample product, i.e. they shall be built to a baseline standard, using traceable materials and production and inspection/testing processes and be released stating conformance / non-conformance to that standard	A
8.2.3.130	**Federal Aviation Administration Parts Manufacturer Approval (FAA PMA)** The organisation and their providers shall not supply PMA parts to ULTRA or ship them on ULTRA's behalf without the written consent of ULTRA's Customer and ULTRA's Head of Quality. PMA is a combined design and production approval for modified and replacement articles. It allows a manufacturer to produce and sell these articles for installation on type certificated aircraft products.	A
8.2.3.140	Risks (e.g. long lead items, new technology) identified shall be evaluated and notified to ULTRA.	B+D

8.2.3.150	The organisation may be required to complete a compliance matrix showing how conformity to requirements is to be achieved. Once implemented the matrix shall be maintained as a quality record and kept up to date so that it continues to demonstrate compliance and shall be available to ULTRA on request.	B+D
8.2.4	**Changes to requirements for products and services**	**T**
8.2.4.010	When new or changed design data is received the organisation shall ensure they have formal coordination from ULTRA as to when this data is to be implemented (E.g. ECM, Change Request Form, Purchase Order amendment).	B+D
8.3	**Design and Development of Products and Services**	**T**
8.3.1	**General**	**T**
8.3.1.010	If an item is defined by the organisation / manufacturer (E.g. supplier design, or customized off-the-shelf item) then the sub-contractor responsibilities in this clause (8.3 and sub-sections) apply to those design characteristics defined by ULTRA and to any work done to design / redesign the item for ULTRA.	B+D
8.3.2	**Design and Development Planning**	**T**
8.3.2.010	The organisation shall fully comply with any applicable statement of work and ensure the following areas are controlled appropriately:	B+D
8.3.2.011	a) Communication: Use a coordinated written system of contact with ULTRA with defined roles and responsibilities for those involved, ensuring those involved are aware of the arrangements.	B+D
8.3.2.012	b) Design Assurance: Maintain planned independent assurance of design activities, including activities of the organisation's sub-contractors. Written records of the planned and actual activities shall be retained and made available on request;	B+D
8.3.2.013	c) Verification Documentation: Compile information throughout the design / development phase in compliance with the applicable requirements for ongoing and final design verification;	B+D
8.3.2.014	d) Development Product: Ensure the status of development product is agreed with ULTRA prior to manufacture and that its status is identified during manufacture and final release. A statement of conformity shall accompany any development product or test article clearly referencing any limitations on use or performance and how these have been agreed with ULTRA;	B+D

8.3.2.015	e) Subcontractor flow-down: The organisation shall ensure that the above requirements are met for any sub-contracted activities.	B+D
8.3.2.020	The Organisation shall agree design and development stages and the structuring of complex design stages with ULTRA, taking full account of stated requirements, e.g. Statement of Work or software requirements document. Tasks shall be defined taking account of the specified safety or functional requirements for the product.	B+D
8.3.2.030	All remedial costs in respect of events that could reasonably have been anticipated shall be the Organisation's liability. (E.g. late delivery, absence of evidence required for certification).	B+D
8.3.3	**Design and Development Inputs**	**T**
8.3.3.010	ULTRA will normally control design activities by issuing a Purchase order and statement of work. Copies of these should be requested prior to commencing design activities. The Organisation shall ensure that inputs to the design are adequate and do not conflict with each other and that they can demonstrate formal coordination with ULTRA over validity of inputs used.	B+D
8.3.4	**Design and Development Controls**	**B+D**
8.3.4.010	The Organisation shall offer ULTRA the opportunity to review and approve the Organisation's design review, verification and validation activities prior to delivery of first production Hardware/Software.	B+D
8.3.4.020	Records of Design Review and Assurance Activities carried out for ULTRA shall be maintained indefinitely and must not be destroyed without prior permission of the ULTRA Quality Department.	B+D

8.3.4.110	When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented such that: a) test plans or specifications identify the test item being tested, the resources being used and define test objectives, conditions, parameters to be recorded and the relevant acceptance criteria; b) test procedures describe the test methods to be used, how to perform the test, and how to record the results; c) the correct configuration of test item is submitted for the test; d) the requirements of the test plan and the test procedures are observed; e) the results clearly state whether acceptance criteria are met. Monitoring and measuring devices used for testing shall be controlled as defined in clause 9.1.3.	B+D
8.3.4.120	At the completion of design and development, the organisation shall ensure that reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.	B+D
8.3.4.130	The organisation shall demonstrate that the design meets requirements under all specified conditions.	B+D
8.3.5	**Design and Development Outputs**	**T**
8.3.5.010	Outputs shall meet all the stated requirements including those in any applicable statement of work. Characteristics essential to safe and proper operation shall be identified. Any applicable Key characteristics and Critical Items shall be identified and specific actions to be taken for these items.	B+D
8.3.5.020	The design outputs shall define all information necessary to verify conformity of the product to requirements and to define its configuration. This includes any designed measurement or test equipment or designed modifications to existing equipment.	B+D
8.3.6	**Control of Design and Development changes**	**T**

8.3.6.010	The Organisation shall review and control design changes throughout design, development and production and shall seek prior approval from ULTRA for those that could affect form, fit, function, airworthiness any other ULTRA applicable requirement. NOTE: ULTRA has defined requirements for change notification and agreement in section 1.3 and the notification of change form (OCP-0038).	A
8.4	**Control of externally provided processes, products and services**	**T**
8.4.1	**General**	**T**
8.4.1.010	The organisation shall be responsible for the quality of all products or services purchased by them, including those from sources designated by ULTRA or other parties.	A
8.4.1.020	The organisation is expected to evaluate, select and approve their providers based on their ability to supply product in accordance with their requirements and those of ULTRA. ULTRA may disallow the use of any Providers that do not meet requirements. The following approvals shall be required for all providers used unless otherwise agreed and documented with ULTRA Quality Department before use: a. All providers shall be certified to ISO9001 or equivalent (see section 4.4); b. Electronic component distributors or stockists shall have explicit approval / franchise from the original component manufacturer; c. Fixing, fastener and metallic raw material Providers shall be certified to AS9120 or AS9100; d. Special process sources shall have NADCAP certification for the relevant process (See 8.5.1.2 for definition of Special Processes); e. Build to print manufacturers producing ULTRA parts shall be certified to AS9100. NOTE: Once a sub-contractor or a special process source has been used for a product, the requirements for notification and acceptance of source change also apply (See 1.3).	B+D
8.4.1.030	The organisation may be required to carry out an assessment of the ability of any sub-contracted element of their supply chain to manufacture in conformance with Design Data supplied by ULTRA or to facilitate such an assessment by ULTRA.	B+D

8.4.1.040	**Other controls** The Organisation shall:	B+D
8.4.1.041	a. Maintain a list of any Suppliers approved for ULTRA work and evidence for the basis of that approval (Visit reports, QMS certificates, Customer confirmation etc.);	B+D
8.4.1.042	b. Maintain quality performance measurement of all Suppliers used for ULTRA;	B+D
8.4.1.043	c. Take appropriate action to control the quality levels of Suppliers not meeting requirements;	B+D
8.4.1.044	d. Use ULTRA specified sources where applicable;	B+D
8.4.1.045	e. Obtain prior agreement of ULTRA for any change in supply sources for material or processing. (See 1.3 Supplier Notification of Change);	B+D
8.4.1.046	f. Manage risk when using suppliers. (See 7.1.2);	B+D
8.4.1.050	**Obsolete Material Monitoring** The organisation shall periodically review obsolescence as detailed below or as otherwise agreed in writing by their current ULTRA Procurement contact. Suppliers are encouraged to structure their supply chain and form relationships within it to support this.	B+D
8.4.1.052	Electronic components: The organisation shall review products containing these for obsolete items using the following criteria: - New products: Review during quote, finalize on receipt of purchase order. - Existing or re-entered products: once per quarter. Outputs of reviews shall be forwarded to the relevant ULTRA Procurement contact and shall include risk management plans on how they can mitigate risk of obsolescence to ensure continuity of supply for the product and shall include identified obsolete components/material/processes and suggested course of action (E.g. last time buy).	B+D
8.4.1.054	All other materials and processes: The organisation shall review the risk of the materials or processes specified by ULTRA drawings and items lists becoming unavailable at least once per year or, for items with no ULTRA demand, on receipt of next requirement. The organisation shall advise ULTRA of any risks detected.	B+D

8.4.1.060	**REACH Compliance** All substances shall be REACH compliant. Any substances used in the product or associated processes that listed as 'Sunset' shall be notified to the Buyer, as soon as this is known. It should not be automatically accepted that the recommended substitutes are fit for purpose and must be verified as fit for purpose and accepted by ULTRA prior to being introduced. Any substances that are identified as hazardous to health shall be suitably identified, assessed, stored and handled in accordance with legislation requirements. The organisation shall provide a material data sheet and a REACH compliant statement with any other information needed to enable Ultra to conduct a risk assessment.	A
8.4.1.070	If any alternative parts or materials are identified that do not conform to the applicable ULTRA items list or drawing, they shall not be used without formal approval of ULTRA via design change or an approved ULTRA concession / production permit.	B+D
8.4.1.080	Supplier shall take note of ULTRA Conflict Minerals Policy Ultra PCS is committed to sourcing materials from companies that share our values regarding respect for human rights, integrity,ethics and environmental responsibilities. We undertake to Support the aims and objectives of the US legislation on the supply of 'conflict minerals' (the Dodd-Frank Act of 2010)	
8.4.1.090	<u>Conflict Minerals Reporting</u> The organisation shall perform an initial survey at the Contract Review stage following receipt of a UEPCS purchase order, to determine compliance ULTRA's requirements. To assist this review, use the links below and complete the Conflict Minerals Template CFSI CMRT3 excel spreadsheet and retain a copy for their records. - www.conflictfreesmelter.org. - http://www.conflictfreesourcing.org/conflict-minerals-reporting-template/ All non-conformances shall be notified to PCS Quality	
8.4.2	**Type and Extent of Control**	T

8.4.2.010	The Organisation is responsible for controlling product supplied to them and for keeping records of this activity. These responsibilities extend to equipment supplied by ULTRA, its Providers, suppliers, partners and customers.	B+D
8.4.2.012	**ULTRA Supplied Material (Free Issue)** The organisation shall retain history and traceability information for parts supplied by or on behalf of ULTRA and apply their normal Quality Management Processes to them. The organisation shall: - Ensure procedures are in place to properly identify and control all ULTRA supplied materials. - Review parts delivered from or on behalf of ULTRA and only accept parts in accordance with their normal rules for accepting goods from external providers. - Store parts delivered from or on behalf of ULTRA appropriately to prevent loss, damage or other detriment to quality. - Ensure any parts found to be non-conforming are quarantined and notified to Ultra for disposition.	A
8.4.2.020	<u>CofCs for all externally provided items</u> For all ULTRA specified or nominated materials and parts, the seller shall at minimum obtain a CofC from the provider and maintain it and any other certifications provided as a quality record.	A
8.4.2.022	<u>CofCs for externally provided electronic components - General</u> The following shall apply for electronic components provided to the organisation by parties other than the original manufacturer: a. A manufacturer's CofC shall always be obtained for the following types of electronic component: - Components for which a Manufacturer's CofC is normally available including "Hi-Rel" items that have their approval regulated by a third party such as MIL-STD-883, JANTX, CECC and DSCC - Components with an ULTRA Drawing, ULTRA Control Drawing, ULTRA Purchasing Specification or ULTRA Vendor Data Sheet (VDS) b. Where a. does not apply the organisation shall obtain at minimum a CofC from the original component manufacturer (OCM) or from an OCM authorised / franchised source with valid certification to ISO9001.	A

8.4.2.024	Manufacturer's CofCs Requirements for Specific Electronic Assemblies If, for a given electronic assembly, ULTRA has issued an "Items List Report" as defined in OCP-0043 "Manufacturers' Certificates of Conformity Guidance Document", then the full requirements of OCP-0043 shall apply for all electronic components.	B
8.4.2.030	Verification of externally provided product shall include verification of the CofC from the seller and if applicable the original manufacturer. All applicable CofCs provided to the organisation with the part shall be retained as a Quality record. Verification shall ensure as applicable that: - The manufacturer named is in accordance with the ULTRA design data. - The manufacturer's part number stated on each CofC is identical to that stated on the ULTRA design data. - Each CofC supports any specifications named in the ULTRA design data and does not contradict any part of that data. - Each CofC expresses no reservations regarding the item's conformity or about its suitability for its' intended use. - If any of the above is unsatisfactory the parts shall be treated as non-conforming, quarantined, investigated, documented dispositioned, and reported accordingly.	B+D
8.4.2.050	Where purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement.	B+D
8.4.2.060	Where responsibility for verification of purchased product is delegated to an external provider a register of delegations shall be maintained.	B+D
8.4.2.070	When external provider test reports are utilised to verify externally provided products, the organisation shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. Raw material represents a significant operational risk to ULTRA so the organisation shall implement a process to validate the accuracy of test reports.	B+D
8.4.3	**Information for External Providers**	T
8.4.3.010	NOTE: Key requirements (1.3) apply regarding flow-down of ULTRA requirements to the organisation's supply chain.	A
8.4.3.020	The organisation shall ensure that all required certifications as described in section 8.4.2 are requested at time of ordering.	A

8.4.3.030	The organisation shall ensure that their purchasing information is compatible with all the applicable purchasing documents and design data provided by ULTRA such that the correct item will be obtained. Distributors providing parts defined by ULTRA drawings must ensure all the applicable requirements of this document and ULTRA's design data applicable to those parts are flowed down.	A
8.4.3.040	The organisation shall communicate to external providers its requirements for the processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions and:	B+D
8.4.3.041	g. design and development control;	B+D
8.4.3.042	h. special requirements, critical items, or key characteristics;	B+D
8.4.3.043	i. test, inspection, and verification (including production process verification);	B+D
8.4.3.044	j. the use of statistical techniques for product acceptance and related instructions for acceptance by the organisation;	B+D
8.4.3.045	k. the need to: - implement a quality management system; - use customer-designated or approved external providers, including process sources (e.g., special processes); - notify the organisation of nonconforming processes, products, or services and obtain approval for their disposition; - prevent the use of counterfeit parts (see 4.4.040); - notify the organisation of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organisation's approval; - flow down to external providers applicable requirements including customer requirements; - provide test specimens for design approval, inspection/verification, investigation, or auditing; - retain documented information, including retention periods and disposition requirements;	B+D
8.4.3.046	l. The key requirements of this document (ref section 1.3);	B+D
8.4.3.047	m. ensuring that persons are aware of: - their contribution to product or service conformity; - their contribution to product safety; - the importance of ethical behaviour.	B+D

8.5	**Production and Service Provision**	**T**
8.5.1	**Control of Production and Service Operations**	**T**
8.5.1.010	If a document describing or defining the manufacturing process has been approved by ULTRA, then any deviations from that document shall require the written approval of ULTRA unless otherwise agreed.	B+D
8.5.1.020	The Organisation shall carry out work under controlled conditions and in accordance with the agreed plans, procedures and work instructions, ensuring conformity to requirements of all applicable ULTRA design data, and all other purchasing information, including this document.	B+D
8.5.1.030	When key characteristics are identified they shall be monitored and controlled. Sampling inspection, if used to support the release of product, shall not allow the release of lots where non-conformities are found (i.e. accept zero sampling plans).	B+D
8.5.1.040	Controlled conditions shall include:	B+D
8.5.1.041	i. the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations). Unless otherwise specified, electronic assemblies shall have a level of workmanship which meets or exceeds IPC-A-610 Acceptability of electronic assemblies Class 3 for High Performance Electronic products;	B+D
8.5.1.042	j. the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);	B+D
8.5.1.043	k. the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;	B+D
8.5.1.044	l. the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);	B+D
8.5.1.045	m. the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;	B+D
8.5.1.046	n. the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorised;	B+D
8.5.1.047	o. the provision for the prevention, detection, and removal of foreign objects;	B+D

8.5.1.048	p. the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 8.1.2);	B+D
8.5.1.049	q. the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.	B+D
8.5.1.1	**Control of Production Equipment, Tools and software programs**	**T**
8.5.1.110	Production equipment, tools and software programs used to automate, control or monitor product realisation processes shall be validated before release and shall be preserved and maintained to ensure product conformity.	B
8.5.120	Where necessary to ensure ongoing product conformity, models or drawings shall be maintained for tooling to enable it to be re-recreated, re-validated and maintained.	B
8.5.1.130	For ULTRA owned or specifically funded equipment, tooling and gauges the Organisation shall: - Ensure appropriately detailed drawings are available and approved by ULTRA prior to commencing work. - Implement a documented schedule for Preventive Maintenance for all and tooling and identify any critical spares. - Liaise with ULTRA for maintenance and calibration of equipment as required. - Clearly identify Ultra owned items using permanent markings so that the ownership status is visible and readily determined. E.g. engraving on an affixed metal tag or onto the tool : 'ULTRA Proprietary Tool'. - As appropriate mark other pertinent information to enable the purpose of the item to be determined. E.g. part number or tool number.	B
8.5.1.2	**Validation and Control of Special Processes**	**T**

8.5.1.210	Processes where the resulting output cannot be verified by subsequent monitoring or measurement shall be considered "Special Processes". The organisation shall establish arrangements for these processes including, as applicable: a. definition of criteria for the review and approval of the processes; b. determination of conditions to maintain the approval; c. approval of facilities and equipment; d. qualification of persons; e. use of specific methods and procedures for implementation and monitoring the processes; f. requirements for documented information to be retained.	B+D
8.5.1.220	At minimum the following processes shall be considered special processes unless proven otherwise: - Non-destructive testing - Heat treatment - Chemical processing - Painting - Welding - Soldering (All types) - Electrical test - Environmental Stress Screening (E.g. temperature cycling) - Conformal coating of electronics, conventional or by vapour deposition - Printed Circuit Board Manufacture	B+D
8.5.1.230	Design Responsible Supplier (ULTRA) shall have a comprehensive special process management program in place for the special processes listed in paragraph 8.5.1.220. The program includes maintaining a list of qualified Special Process Suppliers along with their Nadcap approval status.	B+D
8.5.1.240	If Special Process Suppliers do not hold Nadcap certification, ULTRA shall maintain appropriate oversight of internal and supplier processes including, but not limited to, onsite special process audits, periodic testing of product, and other means to validate product integrity.	B+D
8.5.1.250	For parts under PUR-SOPS-003 control, to comply with the requirements of 8.5.1.2 ULTRA require suppliers to generate a Special Process Supplier list on an annual basis and provide to ULTRA Quality Function by the end of March each year. The list should coincide with the following example for content as a minimum:	B+D

	<table><tr><th>Part number</th><th>Revision</th><th>Special process</th><th>Supplier</th><th>Nadcap Approval No.</th><th>Planned audit date</th><th>Periodic testing of product</th><th>Other means of product validation</th></tr><tr><td>Example</td><td>A</td><td>Chemical</td><td>Supplier A</td><td>ABC123</td><td>N/R</td><td>N/R</td><td>N/R</td></tr><tr><td>Example</td><td>B</td><td>Coating</td><td>Supplier B</td><td>N/A</td><td>06/06/2021</td><td>Validated per batch, see CofC's. Spec XYZ</td><td>N/R</td></tr><tr><td>Example</td><td>C</td><td>Welding</td><td>Supplier C</td><td>N/A</td><td>08/08/2021</td><td>Validated per batch, see CofC's. Spec XYZ</td><td>Welsing process specification</td></tr></table>	B+D
8.5.1.3	**Production Process Verification**	**T**
8.5.1.310	NOTE: This activity is often referred to as First Article Inspection. (FAI)	A
8.5.1.320	Where an ULTRA drawing or other ULTRA design data relates to the product then the organisation and / or their providers shall ensure first article inspection reporting is implemented in accordance with AS9102 latest issue and provide all applicable FAI reports to ULTRA. Training materials on FAI reporting can be provided if requested. AS9102 includes requirements to: - Perform FAI on new Product representative of the first production run. - Re-accomplish FAI when certain events occur. Conducting FAI does not remove any obligation to notify changes in advance to ULTRA (See 1.3). FAIs shall address all items with applicable ULTRA Design Data, including those items provided externally (e.g. by suppliers). It is not normally necessary to provide a FAIR against the organisation's own design data provided that the organization implements production process verification activities to ensure the production process is able to produce products that meet requirements.	A
8.5.1.330	All FAIRs shall be accompanied by the ULTRA FAIR checklist, available from ULTRA QA Function and the applicable supporting evidence specified within it. ULTRA may verify the FAIR onsite at the organisation where appropriate.	A
8.5.1.340	**Process Failure Mode Effect Analysis (PFMEA) and Control Plans** Where appropriate to the product the organisation may be asked to support PFMEA activities to identify process elements, analyse their potential failure modes in terms of severity, likelihood of occurrence and detection, quantify risks and develop countermeasures for them as part of a specific or generic control plan.	B+D
8.5.2	**Identification and Traceability**	**T**

8.5.2.010	Systems shall exist for the identification of materials throughout all stages of manufacture, including those performed in the supply chain of the Organisation. This will normally be achieved by segregation of manufacturing batches with travelling records giving identification of material specification and source of supply.	B+D
8.5.2.012	The organization shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.	
8.5.2.014	When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish controls for the media.	
8.5.2.020	Traceability shall include at minimum: - The ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to destination (e.g. delivery, scrap). - For an assembly, the identity to trace its components to the assembly then to the next higher assembly. - For a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.	B+D
8.5.2.030	**For a serialized electronic assembly, traceability shall also include retention of documented information regarding:** - **The manufacturing lot or date code of any Printed Circuit board used in that assembly.** - **The batch or lot code of any chemical used during assembly processing** - **The stage of manufacturing at which any rejection, rework or scrap occurs traceable to any assembly level.**	B
8.5.3	**Property belonging to customers or external providers.**	T

8.5.3.010	Ultra property can include: - Design, Production or Inspection data provided by ULTRA or their customers - Equipment owned, provided or specifically funded by Ultra, e.g. Tooling, Gauges, Fixtures or Test Equipment Such articles shall be treated as Customer property and identified, verified, protected and safeguarded. If lost, stolen, damaged or otherwise found unsuitable this shall be reported to ULTRA. ULTRA agreement or direction shall be obtained before transferring any ULTRA property between countries.	B+D
8.5.3.020	Trade Compliance	T
8.5.3.021	It is the organisation's responsibility to comply with all export and import regulations (UK U.S. and others, as applicable) associated with the storage, transfer and export of technical data and hardware received from and/or manufactured for PCS. Requirements include: - Technical data and shipping documents must carry the appropriate export control statements, if applicable; - ITAR-controlled technical data must be transferred using encrypted means (e.g. ftp site) and must not be emailed; - The supplier must complete a Supplier Export Control Classification Form for all items supplied to PCS. The form can be found on PCS' supplier download page online: https://www.ultra-pcs.com/supplier-downloads/ltra PCS » Supplier downloads for Cheltenham suppliers (ultra-pcs.com).	B+D
8.5.3.022	Where the organisation is a licensee or sub-licensee under the terms of a Technical Assistance Agreement (TAA) or Manufacturing License Agreement (MLA) and is in receipt of Technical Data subject to the International Trade in Arms Regulations (ITAR), the organisation shall maintain a Technology Control Plan (TCP) that prescribes all security measures determined necessary to reasonably foreclose the possibility of unauthorised access to such export controlled information by non-U.S. citizen employees not authorised by such TAA or MLA or by visitors.	B+D
8.5.3.023	The TCP shall also establish measures to assure that access or potential access to hardware subject to the ITAR by non-U.S. citizen employees not authorised by such TAA or MLA or by visitors is prevented. This requirement for a TCP shall also be flowed down to any sub-tier suppliers of goods or services that are authorised under the terms of the relevant TAA or MLA.	

8.5.4	**Preservation**	T
8.5.4.010	Preservation of product shall also include, where applicable / appropriate, provisions for:	B
8.5.4.011	a. Cleaning **and the prevention of fluid entrapment;**	B
8.5.4.012	b. Prevention, detection and removal of foreign objects **and liquids (Ultra encourage the implementation of FOD systems in line with NAS412 or AS9146);**	B
8.5.4.013	c. Special handling for sensitive products;	B
8.5.4.014	d. Marking and labelling;	B
8.5.4.015	e. Shelf life control and stock rotation to ensure items are not used or supplied outside their expiry date;	B
8.5.4.016	f. Special handling for hazardous products.	B
8.5.4.100	**ELECTROSTATIC DISCHARGE (ESD) CONTROL** Where applicable, the organisation shall institute adequate procedures and controls to prevent damage to electronic equipment and components which are sensitive to ESD. Provisions shall be made for protection of electronic and electrical material which is sensitive to electronic discharge (ESD), per MIL-STD-1686, ANSI/ESD S20.20, IEC 61340-5-1 or as otherwise agreed with Ultra. NOTE: ESD control requirements shall apply where equipment containing ESD sensitive parts are used during the process of fabrication, calibration, testing or packaging of the item, whether or not the end item itself is ESD sensitive.	A
8.5.5	**Post Delivery Activities**	T
8.5.5.010	In the event of Airworthiness or safety Issues arising relating to products or services supplied the organisation is expected to nominate a point of contact / coordinator and to ensure their Top Management or Head of their Quality has suitable oversight. Support may include providing relevant Design Data held by the organisation, traceability for materials and processes used, and expertise in the organisation's processes. NOTE: These requirements may continue for the lifetime of the product.	A

8.5.5.020	ULTRA requires support post-delivery from the organisation. This includes assistance with investigation and rectification of issues appearing post-delivery. Parts requiring support normally fall into 3 categories: - Review / Rework at ULTRA: The organisation might attend to parts at ULTRA. - Production Returns: Returned prior to use by the product's end user - Service Returns: Returned after use by the product's end user	B+D
8.5.5.030	ULTRA identify product returned to Suppliers with an Supplier Reject Number or MRB number. It is essential that traceability to the relevant MRB number is maintained while the item is with the organisation and if/when it is returned to ULTRA.	B+D
8.5.5.040	The organisation shall:	B+D
8.5.5.041	a. Support ULTRA in identifying production issues appearing in returns;	B+D
8.5.5.042	b. Inform ULTRA if trends are identified that could affect the performance of units already supplied;	B+D
8.5.5.043	c. Assist as required (within the organisation's capabilities) with preparing ULTRA's technical information;	B+D
8.5.5.050	When providing assistance onsite at ULTRA, personnel shall always work under ULTRA supervision and provide a certificate of conformity for any work carried out on product. The work carried out shall comply with ULTRA requirements and with all applicable controls of the organisation's quality system, (e.g. traceability of materials, training etc.). Requirements for changes to repair and overhaul procedures and materials are defined in 1.3).	B+D
8.5.5.070	US based organisations processing service returns shall actively participate in a U.S. Department of Transportation anti-drug and alcohol misuse prevention program as required per 14 CFR Part 121 appendices I and J. The organisation shall provide evidence of this on request.	B+D
8.6	**Release of Products and Services**	T

8.6.010	Federal Aviation Administration Parts Manufacturer Approval (FAA PMA) The organisation and their providers shall not supply PMA parts to ULTRA or ship them on ULTRA's behalf without the written consent of ULTRA's Customer and ULTRA's Head of Quality. PMA is a combined design and production approval for modified and replacement articles. It allows a manufacturer to produce and sell these articles for installation on type certificated aircraft products. Refer to FAA regulations for further information.	A
8.6.020	Release documentation shall accompany each delivery describing the items provided, and certifying that they have been inspected and, unless otherwise stated, conform to all requirements, applicable drawings and/or specifications. Specific Requirements: - The documentation shall reference the applicable Purchase Order (PO) number, line number (LN) and release number (RL) as stated on the Purchase Order. - The form of certification shall be as defined on the Purchase Order. - The release shall be against the ULTRA part number (if stated on the Purchase Order), - The documentation shall confirm the relevant specification(s), drawing(s) and documents associated issue numbers as stated on the Purchase Order. - The documentation shall state the applicable serial numbers, manufacturing lot(s) or date code(s) - Serial numbers shall be stated individually (not as a range) and in the form that they appear on the item (not abbreviated). - The documentation shall reference any Concessions / Permits / Waivers / Deviations applicable to the product, including elements provided by the organisation's supply chain and ULTRA. - Any shelf-life expiry date or other special conditions that apply shall be stated on the documentation. - Where a product has been provided by ULTRA under a non-conforming product reference number (E.g. MRB number) that number shall also appear on the documentation and a description of how the issue was resolved shall accompany the part. - Where specified on the PO a Release Certificate against the Organisation's National Airworthiness Approval shall be supplied, quoting the relevant approval reference.	A
8.6.030	Where the organisation is not the manufacturer of the Relevant Item, then a CofC from the manufacturer shall also be provided unless otherwise agreed with ULTRA QA.	A

8.6.040	Where an item is defined by ULTRA design data (E.g. an off the shelf component supplied in accordance with an ULTRA control drawing) then the organisation shall ensure that compliance to all ULTRA defined characteristics is verified prior to certification.	A
8.6.050	Suppliers providing chemicals to ULTRA shall comply with applicable COSSH and REACH requirements and shall supply Manufacturers Data Sheets upon request.	A
8.6.070	The organisation shall:	B+D
8.6.071	a. Identify and control all staff authorised to perform final verification of Product conformance to ULTRA Design Data and those authorising CofCs;	B+D
8.6.072	b. Identify the inspection and other operations required to be completed in order to release product and ensure they are complete prior to release of product;	B+D
8.6.073	c. Keep records of tests or measurements done to accept product prior to release. These records shall include any relevant ULTRA characteristic requirements.	B+D
8.7	**Control of nonconforming outputs**	T
8.7.010	Review of non-conforming material shall include review of any applicable ULTRA requirements. Dispositions of use-as-is or repair shall only be used after approval of an authorised representative of the organisation responsible for the design. If the non-conformity results in a departure from contract requirements then dispositions of use-as-is shall not be used, unless specifically authorised by ULTRA.	A
8.7.020	Changes to component design, notifications regarding deviations from specification, non-completion of planned inspection / test or unexpected issues potentially manifesting in service shall be identified to ULTRA prior to delivery. NOTE: Key requirements (1.3) apply regarding concessions and permits for non-conforming product and the reporting of delivered non-conforming product.	A
8.7.030	Relevant Items not conforming to requirements shall be clearly identified and segregated from conforming product. Production documentation shall clearly state the non-conformity or reference non-conformance documentation.	B+D
8.7.040	Product dispositioned as scrap shall be physically rendered unusable within 30 days unless otherwise instructed in writing by ULTRA.	B+D

9	**Performance Evaluation**	T
9.1	**Monitoring, measurement, analysis and evaluation**	T
9.1.3	**Analysis and Evaluation**	T
9.1.3.010	Monitoring and measurement shall include review of appropriate yield indicators (e.g. scrap, re-work or test fail) and investigation of unusually high yield to determine any potential for escape of non-conforming product.	B+D
9.1.3.020	In the event of a process at the organisation being found to be non-conforming, through audit, or otherwise, the organisation shall establish whether any product non-conformance has resulted and control any such non-conformance in accordance with 8.7 and 1.3.	B+D
9.1.3.030	When required, the organisation shall provide the appropriate quality data (charts, indicators, acceptance rate, shop findings, etc.) that demonstrates the organisation's internal quality performance and the corrective actions taken in order to prevent impacts to ULTRA.	B+D
9.2	**Internal Audit**	T
9.2.010	The organisation shall provide training or take other action to ensure the necessary competence of internal auditors.	B+D
9.2.020	Any applicable Safety and / or Airworthiness requirements or concerns shall be considered when planning audits.	B+D
9.2.030	Where process or product non-conformity is found during an audit it shall be considered for notification to ULTRA in accordance with 8.2.3, 8.7 and 1.3.	B+D
9.2.040	The organisation's audit program shall ensure review of ULTRA purchase order requirements as appropriate to the volume of work. Reviews shall include verification that product is manufactured in accordance with ULTRA's Purchase Order, Design Data and Quality Requirements and that any applicable Production Data and Quality Plans accurately describe the processes being performed.	B
9.3	**Management Review**	B
9.3.010	The organisation shall ensure that issues notified by ULTRA are addressed by the Management Review process.	B+D
10	**Improvement**	T

10.1	**General**	T
10.1.010	Organisations are encouraged to expand their knowledge of continuous improvement tools, identify potential improvements and notify to Ultra as applicable. Changes requiring notification to or acceptance from ULTRA are defined in section 1.3)	A
10.2	**Nonconformity and Corrective Action**	T
10.2.010	In the event of product non-conformity found post-delivery and attributable to the organisation (normally notified by an ULTRA supplier return document) the organisation shall investigate the non-conformity and report to ULTRA on the corrective action taken to prevent recurrence. The response shall include consideration of the root cause and any consequential effects (if known).	A
10.2.120	The Organisation shall:	A
10.2.121	- Determine the causes of the nonconformity, including, as applicable, those related to human factors;	A
10.2.122	- Obtain corrective actions from their external providers when it is determined that the external provider is responsible for the nonconformity;	A
10.2.123	- Take action to ensure satisfactory delivery and quality and delivery performance if timely and / or effective corrective actions are not achieved;	A
10.2.124	- Determine if additional non-conforming product exists based on the causes of the non-conformities and taking further action when required including notification of escape. (See 1.3);	A
10.2.125	- Use an ULTRA provided template when responding to non-conformities corrective action requests or an alternative format agreed with ULTRA Quality Function.	A
10.2.126	**Supplier Corrective Action Response Content and Timescales** A Corrective Action Request may be submitted to a supplier when the product or process fails to meet requirements. The supplier must respond to the request based on the schedule shown below:	A

	WHEN	DELIVERABLE	
	Immediately (within 24 hours)	Containment- Supplier must perform 100% inspection of all parts in process (WIP) and in storage. The containment plan must clearly define the containment actions at the supplier's facility to assure that no nonconforming product is shipped to ULTRA. If suspect product has already been shipped, the supplier must address all suspect stock in transit and any stock at ULTRA. The supplier will assist ULTRA in identifying customer risk by identifying all suspect lot numbers and associated quantities involved.	
	Within 2 Weeks	Root Cause- Investigate and provide the Root Cause of the issue.	
	Within 4 Weeks	Corrective Action- Establish the corrective and preventive action to eliminate the recurrence of the problem, and the effective date. When applicable provide a list of further actions required to ensure that within 3 calendar months of the finding conformity is restored.	
	Future shipments	Verify/Validate- As part of the Preventive action, devise a plan to validate/verify that the corrective / preventive action does not repeat for all future shipments.	

*** End of document ***