Supplier Quality Assurance Manual: CCSM

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## **Supplier Quality Assurance Manual: CCSM**

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## **1. Introduction**

#### **Purpose**

This manual aims to provide guidance to ASC suppliers about their Quality Management System (QMS) obligations and requirements for the supply and refurbishment of goods and/or services to ASC's Collins Class Submarine (CCSM) Program. Note: for the purpose of this manual wherever the term "supplier" is used it can be taken to include (where applicable) contractor, subcontractor and sub-tier suppliers.

#### Scope

This manual is applicable to all ASC purchases of goods and services under ASC's purchase order terms and conditions (PO) and applicable contracts in support of the ASC CCSM Program.

## **Definitions and Acronyms**

AICIP	Australian Institute for the Certification of Inspection Personnel
AINDT	Australian Institute for Non-Destructive Testing
ASC	ASC Pty Ltd
CCSM	Collins Class Submarine
CMP	Configuration Management Plan
CMS	Corporate Management System
CoA	Commonwealth of Australia
CoC	Certificate of Conformance
DoD MIL HDBK	Department of Defence (USA) Military Handbook
FTP	File Transfer Portal
IMTE	Inspection Measuring and Testing Equipment
IP	Intellectual Property
ISO	International Standards Organisation
ITAR	International Traffic in Arms Regulations
ILAC	International Laboratory Accreditation Corporation
ITP	Inspection and Test Plan
MDR	Manufacturers Data Report
NATA	National Association of Testing Authorities
NATO	North Atlantic Treaty Organisation
NDT	Non Destructive Testing
OQE	Objective Quality Evidence
PO	Purchase Order
QA	Quality Assurance
QMS	Quality Management System
SDS	Safety Data Sheet
SME	Small, Medium Enterprise
SQA	Supplier Quality Assurance
SQAM	Supplier Quality Assurance Manual
SQQ	Supplier Qualification Questionnaire
US	United States (of America)
WHS&E	Work Health Safety and Environment

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ASC SUPPLIER QUALITY ASSURANCE MANUAL: CCSM, VERSION 10, FEBRUARY 2022

# Monitoring, Evaluation and Review

The content and effectiveness of this manual will be monitored and evaluated via metrics and key performance indicators associated with the Supplier Quality Assurance (SQA) audit schedule and reported to management accordingly.

# ASC Vision, Mission and Values

**ASC's Vision:** To be an enduring and integral part of Australia's maritime strategy and national security.

**ASC's Mission:** To be a trusted and efficient partner with sovereign design, build and sustainment capabilities, driving best value for our customers.

#### **ASC's Values and Behaviours:**

Strongly held corporate values are an important element of the strategic framework that underpins successful companies. ASC employees aspire to a set of values and exhibit corresponding behaviours, which are the guiding principles that define how we conduct our business and what we stand for as a company. ASC's corporate values are:

- Protect
- Respect
- Integrity
- Discipline
- Excellence

#### Customer/Supplier Relationship and Feedback

ASC is fully committed to maintaining a good relationship with all of its suppliers.

ASC believes that without the assistance and commitment of its suppliers, the requirements specified in this manual cannot be adequately achieved.

Suppliers should contact ASC Supply Chain personnel in the event that any requirement contained in an ASC contract, PO or this manual is not fully understood.

# Supplier Approval Process (Evaluation and Approval)

To be included in the ASC Approved Suppliers List, suppliers will undergo systematic levels of reviews and checks which may also include on-site SQA audits by ASC Quality Assurance (QA) and Supply Chain Departments.

As part of this approval and re-approval process, suppliers shall be requested by ASC Supply Chain to complete a Supplier Qualification Questionnaire (SQQ), which must be submitted together with supporting documentation (as specified in the SQQ), prior to being awarded 'ASC Supplier' status. Once suppliers have been approved, ASC QA and Supply Chain Departments may conduct regular quality audits, including on-site visits, to ensure the supplier can consistently meet ASC quality, safety and delivery requirements.

#### **Right of Access**

During the course of the relationship between ASC and the supplier as an active approved supplier, ASC may (with reasonable notice) require access to the supplier's manufacturing/production areas and/or the supplier's sub-tier facilities for auditing purposes and for assessing capability processes to meet the ASC PO/contract requirements.

### Mutual Recognition for Test Laboratories

ASC requires all testing (mechanical, chemical, non-destructive or calibration) to be performed by, and/or traceable back to, a suitable laboratory accredited to ISO 17025. Acceptable national certification bodies will be members of the International Laboratory Accreditation Corporation (ILAC). The approved Australian certification body is the National Association of Testing Authorities (NATA), which is a member of ILAC. All international testing laboratories shall be affiliated with ILAC.

## 2. Requirements

# General Expectations of ASC Suppliers

Suppliers are expected to maintain an effective QMS based on the requirements of ISO 9001 (latest version) unless otherwise agreed, in which case the minimum requirements of this Supplier Quality Assurance Manual must be implemented and maintained.

ASC expects suppliers to share its commitment to meeting ASC's end customer requirements for quality, technical performance and on-time delivery. This can be achieved through flexibility in assisting ASC to meet its end goal which can be achieved by implementing continuous improvement initiatives and business continuity plans.

All suppliers are responsible for ensuring compliance to the requirements contained in this manual and are responsible for the quality, timeliness and integrity of delivered goods and services, including those provided by sub-tier suppliers/manufacturers/mills.

All delivered goods and services must comply fully with ASC's quality requirements, including the provision of appropriate Objective Quality Evidence (OQE) documentation.

All OQE for commodity items shall comply with the ASC attributes defined in this manual.

#### Work Health Safety and Environment (WHS&E)

Suppliers are responsible for all aspects of WHS&E connected with the goods and services supplied to ASC and must at their own cost comply with all WHS&E related legislation (including the WHS Commonwealth Act and associated regulations) that is in any way applicable to the goods and services supplied, including in respect of their sub-tier suppliers or subcontractors. Suppliers must demonstrate to ASC that they have the necessary knowledge, ability and resources to comply with all applicable WHS&E legislation and, on request, must provide ASC with all necessary information to allow ASC to properly assess the supplier's capacity to provide goods/ services in accordance with all relevant WHS&E legislation.

Suppliers providing services at ASC sites will also be required to demonstrate compliance through:

- Work, Health & Safety Management
  Plans
- Environmental Management Plans
- Competency and licensing of personnel
- Risk Registers and Assessments

Suppliers must notify ASC immediately of any incident or event occurring in connection with the supply of goods or services to ASC that is in breach of or is notifiable under the relevant WHS&E legislation.

ASC requires suppliers to provide a copy of their environmental and WHS policies detailing environmental and safety commitments. ASC highly recommends suppliers maintain ISO 14001 and ISO 18001 or ISO 45001 certification to demonstrate commitment to environmental and safety performance or a system based on those requirements.

### **Sustainability**

ASC's sustainability vision is to successfully carry out ASC's operations to minimise our environmental footprint and positively influence social, workforce and business outcomes.

As such, ASC values the consideration of the impacts on the environment, society and cost across the full lifecycle of products and services supplied to ASC. Where available, the supplier will provide ASC with sustainability information for their operations, including how the supplier has worked to reduce the environmental impacts associated with the supply of their product or services to ASC.

Impacts ASC has identified as specifically relevant for its business include:

- Energy consumption
- Pollution Air/Water/Land
- Water Resources
- Waste Management and Recycling
- Carbon emissions

### Hazardous Materials/ Hazardous Substances

When a hazardous material or substance (which may include, but is not limited to, hazardous substances, dangerous goods and scheduled poisons) is to be delivered to ASC, the supplier must provide a material specification. A Safety Data Sheet (SDS) which is compliant with WHS regulations must be provided with all hazardous materials or substances.

**Hazardous Materials:** Materials which because of chemical, biochemical, microbiological or radiological properties, temperature or state of compression could, in sufficient concentration, cause:

- Harm to human health and safety or personal injury
- Property damage, or
- Environmental harm or environmental nuisance

**Hazardous Substances:** Substances that are listed on Safe Work Australia - Hazardous Substances Information System (HSIS) found at <u>http://hcis.</u> <u>safeworkaustralia.gov.au/</u> or are determined to be a hazardous substance by the manufacturer, importer or distributor of the substance. Problematic Substances: The supplier must supply to ASC in advance of delivery to site, or upon identification of such a substance, information regarding the proposed use of a chemical listed in Schedule 14 of the WHS regulations, and ensure no chemicals listed in Schedule 10 of the WHS regulations are brought to an ASC site unless specifically approved for use by ASC. Where ASC agrees to accept deliveries of such dangerous goods or hazardous substances, the supplier must affix a warning label and include the latest revision of the SDS that complies with Australian health and safety law Chapter 7. Division 2 of the Work Health and Safety Regulations 2011 (Cth). Supplies provided without a compliant SDS or dangerous goods labelling satisfactory to ASC will not be accepted by ASC.

#### Purchase Order/Contract Requirements

Suppliers are expected to be able to demonstrate that they have a process that ensures they fully understand ASC's PO or contract requirements.

If a supplier is uncertain about any aspect of what ASC has ordered, the supplier must contact ASC as soon as practical to resolve this uncertainty prior to incurring any costs or committing to supply.

#### Inwards, Outwards and Inprocess Goods Assurance/ Controls

Suppliers to ASC are expected to be able to demonstrate they have processes for the management of Goods Inwards, Goods Outwards and In-process QA/Inspection activities.

Suppliers must ensure that goods undergo the required level of checks and balances (e.g. visual inspections, traceability checks, sample dimensional inspections) as specified by ASC, via Technical Specifications (TS) or as contractually agreed during production and prior to delivery.

#### Handling of ASC Supplied Materials

Customer (ASC) supplied materials must undergo the same level of Inwards Goods inspection and traceability control as any other materials purchased by the supplier.

Where required, Inwards Goods inspections must include sample dimensional inspection, visual inspection and marking/traceability checks (validated against the delivered certification/OQE).

Material traceability must be maintained up until the point of use in production.

Unused material (including off cuts/ remnants) must be marked and remain fully traceable up until the point of use in the supplier's production or return to ASC.

ASC recommends that suppliers photograph ASC supplied plant and equipment on receipt as a record of the condition of these items when transferred to the supplier's control.

#### **Control of Sub-tier Suppliers**

It is a requirement that all ASC direct suppliers can demonstrate they maintain effective control over their sub-tier suppliers (e.g. manufacturers/mills) including a process for monitoring the performance of sub-tier suppliers.

Direct suppliers to ASC must (on request) provide to ASC the necessary OQE to confirm that their sub-tier suppliers have been adequately assessed and are approved to supply.

The supplier must flow down all ASC PO requirements (e.g. technical/OQE requirements) to their sub-tier suppliers. The expectation of sub-tier suppliers to ASC is the same as the requirements detailed in this manual, particularly in relation to the controls, restrictions and protocols with ITAR, IP and Commercialin-Confidence documentation.

ASC may undertake quality audits of a supplier's sub-tier suppliers on a case by case basis.

#### **Internal Audit**

Suppliers are expected to be able to demonstrate that they maintain an effective internal audit program that meets the requirements of ISO 9001 (latest version).

#### Control of Non-Conforming Products and Services

Suppliers shall ensure that products that do not conform to requirements are identified and controlled to prevent their unintended use or delivery. Appropriate action based on the nature of the nonconformance of products and services shall be taken. This applies also to products and services discovered during or following delivery.

If a non-conforming product or service is provided, ASC will advise the supplier of the non-conformance and raise a Quarantine Report in accordance with CMS-56091. A triggered audit may be undertaken and a formal non-conformance raised and monitored with the supplier. In exceptional cases, removal of the supplier from the Approved Supplier List may be considered.

#### Qualified and Trained Personnel

It is a requirement that the supplier can provide evidence of its employees' current training and skills including all relevant personnel qualifications, certificate expiry dates (as applicable) and information pertaining to the skills relevant to tasks to be undertaken for ASC work. Suppliers must satisfy ASC that there is a system in place to maintain currency of delegations, licences and qualifications relevant to the scope of work.

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#### Control of Design Development Planning

Suppliers shall plan and control the design and development of good and services.

During the design and development planning, the organisation shall determine:

- The design and development stages
- The review, verification and validation (including Inspection and Test Plans) that are appropriate to each design and development stage
- The responsibilities and authorities for design and development

The organisation shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.

The supplier shall ensure that a process exists for configuration management of items or goods provided to ASC that are used on the CCSM. A Configuration Management Plan (CMP) or equivalent is expected of large organisations. For a small-medium enterprise (SME), evidence that a scheme is in place for managing the configuration baseline of the product would suffice. ASC is to be notified of any change to baseline configuration to ensure any change does not impact fit, form or function of the system.

### Inspection and Testing Planning (ITP) Applicability/ Controls

Where a PO/contract OQE requires a supplier to submit an ITP to ASC, the supplier's ITP document will be subject to ASC approval and must be submitted prior to commencement of work.

As part of ASC's approval of the supplier's ITP, ASC may add hold and witness points at its discretion; when hold and/or witness points are required to be observed the

supplier must inform ASC of the upcoming event with adequate notice in accordance with the terms of the ITP.

Hold points shall not to be conducted without an ASC representative present unless the hold point has been formally waived by ASC. Evidence of waivers must be retained and be submitted with the ITP as OQE.

As an exception, witness points may be conducted on the assigned date without ASC's presence if appropriate notification had been provided to ASC. Evidence of this notification must be retained and be submitted with the ITP as OQE.

The ITP document must contain sufficient information to identify what inspection and/or testing will be carried out to meet PO/contract requirements and must be signed and dated by an ASC Engineering representative to authorise the ITP. It is the supplier's responsibility to ensure ASC endorses the ITP prior to commencement of work.

#### Inspection Measuring and Testing Equipment (IMTE) – Calibration

All IMTE used for final compliance measurements performed on ASC components in Australia, the supplier shall ensure the equipment has been calibrated at specified intervals traceable to national measurement standards endorsed by NATA to the latest revision of ISO/IEC 17025. The NATA accredited laboratories must be certified to conduct the applicable calibration within their scope and appear on the national register website.

For all work conducted outside Australia, all final measurement equipment shall be traceable to a calibration laboratory accredited to the latest revision of ISO/IEC 17025 (ILAC). All international accredited laboratories must be certified to conduct the applicable calibration within their scope and appear on the relevant body's register website. ASC reserves the right to ask for equipment calibration certificates to be supplied on demand (if required) as indicated in the PO.

IMTE shall be maintained in a manner that protects ASC from receiving non-conforming goods.

A register including history of all IMTE used on ASC work must be maintained in order to capture the latest test date, validity, including periodicity of calibration. The IMTE must also contain a unique serial number or identifier to assist with traceability in the event of a nonconformance.

The supplier's IMTE calibration procedure shall ensure the validity of previous measuring results should any IMTE be found to be defective or out of calibration.

ASC must be notified in the event of potential and/or non-conforming goods and services as a result of IMTE used to inspect ASC components failing at the subsequent calibration.

#### Testing Laboratories and Inspection Providers

All Non Destructive Testing (NDT) shall be completed by suitably qualified operators to ISO: 9712 (minimum level 2) by a relevant certification body, such as Australian Institute for Non-Destructive Testing (AINDT) or international equivalent. All NDT reports shall be issued by a laboratory accredited to ISO/IEC 17025 on an endorsed (ILAC/NATA) certificate.

All laboratories performing mechanical and chemical testing shall be issued by a laboratory accredited to ISO/IEC 17025 on an endorsed (ILAC/NATA) certificate.

All facilities performing pressure equipment inspections on pressure vessels (new or in-service) shall ensure the operators are suitably experienced and qualified by a relevant certification body such as the Australian Institute for the Certification of Inspection Personnel (AICIP) in Australia or international equivalent.

#### Manufacturers Data Report (MDR)

A folder or similar which contains all the required OQE documentation shall be supplied with the goods to confirm compliance to the required standards and PO/contract requirements.

### **Objective Quality Evidence Requirements (OQE)**

Provision of clear and unambiguous OQE is essential to ensure that goods and services meet ASC technical and contractual requirements. OQE requirements must be provided for individual line items as specified in the PO or contract unless otherwise stated.

The Master List of OQE Attributes for Commodities supplied to ASC can be found at <u>www.asc.com.au</u>, under 'Supply Chain'.

Serial Number (SN OQE Attribute) shall be documented on all supporting OQE exactly the same as the SN stamped, stencilled, etched or engraved on the physical part. All numbers, letters, characters and spaces must be exact (e.g. A01-ABC0123/1). It is the supplier's responsibility to ensure the OQE serial number requirements are passed onto any contractor or sub tier suppliers to ensure the serial number is consistent and matching throughout the supporting OQE.

### Submission of OQE to ASC

A process has been created for the loading of all PO documentation OQE electronically. It is to be submitted via email and the title naming convention detailed below must be adhered to. This includes that a valid PO number is fundamental in ensuring the artefacts are automatically loaded to ASC's ERP, the email address for this process is <u>podocs@asc.com.au</u>. Every time an email is sent to this email address it will be loaded to ERP against the relevant PO. Format as follows must include OQE which will then notify Supplier Quality Control of OQE being uploaded.

Naming Convention

'OQE \*PO #\* Line # Date Rev #'

Example

OQE M000074521 Line 3 19-2-18 Or

OQE M000075369 Line 1 21-5-17 Rev 2

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Or
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OQE SDR for M000078963 Line 2 5-5-17 Rev 3

If unclear on what OQE is required and in what format, the supplier must consult with their ASC point of contact before actioning the PO or contract.

### Opening and Closing Reports (for refurbished goods)

PO for the refurbishment of ASC plant and equipment may require an opening and closing report to be provided as part of the delivered OQE. This report should include photos that clearly capture the condition of plant and equipment as received, a clear list of parts required to refurbish the plant and equipment and photos of the refurbished item prior to dispatch to ASC.

The report should identify any abnormal condition that is not considered fair wear and tear for the service that the item has experienced.

All items sent to suppliers for refurbishment due to the item failing whilst in-service rather than being sent for routine scheduled maintenance service, should have an opening and closing report provided.

The opening report should clearly identify items that would not normally require replacement or areas of concern/defects/ abnormal conditions that ASC engineering should be made aware of.

#### Product Marking/ Traceability/Packaging and Preservation

Each item delivered to satisfy a PO/ contract must be identified with the following information (where applicable):

- PO/contract number and revision number
- PO line/item number
- Item description
- ASC part number (NATO Stock Number or ASC Catalogue Number)
- Quantity
- Manufacturer's part number, identification of OEM and country of origin
- Controlled goods identification (non ITAR)

Unless specified in the PO or contract packaging of items is to be at the discretion of the supplier and is to be appropriate for the method of transport and for the storage/shelf life requirements of the item.

#### ASC Quality Requirements for Shelf Life Products

Shelf life products (e.g. synthetic rubber, epoxies, paints, adhesives, sealants and fastener-locking compounds) must comply fully with ASC OQE attributes and the information supplied on the product CoC must contain the following:

- Lot traceability number or batch number
- Shelf life expiration date/use by date (in accordance with specification)
- Cure dates and shore hardness as applicable

Shelf life products must be stored correctly and have a minimum of 85 percent of shelf life remaining upon receipt at ASC, unless agreed otherwise by ASC.

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### ASC Quality Requirements for Fasteners

Fastener material specification, dimensional specification and delivery conditions (e.g. surface treatment) must be clearly stated in the ASC PO and must be fully complied with.

**Fastener Threads** must be sampleinspected by the manufacturer or supplier to ensure conformance to the specified standards.

**Fastener Surface Treatment**; where specified in the PO/contract plating, galvanising, heat-treatment, etc. must be sample-inspected by the manufacturer or supplier to ensure complete coverage and conformance to the specified standards.

**Fastener Marking**; where stipulated in the PO/contract threaded fasteners must be marked in accordance with standards specified, e.g. carbon steel fasteners to ISO 898-1 & ISO 898-2, stainless steel fasteners to ISO 3506-1 & 3506-2 and must be identified by the manufacturer's marking symbol (including material grade).

Note: For guidance, threaded fasteners manufacturer's marking symbols are listed in *DoD Handbook MIL-HDBK 57 F, 21 June 2011, Listing of Fasteners Manufacturer's Identification Symbols.* 

#### Technical Information and Export Controls

#### Release of Controlled Technology

At ASC, goods and technical data which have restrictions on their use or retransfer under an export authorisation are known as Controlled Technology. Restrictions on Controlled Technology vary considerably, depending on the sensitivity of the technology and where it came from. Such technology is subject to specific restrictions and its unauthorised disclosure, reproduction, re-transfer and/ or use is prohibited by both domestic and international laws which attach significant penalties to non-compliance. Technology originating in the United States may be subject to the International Traffic in Arms Regulations (ITAR) in which penalties are up to USD \$1 million per violation and 10 years imprisonment per criminal violation.

Other Controlled Technology may be subject to the United States' Export Administration Regulations (EAR) or other non-US legislation (including European Community Export Regulations and Australian Export legislation). Again, restrictions on its use by and re-transfer to, other companies usually apply and noncompliance attracts severe penalties.

ASC may be required to provide Controlled Technology to external parties, including suppliers, and it therefore requires recipients to adhere to specific handling requirements.

#### Provision of Controlled Technology to Suppliers by ASC

If ASC is required to provide Controlled Technology, ASC will inform the recipient of such and direct them with respect to any special handling agreements and/or restrictions that are required, including (but not limited to) the following:

- Controlled Technology must not be disclosed to any unauthorised persons or commercial parties including, but not limited to, employees, subcontractors, consultants, suppliers or sub-tier suppliers/manufacturers.
- Controlled Technology must only be used by the recipient in accordance with the terms of documentation signed by the recipient in relation to that specific supply or, in the absence of a such documentation, only the purpose for which it was provided.
- On completion of the contracted activities, the original Controlled Technology and any reproductions made (whether authorised or otherwise) on any format whatsoever (including but not limited to digital media and hard copy print out) must be returned/delivered up to ASC immediately upon request and in

a manner consistent with ASC policy on the receipt of Controlled Technology.

Reproduction includes:

- Copying by any means including printing, 3-D printing, scanning, photocopying, photographing
- Storing it anywhere on any computer, hard disc drive or printer buffer; or on any form of portable media such as a CD, DVD, flash drive, media card or handheld device of any sort; and/or
- Creating derived technology (physical products from controlled data, by 3-D printing, or by replicating or reverse engineering equipment)

As such, recipients of Controlled Technology are expected to be able to demonstrate to ASC that they are able to:

- Securely store Controlled Technology (hard copies and electronic data)
- Both obtain and provide Non-Disclosure Statements when required; and
- Provide evidence that controls are in place to manage access and use of Controlled Technology, including by sub-tier suppliers, which, in the case of Controlled Technology subject to ITAR, must be capable of controlling access with reference to relevant nationality restrictions

#### Receipt of Controlled Technology by ASC

As a recipient of items and/or technical data that may be subject to export controls, ASC is legally required to adhere to any use and/or retransfer restrictions imposed on it and/or other handling requirements required by relevant legislation and export authorisations. ASC will therefore ask suppliers whether items/ data being supplied are subject to any export control legislation.

It is therefore mandatory that suppliers:

 Inform ASC if the items/data being supplied are subject to any export authorisations.

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- Ensure that ASC and any other entities which may be required to receive and access it, are properly authorised to do so.
- Provide ASC with a copy of the relevant export authorisation.
- On both the technical data and part as well as in accompanying correspondence/file name, clearly identify that it is export controlled and refer to the export authorisation reference.

## Delivery of Controlled Technical Data to ASC

Controlled Technical Data is physical/ tangible or electronic/intangible data and material, such as documentation, drawings, photographs, plans, diagrams, models, engineering designs and specifications, manuals, instructions or software, which are regulated by defence trade controls and/or supplied subject to an export authorisation.

Specific information about the functional, performance (including test data) or material specification or attributes of Controlled Goods or which is required to design, develop, produce, assemble, operate, repair, test, maintain or modify Controlled Goods, is also Controlled Technical Data. This is likely to include information contained in, or known as, OQE.

It is the responsibility of the supplier to identify where OQE contains Controlled Technical Data and to adhere to ASC's delivery policy in respect of such. All Controlled Technical Data subject to export controls is required to be provided to ASC in one of the following three ways:

- Directly to ASC's Configuration Management Team using portable media by liaising with the procurement officer to arrange.
- Directly to ASC's Configuration management Team by printed hard copy by liaising with the procurement officer to arrange.
- 3. Using ASC's secure File Transfer Protocol by emailing <u>CMInbox@asc.com.au</u>

Emailing export controlled data to anywhere other than the email address provided above is strictly prohibited.

Sending export controlled data hard copy with/in the same crate as the physical item(s) to which it relates is strictly prohibited.

#### Control and Retention of Quality Records

Suppliers are required to maintain effective control of quality records including the identification, storage, protection, retrieval, retention and disposition of records. All records associated with an ASC order shall be retained for a minimum of 12 years.