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Quality Requirements for Suppliers

QRS 3

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2 Foreword

2.1 Purpose

To flow down the combined submarine specific quality assurance requirements, additional to those specified in ISO 9001, into the Submarines Enterprise (SE) supply chain.

2.2 Applicability

AWE specific requirement: Where referenced, the requirements of this document are applicable to all QC1 and QC2 purchase orders placed in support of AWE contracts.

All documentation that provides evidence that the requirements of this document have been achieved, shall be supplied written in the English Language.

In this publication 'Notes' are not contractual requirements; they are for guidance or clarifying the associated requirement.

NOTE 1 This document replaces Defence Standard 02-884 (Submarine Enterprise Standard Quality Requirements) which has now been withdrawn. The Submarine Enterprise (SE) Quality Group leadership team act as custodian of the Baseline Master Document. The Baseline Master Document is subject to annual review, with SE companies submitting Change Requests, which will be reviewed along with changes to relevant standards.

NOTE 2 The SE comprises of AWE, Babcock Marine & Technology (BM&T), BAE Systems Maritime Submarines, and Rolls-Royce Submarines.
NATO requirements referenced in this document can be found at:
https://nso.nato.int/nso/nsdd/main/list-promulg

2.3 Precedence

Where conflict occurs between this document and any contract related standards, the contract standards take precedence.

3 Introduction

The content of this document has been developed in conjunction with the SE. The Contents list is aligned to ISO 9001 (Quality management systems – Requirements) with the exception of 8.1 and 8.5.1. In line with the terminology used in ISO 9001 the supplier is referred to as the 'organisation' and its sub-suppliers are referred to as 'external providers'.

Where AWE specific requirements apply, these appear as **bold text** within the applicable section.

The organisation **and/or external providers** shall **provide** the customer, and if necessary their customer:

a) the right of access to facilities where the contracted activities are being performed.

b) information pertaining to the fulfilment of requirements in the contract.

c) unrestricted opportunity to evaluate the organisation's compliance with this publication.

d) unrestricted opportunity to evaluate external providers' compliance with this publication. The organisation will be informed before the evaluation takes place.

e) unrestricted opportunity to conduct verification of product conformity with the contract requirements.

f) required assistance for evaluation, verification, validation, testing, inspection or release of the product for the accomplishment of Government Quality Assurance (GQA) to contract requirements.

g) accommodation and facilities for performing GQA.

h) the necessary equipment available for reasonable use for performing GQA.

i) organisation and/or external providers personnel for operation of such equipment as required.

j) access to information and communication facilities.

k) the necessary organisation documentation to confirm product conformance to specification.

l) copies of necessary documents, including those on electronic media.

4 Context of the organisation

4.1 Understanding the organisation and its context

In addition to ISO 9001 4.1

The organisation shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system (QMS). Where applicable the external and internal issues shall include nuclear safety considerations.

4.2 Understanding the needs and expectations of interested parties

In accordance with ISO 9001

4.3 Determining the scope of the quality management system

In addition to ISO 9001 4.3

The organisation shall **establish, document, implement, assess and improve an effective and economical QMS in accordance with this publication which includes** the requirements of ISO

9001:2015 (Quality Management Systems – Requirements) **as necessary to satisfy the contract requirements.**

NOTE 1 The applicable requirements of AQAP-2110 (NATO QA Requirements for Design / Development and Production) are included in this document.

NOTE 2 For software related requirements see AQAP-2210 (NATO Supplementary Software Quality Assurance Requirements to AQAP-2110 or AQAP-2310).

4.4 Quality management system and its processes

In addition to ISO 9001 4.4

The organisation's quality management system shall address applicable customer, statutory and regulatory quality management system requirements.

The customer reserves the right to not accept the organisation's Quality Management System as it applies to the contract. The organisation's documented Scope of their System, records from internal audit, self-assessments and other objective evidence that this system is compliant with this publication and is effective, shall be readily available to the customer.

The organisation and external providers shall have documented quality management systems which include the applicable requirements of ISO 9001 (Quality management systems – Requirements) and this document.

Unless otherwise agreed by the customer the system shall be certified by a third-party organisation accredited by the United Kingdom Accreditation Service (UKAS) or by another body accredited by the International Accreditation Forum (IAF).

In instances where the customer rejects the QMS, the organisation shall make proposals for corrective actions and revisions within an agreed timescale.

Organisations and external providers shall only supply products or services within the scope of their management system certification and any other limitations defined by their customer.

Where an external provider does not have a certified system then it is the organisation's responsibility to **ensure** the work done by that **external** provider **complies with the scope**.

5 Leadership

5.1 Leadership and commitment

In accordance with ISO 9001

5.2 Policy

In accordance with ISO 9001

5.3 Organisational roles, responsibilities and authorities

In addition to ISO 9001 5.3

5.3.1 The organisation shall:

a) appoint a management representative from the organisation's management who, irrespective of other responsibilities, shall have the necessary organisational authority and freedom to resolve matters pertaining to quality. The representative shall have the appropriate competence related to Quality Management.

b) provide the representative with unrestricted access to top management to resolve quality issues.

5.3.2 The organisation's management representative shall have responsibility and authority that includes:

a) ensuring that processes needed for the quality management system are established, implemented and maintained;

b) ensuring that the quality management system conforms to the applicable requirements of ISO 9001 (Quality management systems – Requirements) and this document.

c) liaising with external parties on matters relating to quality.

6 Planning

6.1 Actions to address risks and opportunities

In addition to ISO 9001 6.1

The organisation shall:

a) provide objective evidence that risks, including external provider risks, are considered during planning, including but not limited to risk identification, risk analysis, risk control and risk mitigation;

b) start the planning with risk identification during pre-contract / contract review and be updated thereafter in a timely manner. Documented information arising from the activity shall be retained;

c) ensure that the risk management applied meets the principles and guidelines of ISO 31000 (Risk management – Guidelines) unless otherwise stated in the contract;

d) make the Risk Management Plan available to the customer;

e) the customer reserves the right to not accept Risk Plans and their revisions.

6.2 Quality objectives and planning to achieve them

In accordance with ISO 9001

6.3 Planning of changes

In accordance with ISO 9001

7 Support

7.1 Resources

7.1.1 General

In accordance with ISO 9001

7.1.2 People

In accordance with ISO 9001

7.1.3 Infrastructure

In addition to ISO 9001 7.1.3

The infrastructure shall include an area to segregate nonconforming product (see 8.7).

7.1.4 Environment for the operation of processes

In accordance with ISO 9001

7.1.5 Monitoring and measuring resources

7.1.5.1 General

In accordance with ISO 9001

7.1.5.2 Measurement traceability

In addition to ISO 9001 7.1.5.2

The organisation shall:

a) establish and maintain a register [Note 1] of monitoring and measurement equipment [Note 2] when measurement traceability is a requirement.

b) advise the customer on the impact of the failure when monitoring and measuring equipment is found to be unfit for its intended purpose and this affects delivered products and services or verification, validation and acceptance results. **The customer may request that measurements taken shall be repeated with calibrated equipment.**
Documented information arising from the activity shall be retained.

c) ensure that the measurement and calibration system meet the requirements of ISO 10012 (Measurement management systems - Requirements for measurement processes and measuring equipment).

NOTE 1 The register may include details for example: the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

NOTE 2 Monitoring and measuring equipment can include, but is not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also

includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.

7.1.6 Organisational knowledge

In accordance with ISO 9001

7.2 Competence

In addition to ISO 9001 7.2

The organisation shall establish and maintain a process for identifying training needs and achieving competence of all personnel performing activities affecting product and service quality.

NOTE Consideration may be given for the periodic review of competence.

7.3 Awareness

In addition to ISO 9001 7.3

The organisation shall ensure that persons doing work under the organisations control, including external providers, are aware of the specific arrangements contained in the quality plan(s) (e.g., Deliverable Quality Plan, Inspection and Test Plan) that are applicable to their activities / area of responsibility.

7.4 Communication

In addition to ISO 9001 7.4

The organisation shall determine the internal and external communications relevant to the quality management system. External parties may include licensee / operator, regulatory bodies, national authorities, etc. **The communication procedure set out in the contract is to be used.**

7.5 Documented information

7.5.1 General

In addition to ISO 9001 7.5.1

The organisation shall:

a) ensure that its quality management system includes applicable documented information required by ISO 9001 (Quality management systems – Requirements) and this document.

b) provide the customer, and if necessary, their customer, with the necessary access to the documented information pertinent to the contract in an agreed format written in English.

7.5.2 Creating and updating

In accordance with ISO 9001

7.5.3 Control of documented information

In addition to ISO 9001 7.5.3

The organisation shall:

a) prevent the unintended use of obsolete documented information.

b) retain documented information which is generated to demonstrate conformity to the contract and or purchase order requirements, but not identified as a deliverable to the customer in accordance with the contract and or purchase order requirements.

c) retain documented information and test specimens in accordance with their retention periods **stated in the contract**.

d) store and dispose of retained documented information in accordance with their security classification.

e) ensure that documented information that needs to be retained by the organisation is protected against risks that may pose a threat to document integrity and legibility. Risks may include: unauthorised changes, fire, water damage, cyber-attacks, corruption and electrical surges.

f) ensure that the method of managing and accessing retained documented information allows information to be retrieved in a timely manner to support the:

- exchange of information between organisations;
- periodic reassessment of an item’s acceptability for service;
- repair / maintenance of items;
- traceability of suspect items in the event of problems being recognised elsewhere.

8 Operation

8.1 Operational planning and control

In addition to ISO 9001 8.1

8.1.1 General

The organisation shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6 (Planning).

NOTE Determination of requirements for the products and services may include consideration of:

- personal and product safety;
- producibility and inspectability;
- reliability, availability, and maintainability;

- suitability of parts and materials used in the product;

- selection and development of embedded software;

- product obsolescence;

- prevention, detection, and removal of foreign objects;

- handling, packaging, and preservation;

- recycling or final disposal of the product at the end of its life.

The organisation shall identify and retain the documented information, including acceptance criteria and configuration information, which will be used:

a) as objective evidence of product and service conformance with requirements. This information shall be acceptable to the customer and made available prior to acceptance.

b) for product approval and production process approval. These approvals shall also be applied to external providers.

8.1.2 Deliverable Quality Plan

If requested by the customer, the organisation shall submit a Deliverable Quality Plan [Note 1] which addresses the contractual requirements in a mutually agreed timescale but prior to the start of work which can be defined as a project or contract initiation meeting or as otherwise stated in the contract or purchase order. If changes to the organisation's quality management system impact on product and service quality or processes detailed in the Deliverable Quality Plan, then the customer shall be advised.

Where required the Deliverable Quality Plan shall:

a) be a clearly identified discrete document or part of another document that is prepared under the contract;

b) describe the quality management system requirements 'contract-specific' necessary to satisfy the contract requirements (making reference, where applicable, to the 'company-wide' quality management system);

c) describe and document the planning of the product and service realisation in terms of quality requirements for the product and service, needed resources, required control activities (verification, validation, monitoring, inspection, testing), and acceptance criteria. This shall include specific arrangements and communication requirements where work is to be conducted at locations external to the organisation's premises.

d) document and maintain traceability of requirements from the planning process by including a Requirement and Solution Compliance Matrix, justifying fulfilment of all contractual requirements (making reference where applicable);

The customer reserves the right to **accept** / **not accept** Deliverable Quality Plans and their revisions.

NOTE 1 The contractual requirement for the content of the Deliverable Quality Plan is established in AQAP-2105 (NATO requirements for Deliverable Quality Plans). The Requirement and Solution Compliance Matrix can be a part of the Quality Plan or a separate document as an annex to it. This matrix can be prepared and annexed to the Quality Plan after the initial issue, within a timescale mutually agreed with the customer by taking into account the content of the contract or purchase order.

8.1.3 Software Quality Plan

The organisation shall submit a Software Quality Plan to the customer where required by the scope of work identified in the contract or purchase order.

NOTE Further information on Software Quality Plans is contained in AQAP-2210 (see 4.3).

8.1.4 Source and method change control

The organisation shall:

a) establish, implement and maintain a process to plan and control the temporary or permanent transfer of work and / or changes to the method of manufacture to ensure the continuing conformity of the work to requirements.

b) ensure that work transfer impacts and risks are managed, and that documented information associated with the change is retained.

c) obtain approval from the customer prior to the change.

8.1.5 Configuration management

8.1.5.1 Configuration management requirements

Where requested by the customer the organisation shall manage configuration through the implementation of configuration management planning, configuration identification, change control, configuration status accounting and configuration audit in accordance with the requirements of ACMP 2100 (NATO Contractual Configuration Management Requirements) and any additional configuration management clauses in the contract or a nationally recognised equivalent.

8.1.5.2 Configuration Management Plan

Where requested by the customer the organisation shall prepare a Configuration Management Plan which describes the application of configuration management to the contract in accordance with ACMP 2100 (NATO - The core set of configuration management contractual requirements) and any additional configuration management clauses in the contract or nationally recognised equivalent. The Configuration Management Plan may form part of another plan if appropriate.

NOTE Further information on NATO Configuration Management Policy and Requirements are contained within Allied Configuration Management Publications ACMP 2000 and ACMP 2009, (see 2.2 regarding Notes).

8.1.6 Counterfeit, fraudulent and suspect items (CFSI)

The organisation shall:

a) plan, implement, and control processes, appropriate to the organisation and the product or service, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in products or services delivered to the customer.

b) quarantine the product and inform the customer if a suspect counterfeit item is identified.

8.2 Requirements for products and services

8.2.1 Customer communication

In addition to ISO 9001 8.2.1

If requested by the customer, the organisation and/or External Providers shall attend a Post Award meeting focused on the contract arrangements for Quality Assurance of the product and/or customer practicalities.

The organisation shall communicate to the customer's identified point of contact:

a) the name of the nominated management representative responsible for quality and any subsequent changes.

b) changes to the organisation that affect product and service quality.

c) changes in the organisations ability to meet the requirements of the agreed quality plan(s) (e.g., Deliverable Quality Plan, Inspection and Test Plan).

d) issues with the management system certification including lapse, withdrawal or any major audit findings.

e) where an organisation or its external providers want permission to waiver a customer defined hold and / or witness point.

f) if an external provider's performance is unknown or causes concern the organisation shall notify the customer if the order involves:

- a critical item;
- significant work content;
- design;
- immature technical solutions;
- rejected, reworked, or repaired product.

g) if the organisation needs to clarify an element of the contract or purchase order then a query shall be submitted. The organisation shall maintain a register of queries and the register and associated documented information shall be retained.

NOTE Queries may include but are not limited to: design change, configuration change, source change, product or service quality and commercial.

8.2.2 Determining the requirements for products and services

In addition to ISO 9001 8.2.2

Where required the organisation shall identify product and service requirements and functions that relate to critical characteristics such as health, safety, performance and dependability.

Quality requirements shall be considered for the following phases as appropriate:

a) initial design, manufacture and build.

b) operation.

c) design revalidation, material revalidation, life extension, repair, refurbishment, modification, concession and disposal.

d) investigation and management of emergent materiel shortfalls.

8.2.3 Review of the requirements for products and services

8.2.3.1

In addition to ISO 9001 8.2.3.1

The organisation shall:

a) coordinate the contract review with the applicable functions and significant external providers to ensure that the requirements are understood and adequately defined.

b) include in contract review an assessment of production feasibility to ensure that the product can be produced in accordance with the standards, specifications and tolerances specified by the customer.

c) attend a post contract award meeting focused on the contract arrangements for quality assurance of the product or service if requested by the customer. This may also include external providers if required.

d) confirm to the customer when an Invitation to Tender, Contract or Purchase Order requires BS EN 10204 (Metallic products: Types of inspection documents) 3.2 material certification, that the material requirements are achievable including that the raw material will be sourced from an International Association of Classification Societies accredited (IACS) mill. Where an organisation cannot confirm that BS EN 10204 3.2 material certification requirements are achievable they shall provide in the Invitation to Tender response information regarding which test house they intend to use and which independent International Association of Classification Societies (IACS) approved 3rd party will be certifying it.

8.2.3.2

In accordance with ISO 9001

8.2.4 Changes to requirements for products and services

In accordance with ISO 9001

8.3 Design and development of products and services

8.3.1 General

In accordance with ISO 9001

8.3.2 Design and development planning

In addition to ISO 9001 8.3.2

The organisation shall:

a) where appropriate divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs.

b) create a Design and Development Inspection and Test Plan where required by the contract or purchase order.

8.3.3 Design and development inputs

In addition to ISO 9001 8.3.3

The organisation shall determine the requirements essential for the specific types of products and services to be designed and developed. Where applicable the organisation shall consider:

a) the potential consequences of obsolescence (e.g., materials, processes, components, equipment, products) as part of design and development inputs.

b) the requirement for safety justifications.

c) the presence of hazardous materials.

d) the requirements for availability, reliability and maintainability analysis and design for both system / equipment operation and safety calculations.

e) identified engineering classifications in product definitions.

Generally, all safety related design activity shall be underpinned by proven technology and/or practices embedded in design standards, processes, rules and limits which shall be relevant to, and approved for, the application. Where unproven technology is to be used, the associated risks shall be identified, and arrangements put in place to manage these risks to As Low As Reasonably Practicable (ALARP) as part of the design process.

NOTE The organisation can also consider other information such as benchmarking, external provider feedback, internally generated data and in-service data.

8.3.4 Design and development controls

In addition to ISO 9001 8.3.4

The organisation shall:

a) where applicable, unless otherwise stated in the contract or purchase order, determine the verification and validation methods required and demonstrate conformity with the corresponding requirements at appropriate stages up to and including the final product or service.

b) apply controls to the design and development process to ensure that progression to the next stage is authorised.

c) if stated in the contract or purchase order ensure that dependability issues and related documents, including those from external providers, are controlled.

d) certify people employed in key design positions as Suitably Qualified and Experienced Person (SQEP) in the technology fields concerned.

NOTE Further information on NATO Dependability Management is contained within Allied Dependability Management Publications ADMP-01 & ADMP-02, (see 2.2 regarding Notes).

8.3.5 Design and development outputs

In addition to ISO 9001 8.3.5

The organisation shall ensure that design and development outputs are approved by authorised person(s) prior to use.

8.3.6 Design and development changes

In addition to ISO 9001 8.3.6

The organisation shall

a) establish a process with criteria for notifying its customer about design and development changes that affect customer requirements prior to implementation.

b) ensure that process for any redesign follows the same principles as the initial design. Updates shall take full account of the original Design Intent and Design Record.

c) control design and development changes in accordance with the configuration management process requirements.

8.4 Control of externally provided processes, products and services

8.4.1 General

In addition to ISO 9001 8.4.1

The organisation shall:

a) retain documented information of verification and / or validation of purchased products. The documented information shall be made available to the customer on request.

b) establish and maintain knowledge of the supply chain and external provider's quality assurance activities where the organisation has decided to externally source a critical item, significant work content, design, immature technical solutions or a configuration item.

c) flow down the applicable contractual requirements to external providers by referencing the stated contractual requirements**, including relevant AQAP(s)** and purchase order requirements. **The organisation shall insert the following in all purchasing documents: "All requirements of this contract may be subject to GQA. You will be notified of any GQA activity to be performed."**

d) conduct a formal review of purchasing documents to verify that the correct contractual requirements have been flowed down. The organisation shall retain documented information of this review.

e) document their arrangements for these requirements at the planning stage (see 8.1) and identify their proposed quality assurance activities for specific external provider orders that meet the above criteria.

f) not extend any organisation approval awarded by a customer to the organisation's external providers unless the customer notifies the organisation in writing.

g) provide a copy of external provider purchase orders and contractual documents / modifications for products or services related to the contract when requested by the customer.

NOTE Where the customer undertakes the design of the product, process or service the organisation may select, approve and maintain an external provider network only when authorised / **accepted** by the customer. Where the organisation has undertaken the design of the product, process or service then the organisation may select, approve and maintain an external provider network without authorisation / **acceptance** by the customer.

8.4.2 Type and extent of control

In addition to ISO 9001 8.4.2

The organisation shall:

a) ensure that external providers have a documented quality management system which includes the applicable requirements of ISO 9001 (Quality management systems – Requirements) and this document (see 4.4).

b) ensure that the procedures and processes required to fulfil contract requirements are fully implemented at the external provider's facilities.

c) ensure that only the organisation placing the purchasing documents with an external provider will issue contractual instructions to that provider.

d) where required by the contract or purchase order submit to the customer a supply chain sub-tier map detailing approval / accreditation / certification held and the scope of operations within the timescales

agreed. This map shall list external provider supply chains of key components / services. Changes to sub-tier maps shall be communicated to the customer prior to implementation.

e) establish and implement a process for the avoidance, detection, mitigation and disposition of counterfeit materiel (see 8.1.6 and 8.7).

f) have a goods inward process to check that purchased raw material, product and supporting documents meet the organisation's requirements. Documented information from the checks shall be retained.

NOTE Customer activities at the external provider's facilities do not relieve the organisation from any contractual quality responsibilities.

8.4.3 Information for external providers

In addition to ISO 9001 8.4.3

The organisation shall flow down the applicable customer's requirements to external providers.

8.5 Production and service provision

8.5.1 Control of production and service provision

In addition to ISO 9001 8.5.1

8.5.1.1 General

The organisation shall:

a) develop, maintain and retain documented information for the conduct of activities related to the control of production of material, part, component, sub-system and system level for the product supplied to ensure that the specified requirements are met.

b) establish and maintain criteria for workmanship in the clearest practical manner (e.g., written standards, representative samples or illustrations).

c) ensure that all inputs are available and conform with requirements prior to commencing manufacturing.

d) ensure that items are manufactured in accordance with **accepted** designs and processes.

NOTE 1 Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts lists, materials and process specifications.

NOTE 2 Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (e.g., manufacturing plans, travellers, routers, work orders, process cards) and verification documents.

8.5.1.2 Inspection and Test Plan (ITP)

Where required by the contract or purchase order the organisation shall create and submit an ITP to the customer prior to commencing any manufacturing. Unless otherwise agreed with the customer, ITPs shall be **accepted** prior to commencing manufacturing.

Where an ITP is required:

a) a separate item is required for each part number; groups of products which all follow the same manufacturing process can use the same ITP but must clearly detail all part numbers on the front page of ITP.

b) for highly complex equipment, where multiple external providers exist resulting in multiple ITPs, the organisation shall generate an overarching document indexing how the multiple ITPs link together.

c) it shall describe each process used for manufacturing or service provision in sequence together with the relevant inspection and test points from receipt of material or supplies to the despatch of the finished deliverable. This includes identification of the organisation's external providers and their respective supply chains, and processes or manufacturing operations performed by the organisation / external providers and their respective supply chains in support of the contract or purchase order.

d) each ITP shall include:

- the level of test / inspection to be applied including any sample or reduced inspection;
- the details of any special processes, including any activities that will be undertaken by external providers;
- specific procedures to be used;
- the documentation to be raised to record the results;
- provision for the inclusion of the customers hold / witness points.

It is the organisation's and the external provider's responsibility to:

- seek clarification of customer specific ITP requirements at contract placement;
- manage and assure compliance with the ITP;
- not proceed past a hold and / or witness point without first gaining written permission from the customer;
- ensure that any resulting non-conformance is managed effectively to assure robust resolution;
- inform the customer of failed tests;
- cancel a scheduled Inspection visit a minimum of 24 hours prior to the required visit date.

As part of the ITP review by the customer the organisation will be advised of the inspections and tests selected to be witnessed by the customer.

The customer reserves the right to:

- review and reject / accept the ITP as appropriate;
- require additional witness / hold points as appropriate;
- conduct in process inspections of its suppliers, and any associated external providers, without exception;
- use third parties / representatives to conduct inspections when required;
- raise non-conformances and other findings if issues are identified;
- have full access to all necessary information including, but not limited to; documentation, hardware, personnel, facilities, etc., giving the agreed prior notice, which may be short depending on the severity of the issue.

8.5.1.3 Infrastructure for tooling

The organisation shall establish a system for the management of production tooling that includes but is not limited to the following:

a) unique tool identification.

b) validation of tooling prior to release for production.

c) tooling set-up.

d) tooling life control / tool-change programmes.

e) tooling modification and revision.

8.5.1.4 Special processes

AWE specific requirement in bold:

The organisation shall:

a) Maintain control of special process activities for all production and service provisions. Processes shall be considered special where validation and/or revalidation of results cannot be achieved by subsequent monitoring or measurement.

b) forward Special Process Procedures used by the organisation, external providers and their supply chains, to the customer for approval as requested.

c) document Special Process Procedures.

d) Special Processes shall be controlled in accordance with the contract.

e) maintain a traceable reference to the person authorised to approve documented processes, procedures and manufacturing documents.

f) be able to produce approved procedures to the customer's representative upon request.

g) submit any changes to approved procedures to the customer for re-approval before change implementation unless agreed otherwise in writing.

The customer reserves the right to review and comment on the special process procedures proposed and reject work carried out to an un-agreed special process, or work carried out prior to a formal agreement.

NOTE 1 Customer approval of documents shall not be used by the organisation as evidence of effective control of quality and does not relieve the organisation or its external providers of the responsibility to provide acceptable products and services that comply with all requirements.

NOTE 2 Examples of Special Processes are: Metal joining technique (such as welding and weld repairs, brazing, cladding, crimping), heat treatment (annealing, tempering, stress relieving, hot/cold working, pipe bending), NDE (UT, MPI, DPI, RT, VI), Protective coating (Galvanising, Plating, painting), Pressure testing (Leak test, Strength test), Factory Acceptance Tests, Cleaning (Pickling, plasma), Preservation / packing (identification, handling, contamination control, packing, storage, transmission or transportation, protection).

NOTE 3 Heat treatment certifications are required when heat treatment is a specific activity within the manufacturing process, which alters the base material properties (Mechanical and/or Chemical). Heat treatment certificates must include, as a minimum, the post heat treatment material properties, the location of thermocouples, load map, heat treatment chart, and heat treatment furnace calibration details.

8.5.1.5 First Article Inspection (FAI)

Where required by the contract and or purchase order the organisation and external providers shall:

a) perform a FAI on the first production product to be delivered in accordance with the customer's specification and forms.

b) submit the FAI report to the customer's representative for approval.

c) only release product against the FAI report when authorised by the customer.

d) retain documented information from the FAI activity.

8.5.2 Identification and traceability

In addition to ISO 9001 8.5.2

Where the failure of an item or component could lead to the loss of equipment, performance or life then it is mandatory to maintain traceability.

The organisation shall provide traceability to the raw material manufacturer unless otherwise stated in the contract or purchase order.

NOTE Traceability requirements can include:

- the identification to be maintained throughout the product life;

- the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);

- for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;

- for a product, a sequential record of its production (manufacture, assembly, inspection / verification) to be retrievable.

AWE specific requirement: The identification and traceability requirements apply to all QC1 and QC2 product/materiel and may apply to QC3 or QC4 if required by the contract.

8.5.3 Property belonging to customers or external providers

In addition to ISO 9001 8.5.3

The organisation shall:

a) exercise care with property belonging to customers while it is under the organisation's control. [Note 1]
If products provided by the customer are lost, damaged or otherwise found to be unsuitable for their intended use in accordance with the contract, the organisation shall immediately inform the customer and retain documented information.

b) **Immediately** report to and coordinate with the customer remedial actions to be taken where it is established that a customer supplied item [Note 2] is unsuitable for its intended use.

NOTE 1 Appropriate control may include:

- identification as customer owned;

- the establishment of a register;

- use only for applicable contracts or purchase orders;

- periodic stock take;

- periodic preservation / condition checks for items held in storage;

- modification only after customer authorisation;

- disposal only after written customer authorisation.

NOTE 2 Items supplied by the customer may include but are not limited to raw material, components, documentation, tooling, measuring equipment and storage / transportation containers.

8.5.4 Preservation

In addition to ISO 9001 8.5.4

The organisation shall preserve the outputs during production and service provision to ensure that:

a) products with limited shelf life are subject to control of their expiry dates and that where applicable this shall be applied during maintenance, servicing, storage or when fitted.

b) the remaining shelf-life shall be identified and communicated to the customer prior to delivery.

c) products are stored in an environment that provides protection from contamination, degradation or damage and is in accordance with security classification requirements.

d) products are not contaminated, degraded or damaged during delivery through the use of appropriate protection and packaging.

e) documented information is retained of key safety parameters and maintenance whilst materiel is in storage or transport (see 8.3.5).

8.5.5 Post-delivery activities

In accordance with ISO 9001

8.5.6 Control of changes

In accordance with ISO 9001

NOTE Source and method change control requirements are defined in 8.1.4.

8.6 Release of products and services

In addition to ISO 9001 8.6

The organisation shall:

a) ensure that only acceptable products, intended for delivery, are released. The customer reserves the right to reject nonconforming products.

b) ensure that all documented information required to accompany the products and services are present at delivery.

c) provide a Certificate of Conformity at release of product to the customer unless otherwise instructed by the contract or purchase order.

NOTE Further information is contained in DEFCON 627 (Requirement for a Certificate of Conformity).

The customer reserves the right to conduct in process inspection and / or final inspection activities at the organisation or external providers.

Where the customer is required to perform any final inspection or other formal acceptance activities, the organisation shall provide the customer with a minimum of 10 working days notification of the event unless otherwise stated in the contract or purchase order. If the organisation needs to cancel a scheduled event, then at least 24 hours' notice shall be given to the customer.

The organisation is solely responsible for the conformance to requirements, of products and services provided to the customer.

8.7 Control of nonconforming outputs

In addition to ISO 9001 8.7

The organisation shall:

a) establish a documented procedure which identifies, controls and segregates nonconforming products. **Documented procedures for the identification, control, and segregation of nonconforming product are subject to disapproval by the customer when it can be shown that they do not provide the necessary controls.**
Product with unidentified or unknown status shall be classified as nonconforming product.

b) determine, provide and maintain an area to segregate nonconforming product.

c) control counterfeit, or suspect counterfeit, parts to prevent re-entry into the supply chain (see 8.1.6).

d) notify the customer of non-conformities and corrective actions required, unless otherwise agreed with the customer. The customer reserves the right to reject rework, repair and use as is dispositions.

e) notify the customer of a nonconforming product or service received from an external provider that has been subject to Government Quality Assurance.

f) create concession procedures in accordance with the contract or purchase order requirements.

g) obtain appropriate authorisation from the customer when the organisation proposes to raise a concession for the use, release or acceptance of a nonconforming product**, unless otherwise agreed**.

h) review any request from external providers before submission to the customer. The customer requirements for concessions apply equally to outsourced processes or purchased products.

i) retain documented information of quantity authorised and / or expiration date for concessions or deviation permits. The organisation shall ensure compliance with the contract requirements when the authorisation expires.

j) notify the customer of nonconforming product received from an External Provider that has been subject to Government Quality Assurance.

NOTE The term 'nonconforming outputs' includes nonconforming product or service generated by the organisation, received from an external provider, or identified by a customer.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

In accordance with ISO 9001

9.1.2 Customer satisfaction

In addition to ISO 9001 9.1.2

The organisation shall:

a) record any complaints or deficiencies relevant to the contract or purchase order reported by the customer as customer complaints;

b) provide a response to the customer on the complaint or deficiency that shall include information on root cause analysis and corrective action (see 10.2).

NOTE 1 Customer complaints could be in the form of quality non-conformance, deficiency or occurrence reports or another format **but regardless will be identified by the customer as 'customer complaints'.**

NOTE 2 Information to be monitored and used for the evaluation of customer satisfaction may include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. The organisation may develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations and assess the effectiveness of the results.

9.1.3 Analysis and evaluation

In accordance with ISO 9001

9.2 Internal audit

In addition to ISO 9001 9.2

The organisation shall:

a) conduct internal audits at planned intervals to provide information on whether the quality management system conforms to the applicable requirements of ISO 9001 (Quality management systems – Requirements) and this document.

b) ensure that during the planning of internal audits that on an annual basis their audit programme covers all contract related critical processes and activities and includes contractual requirements and **NATO supplements**.

c) consider the output from the actions to address risk and opportunities assessment (see 6.1).

d) ensure that auditors shall not audit the work that they have undertaken or had direct responsibility for.

e) consider extending the scale of the audit to establish whether the issue is isolated or widespread should concerns arise during an audit.

f) inform the customer of deficiencies or findings identified during internal audit unless otherwise agreed by the customer.

g) retain documented information that demonstrates auditor training and experience;

h) allow the customer to conduct audits at the organisation and its external providers when requested. Such audits may be conducted by the customer or a nominated third party identified by the customer. The customer reserves the right to share the output of the audit activities with other Submarines Enterprise companies.

9.3 Management review

9.3.1 General

In accordance with ISO 9001

9.3.2 Management review inputs

In addition to ISO 9001 9.3.2

When requested by the customer the organisation shall make available documented information of the review input that is relevant to the contract and or purchase order.

9.3.3 Management review outputs

In addition to ISO 9001 9.3.3

The organisation shall:

a) make available documented information of the review output that is relevant to the contract and or purchase order when requested by the customer.

b) notify the customer of proposed action resulting from the Review Output that will affect compliance with the contract and or purchase order requirements. Review Output shall, where actions items are identified, specify the responsible person**/function** and due date of the action item.

10 Improvement

10.1 General

In accordance with ISO 9001

10.2 Nonconformity and corrective action

In addition to ISO 9001 10.2

The organisation shall:

a) define and operate a process [Note 1], including tools and techniques, used to support root cause analysis for nonconformities in a timely manner [Note 2].

b) where applicable flow down corrective action requirements to external providers.

NOTE 1 Submarine Enterprise Quality Group (SEQG) recognises the 8D (Eight Disciplines) problem solving process for investigating medium / complex issues. Details can be found in AS13000 (Problem Solving Requirements for Suppliers).

NOTE 2 Indicative timescales for problem resolution are 48 hours for completing containment action on work in progress / stock of similar products and 8 weeks for establishing root causes, defining the actions and completing the process.

AWE specific requirement: 12 weeks for establishing root causes, defining the actions and completing the process.

10.3 Continual improvement

In accordance with ISO 9001

11 Change History

Issue No and Date	Revisions Made
3, December 2021	Classification added to all pages, reference withdrawal of Def Stan 02-884, amended typographical errors, add reference to NATO website, removal of source information table and rewording of section 8.5.1.4 to standardise special processes' requirements across the SE.
4, January 2023	Changes to wording of sections 8.1.2, 8.4.1, 8.5.1.1d and 8.5.1.2; specifically to change approve/approved to accept/accepted following a request from IPD to bring terminology in line with NEC3/4 contracts. Changes made to Appendix 4, highlighting the need for a quality plan, ITP and supply chain sub-tier map for QC1 and QC2.
5, August 2023	Additions to sections 2.2, 3, 4.3, 4.4, 6.1, 7.1.3, 7.1.5.2, 7.4, 7.5.3, 8.1.2, 8.2.1, 8.4.1, 8.5.2, 8.5.3, 8.7, 9.1.2, 9.2, 9.3.3 to ensure compliance with AQAP 2110, Edition D, Version 1; and Appendix 4 in line with MS400 – Quality Grading.

Appendix 1 - Definitions

Contract – The agreement made between the customer and the organisation

Customer – Member of Submarine Enterprise

External Provider – Provider of products or services to the organisation.

Organisation – Person, firm or company who accepts to supply the customer (SE member) with the contracted deliverables.

Submarine Enterprise – Collaboration of AWE, Babcock Marine & Technology (BM&T), BAE Systems Maritime Submarines, and Rolls-Royce Submarines.

Appendix 2 - Abbreviations

ACMP Allied	Configuration Management Publication
ADMP Allied	Dependability Management Publications
ALARP	As Low As Reasonably Practicable
AQAP	Allied Quality Assurance Publication
ASNT	American Society for Non-destructive Testing
AWE	Atomic Weapons Establishment
CFSI	Counterfeit, Fraudulent & Suspect Items
FAI	First Article Inspection
GQA	Government Quality Assurance
IACS	International Association of Classification Societies
IAF	International Accreditation Forum
ITP	Inspection and Test Plan
NATO	North Atlantic Treaty Organisation
PCN	Personnel Certification in Non-destructive testing
QC	Quality Control
QMS	Quality Management System
SSC	Structures, Systems or Components
SE	Submarine Enterprise
SEQG	Submarine Enterprise Quality Group
SQEP	Suitably Qualified and Experienced Person
UKAS	United Kingdom Accreditation Service
8D	Eight Disciplines of problem solving

Appendix 3 - **Retained Documented Information and Retention Periods**

AWE specific requirement:

The organisation and its external providers shall retain documentation information for 12 years, unless specified otherwise in the contract.

Appendix 4 - Part Classification and Quality Requirements Matrix

AWE specific requirement:

Quality Grading is described in AWE/MAN.Q/01/4917, Management Standard MS400 – 'Quality Grading.'

A grade indicates the extent to which quality assurance and control shall be applied to a product or service, based upon the consequence of failure/level of risk associated with failure. In addition, it involves a process by which the scope, depth and rigour of the management controls (oversight, testing and surveillance etc.) are to be applied to a structure, system or component (SSC), product or activity commensurate with the determined consequence and risk.

QC1

The highest grade, having a major impact on quality, environment, health and safety, where an ill conceived or inadequately executed activity or the failure of the item could lead directly to:

- **The initiation of a beyond design basis accident**
- **An uncontrolled radioactive release to the environment or other catastrophic event with widespread effects, affecting both on and off site, requiring the public to take action**
- **Risk of death or serious injury**
- **Loss of more than one lines of defence**
- **Catastrophic impact on the safety and effective performance of the nuclear deterrent**

A Quality Plan, Inspection and Test Plan (ITP), Supply Chain Sub-Tier Map, Certificate of Conformity and Lifetime Quality Records required.

QC2

Having a significant impact on quality, environment, health and safety, where an ill conceived or inadequately executed activity or the failure of the item could lead directly to:

- **A risk of radiological or other consequential hazard with widespread effects onsite and potentially offsite**
- **A risk of serious injury for personnel**
- **A loss of functionality of the physical protection system and/or components affected**
- **Loss of a line of defence**
- **Critical impact on the safety and effective performance of the nuclear deterrent**

A Quality Plan, Inspection and Test Plan (ITP), Supply Chain Sub-Tier Map, Certificate of Conformity and Lifetime Quality Records required.

QC3

Having a minor impact on quality, environment, health and safety, where an ill conceived or inadequately executed activity or the failure of the item could lead directly to:

- **A risk of radiological hazards limited to facility/building, may affect other facilities or buildings**
- **A low risk of serious injury for personnel**
- **The possible failure of a system performing control functions, physical protection systems or breach of security**
- **Possibly affect a line of defence**
- **A risk of reportable events in relation to statutory requirements**

Certificate of Conformity and Lifetime Quality Records required.

QC4

Having a slight risk of impact on quality, environment, health and safety but not lead to the loss of a line of defence.

If necessary provide Delivery Note, COSHH Documentation.

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