

NAVSEA
STANDARD ITEM

FY-20

ITEM NO: 009-04
DATE: 01 OCT 2018
CATEGORY: I

1. SCOPE:

1.1 Title: Quality Management System; provide

2. REFERENCES:

2.1 Standard Items

2.2 ANSI/ISO/ASQ Q9001-2015, Quality Management Systems - Requirements

2.3 ANSI/NCSL Z540-3, Requirements for the Calibration of Measuring and Test Equipment

2.4 ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories

2.5 NAVSEA 04-4734, Navy and Marine Corps Calibration Laboratory Audit/Certification Manual

2.6 SSPC QP1 Application, Instructions, and Program Rules

2.7 NAVSEA OD 45845, Metrology Requirements List (METRL)

3. REQUIREMENTS:

3.1 Establish, document, implement, and maintain a Quality Management System (QMS) as a means of ensuring that product conforms to specified requirements.

3.2 A written QMS Manual addressing all elements of 2.2 and supporting documented procedures **must** be submitted to the SUPERVISOR for review and acceptance. **Required documented procedures may be contained in either the Manual or Level II QMS procedures.** The contractor **must** have an | accepted QMS, in accordance with this Standard Item, in place to receive an award of a Job Order. Include the following documented procedures **if not addressed in the contractor's Quality Manual:**

3.2.1 Support: Address all areas of Paragraphs 7.1.5, 7.2 and 7.5 of 2.2.

3.2.1.1 Calibration laboratories **must** be accredited to either 2.3 or 2.4 by a Commercial Accreditation Activity, or certified by a Navy Certification Activity to 2.5, and the scope of accreditation must cover the appropriate measurement parameters and ranges of the calibrations performed.

3.2.1.2 Calibration intervals assigned to Measuring and Test Equipment used by the contractor for acceptance testing **must** meet those recommended in 2.7 unless alternate calibration intervals are established in accordance with 2.3.

3.2.2 Operation: Address all areas of Paragraphs 8.2, 8.4, 8.5, 8.6, 8.7 of 2.2

3.2.2.1 Verification of Purchased Product: Identify, in the purchasing documents, verification arrangements at the subcontractor or vendor location/premises. Purchasing documents **must** contain the following statement when the SUPERVISOR requests government inspection: "Government Inspection is required prior to shipment from your plant. Upon receipt of this order, promptly notify and furnish a copy to the Government representative who normally services your plant so that appropriate planning for government inspection can be accomplished. In the event the government representative or office cannot be located, our purchasing agent **must** be notified immediately.

3.2.2.2 Unless otherwise specified in a higher tier document, Receipt Inspection of contractor furnished materials **must** be based on supplier performance history and one or more of the following: certificate of compliance, vendor material test certification data, manufacturer's mill certificate, or testing using sampling techniques.

3.2.3 Performance evaluation: Address all areas of Paragraphs 9.2 and 9.3 of 2.2

3.2.4 Improvement: Address all areas of Paragraph 10.2 of 2.2.

3.2.5 The documented QMS **must** include a matrix listing the correlation between 2.2, 3.2 and the **corresponding paragraph/sub-paragraph(s) of the submitted documented procedures.**

3.3 Subsequent to SUPERVISOR acceptance, a contractors QMS certification is acceptable in all other geographic location in which the contractor maintains the same QMS, providing:

3.3.1 The contractor uses the same QMS Manual.

3.3.2 The contractor uses the same QMS Manager as the final decision authority for QMS policy.

3.3.3 Successful completion of Contractor's QMS Review Checklists (Attachment B, C, and D) in their entirety by the SUPERVISOR.

3.4 The QMS **must** be subject to audits by the SUPERVISOR throughout the contract. Retain documented information to demonstrate the processes are carried out as planned. **Audits must be conducted on active contracts, but may be conducted on completed contracts when there are limited or no active contracts available.**

3.5 Submit one legible copy, in hard copy or approved transferrable media, of any revisions to the accepted QMS identified in 3.2 to the SUPERVISOR within 7 days of contractor approval **and include the planned implementation date.**

3.6 Submittal of procedures invoked by NAVSEA Standard Items, MIL-STDs, drawings, technical publications, and specifications, although an integral part of the QMS, **must** be submitted to and approved by the SUPERVISOR independent of the QMS a minimum of 14 days prior to start of required process for planned availabilities, or as otherwise approved by SUPERVISOR.

3.7 The corrective action program **must** require that a copy of the written responses to contractor generated corrective actions will be provided to the SUPERVISOR when requested.

3.8 Respond in writing to each SUPERVISOR issued Method B/C/D Corrective Action (CA) within 3 business days unless otherwise specified by the SUPERVISOR. Initial response **must** include immediate corrective action taken and a plan of action for CA completion, **including estimated completion dates.** Final response **must** include preventive action for recurrence of identified nonconformance, root cause analysis and Objective Quality Evidence (OQE) for corrective action completed. All follow up responses **must** be as specified by the SUPERVISOR.

3.8.1 Inform the SUPERVISOR when corrective actions are complete for each SUPERVISOR issued Method A (CA). Response required within **3 business days** unless otherwise specified by the SUPERVISOR. Response **must** state that the non-conformance has been corrected.

3.8.2 Use NMD, or approved Web interface, to perform all CAR functions for contracts managed in NMD.

3.9 Attend **SUPERVISOR conducted** fact-finding/investigative meetings when requested by the SUPERVISOR **not to exceed 4 hours.** (See 4.4)

3.10 Develop a Test and Inspection Plan (TIP) incorporating each Work Item in the job order, LOA Chits or Statements of Work (SOW). The initial TIP **must** include all inspections and tests required by zero-tier references and first tier references, as well as symbols (I) (V) (Q) test/inspections and (G) government notification identified in the Work Item, and any additional tests and inspections the contractor deems necessary to substantiate product conformance.

3.10.1 Submit one legible copy, in hard copy or approved

transferrable media, of initial copy of the TIP to the SUPERVISOR prior to start of productive work for non-CNO availabilities and no later than **3** days prior to the availability start date for CNO availabilities.

3.10.1.1 Submit one legible copy, in hard copy or approved transferrable media that can be sorted (e.g., Excel spreadsheet) of an updated TIP when requested by the SUPERVISOR **not to exceed one per week**.

3.10.2 A TIP **must**:

3.10.2.1 Be revised prior to the start of productive work and updated as work proceeds on each Work Item. Supporting data for tests and inspections requiring government notification (G), including accept/reject criteria, **must** be available at the location of each test and inspection. Include provisions for documenting the date, time, and identification of the SUPERVISOR's representative notified and government representative attending each (G)-Point on the TIP. The TIP **must** annotate the relationship to a specific key event **unless otherwise agreed upon by the SUPERVISOR**. The following key events **must** be considered at a minimum (as applicable): Undocking, Production Completion Date (PCD), Command, Control, Communications, Computer, Combat Systems, and Intelligence (C5I) Light-Off (C5ILO), Dock Trials (DT), Fast Cruise (FC), Sea Trials (ST), and Availability Completion (AC).

3.10.2.2 Each test and inspection **must** be identified by its respective Work Item number and Work Item paragraph number, including Standard Item paragraph number, and **must** include inspection symbols (I) (Q) and (V), and the government notification (G) Point symbol where applicable.

3.10.2.3 Provide identification of the item to be inspected by name, number, and location (e.g., number 3 main feed pump, 5-180-0-E).

3.10.2.4 Provide identification of each characteristic of the items to be inspected and provide the criterion for acceptance for each characteristic (e.g., air test; 2 PSIG for 10 minutes; no drop).

3.11 Test and Inspection records **must**:

3.11.1 Include the ship's name and hull number, Job Order and Work Item number, applicable PCP number, paragraph number, component identification, accept/reject criteria, date, time, and signature of the contractor's authorized representative who witnessed or performed the test or inspection. The signature occurs after the checkpoint is determined to be satisfactory or unsatisfactory and any exceptions are documented.

3.11.2 Be maintained at a contractor location accessible to the site of the work required by the Job Order.

3.11.3 Be documented within one day of accomplishment or prior to the subsequent tests or inspections, whichever is less. The records **must**

indicate the results of the test and or inspection accomplished. Records **must** be incorporated into the TIP within 4 days after completion of each test or inspection.

3.11.3.1 For tests and inspections involving (G)-points, records **must** be documented upon acceptance or rejection and a hard copy (or electronic copy as authorized by the SUPERVISOR) provided to the SUPERVISOR at the conclusion of each (G)-Point. (See 4.5) |

3.11.4 Required reports resulting from tests or inspections **must** include the appropriate design criterion for each attribute or measurement required by the Work Item.

3.12 The SUPERVISOR will consider the Work Item incomplete if the contractor's documentation and records are not complete.

3.13 Accomplish (I), (V) and (Q) tests/inspections that do not have associated (G)-points, with qualified and/or currently certified personnel where required by the technical documents (e.g., NBPI, NACE, nondestructive testing, electrical cableway inspection, **Oxygen Cleanliness Inspector**, etc.) as follows:

3.13.1 (I) inspections require verification and documentation by a separate individual, other than the person who has accomplished the work, who is qualified as an inspector.

3.13.2 (V) inspections require verification and documentation by the qualified tradesperson, trade supervisor, or inspector.

3.13.3 (Q) inspections require verification and documentation by a qualified Technical Representative in accordance with 009-90 of 2.1 and associated PCP requirements.

3.13.4 The authority to accomplish, document, accept and reject (I) and (V) inspections may be delegated to qualified subcontractor personnel, without regards to geographical location, subject to SUPERVISOR approval.

3.14 Accomplish (G)-Point (government notification) as follows:

3.14.1 (G) is a symbol inserted in a Work Item to establish a point in the sequence of accomplishment of work at which time the SUPERVISOR **must** be notified by the prime contractor in all cases to permit observation of a specific test or inspection (I)(V) by the government. When the symbol (G) precedes tests or inspections in a Work Item which are applicable to more than one action, the symbol (G) **must** identify the action required, e.g., (G) "HYDROSTATIC TEST". When more than one unit is involved, the (G) notification requirement applies to each unit. |

3.14.2 Notify the SUPERVISOR's designated representative as **directed by the SUPERVISOR** via FAX, hard copy, or by electronic method. |

3.14.2.1 Notify the SUPERVISOR during normal day shift working hours, at least 4 hours, but not more than one day, prior to commencing the specific requirements in the paragraph annotated with the symbol (G). Notify the SUPERVISOR to cancel a scheduled test or inspection no later than 30 minutes prior to the scheduled event **or as negotiated with the SUPERVISOR.**

3.14.2.2 Notify the SUPERVISOR not later than 4 hours before the end of the last preceding day shift when tests or inspections following a (G) Point are scheduled after normal day shift working hours, on a weekend, or on a federal holiday.

3.14.2.3 Notify the SUPERVISOR at least 48 hours, but not more than 72 hours, prior to commencing (G)-Points at contractor's/subcontractor's plants located in excess of 50 miles by the most direct roadway nearest to the place of performance of the contract. Document the date, time, and identification of the SUPERVISOR's representative notified.

3.14.2.4 For (G)-Points scheduled after normal day shift working hours, on a weekend, or a Federal holiday, notify the SUPERVISOR to cancel a scheduled test or inspection as soon as known, but no later than 2 hours prior to the scheduled event.

3.14.3 Proceed with the test or inspection if the SUPERVISOR is not present, provided the required advance notice has been furnished to the SUPERVISOR and the contractor has completed and documented the preceding tests and inspections.

3.14.4 A partial test or inspection requiring (G) notification may be accomplished in the event that all work cannot be completed and work progress would be delayed in waiting for total completion of work. Comply with the requirements of 3.14.2 when the incomplete work is completed and ready for the remainder of the test or inspection. Note partial inspections on the test or inspection form.

3.14.5 A qualified contractor representative **must** be present to accomplish, accept or reject and document tests or inspections associated with the symbol (G).

3.14.5.1 The authority to witness or perform, document and accept/reject (I) (G), (Q) (G), and (V) (G) tests and inspections is a prime contractor's responsibility but, subject to SUPERVISOR approval within a 50-mile radius of the contractor's plant nearest to the place of performance of the contract, may be delegated to subcontractors who are MSRA or ABR agreement holders, SSPC QP1 certified, NDT certified, or have a current QMS accepted by the SUPERVISOR.

3.14.5.2 The contractor may delegate responsibility to subcontractors to perform, document and accept/reject (I) (G) and (V) (G) tests and inspections performed at plants located outside a 50-mile radius of the

contractor's plant nearest to the place of performance of the contract subject to SUPERVISOR prior approval.

3.14.5.3 Associated (G)-Point notification requirements **must** not be delegated.

3.15 For work being performed outside a 50-mile radius of the place of contract performance, the prime contractor **must** submit one legible copy, in hard copy or approved transferrable media, of purchase orders to the SUPERVISOR within 2 days or otherwise as directed by the SUPERVISOR, prior to issue of purchase order and shipment of equipment. For contractors who do not utilize purchase orders as a vehicle for accomplishing work within their company, a report identifying the delineation of the specific Work Item requirements, in lieu of the purchase order **must** be submitted to the SUPERVISOR.

3.16 Maintain a current list for reference by the SUPERVISOR, designating the contractor's qualified and currently certified inspectors who witness or perform and sign for symbol (I) inspections, indicating the type of tests and inspections for which each inspector is qualified and currently certified. When subcontractors are delegated responsibility, the subcontractor's qualified and currently certified inspectors **must** be included on this list.

3.17 Certify to the SUPERVISOR that work is completed technically correct with all required OQE. All supporting documentation **must** be submitted in support of the following Key Events: Undocking (if applicable), PCD, C5ILO, DT, FC, ST, and CA. **Key Event ties must also be annotated for each item in the TIP as required by 3.10.2.1.**

3.17.1 Notify the SUPERVISOR of the condition and status of each individual Work Item in the availability within 3 days of Work Item completion or a minimum of 5 days prior to the scheduled Key Event to which that item is tied, whichever occurs first, by either of the following methods:

3.17.1.1 Completion and submission of one legible copy of Attachment A, in hard copy or approved transferrable media.

3.17.1.2 **Completion and submission of one legible copy of Event Readiness List (ERL), in hard copy or approved transferrable media.**

3.17.1.3 Completion and submission of centralized signature sheet in record book maintained by the SUPERVISOR.

3.17.2 If work is incomplete or complete with discrepancies, supporting rationale and impact statement with recovery plan must be provided to the SUPERVISOR via submission of one legible copy of Attachment A, in hard copy or approved transferrable media. Upon completion of work or correction of discrepancies, a revised Attachment A with the updated status must be submitted to the SUPERVISOR in hard copy or approved transferrable media.

4. NOTES:

4.1 ANSI/ISO/ASQ Q9001:2015 commercial third party registrar certification is not required.

4.2 The QMS submitted in 3.2 requires a one-time submittal/acceptance unless this NAVSEA Standard Item and/or references change or contractor's status changes.

4.3 A "zero-tier reference" is a specification, standard, drawing, test memo, planning/design memo that is cited in the contract (including its attachments). A "first-tier reference" is either: (1) a specification, standard, or drawing cited in a zero-tier reference, or (2) a specification cited in a first tier drawing. All zero-tier and first tier references are mandatory for use. All lower tier references **must** be used for guidance only.

4.4 Contractor-run critiques or fact findings are accomplished in accordance with 009-120 of 2.1.

4.5 A partial (G)-point may be accomplished for a fraction of the work specification components. When elected, the contractor is responsible to account for the inspection status of each component. A final (G)-point is required for the last remaining component(s).

4.6 ISO compliant Quality Management Systems typically follow a 4-tiered hierarchy comprised of:

- a.** The "first-tier" document related to the QMS is the Quality Manual, which is the high-level document that is authored and approved by upper management of the organization and is the guiding organizational document for which all subsequent tiers within the system should be aligned with.
- b.** The "second-tier" documents are the Quality Procedures making up the center of the documentation system. These procedures span all the required processes and practices within the organization and should include references both upward to the Quality Manual and downward to the Work Instructions associated with each process.

- c.** The "third-tier" documents are Work Instructions comprised of instructions that describe the specific actions required to achieve a quality product.
- d.** The "fourth-tier" documents are the Quality Records which capture all the data, information, records, forms and become the objective evidence which will prove the QMS is being executed per procedure.

4.7 NAVSEA 04RM3 Approved list of Accrediting Bodies (AB).

- . ANSI-ASQ National Accreditation Board (ANAB), <http://anab.org/>
- . Laboratory Accreditation Bureau (L-A-B), <http://l-a-b.com/>
- . Perry Johnson Registrars (PJLA), <http://www.pjr.com/>
- . The American Association for Laboratory Accreditation (A2LA),
<https://www.a2la.org/>
- . National Voluntary Laboratory Accreditation Program (NVLAP),
<https://www.nist.gov/nvlap>
- . International Accreditation Service (IAS), <http://www.iasonline.org>

Contact NAVSEA 04RM3 for information on commercial accreditation in accordance with 2.3 and 2.4 by NAVSEA approved commercial Accrediting Bodies (AB).

Attachment A
Work Completion Certification

SHIP'S NAME :	HULL NO.:																
WORK ITEM NO:	SSP NO.:																
KEY EVENT: <table style="margin-left: 20px; border: none;"> <tr><td><input type="checkbox"/></td><td>Undocking (UD)</td></tr> <tr><td><input type="checkbox"/></td><td>Production Completion Date (PCD)</td></tr> <tr><td><input type="checkbox"/></td><td>Dock Trials (DT)</td></tr> <tr><td><input type="checkbox"/></td><td>Fast Cruise (FC)</td></tr> <tr><td><input type="checkbox"/></td><td>Sea Trials (ST)</td></tr> <tr><td><input type="checkbox"/></td><td>Availability Completion (AC)</td></tr> <tr><td><input type="checkbox"/></td><td>Command, Control, Communications, Computer, Combat Systems, and Intelligence Light-Off (C5ILO)</td></tr> <tr><td><input type="checkbox"/></td><td>Other _____</td></tr> </table>		<input type="checkbox"/>	Undocking (UD)	<input type="checkbox"/>	Production Completion Date (PCD)	<input type="checkbox"/>	Dock Trials (DT)	<input type="checkbox"/>	Fast Cruise (FC)	<input type="checkbox"/>	Sea Trials (ST)	<input type="checkbox"/>	Availability Completion (AC)	<input type="checkbox"/>	Command, Control, Communications, Computer, Combat Systems, and Intelligence Light-Off (C5ILO)	<input type="checkbox"/>	Other _____
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<input type="checkbox"/>	Availability Completion (AC)																
<input type="checkbox"/>	Command, Control, Communications, Computer, Combat Systems, and Intelligence Light-Off (C5ILO)																
<input type="checkbox"/>	Other _____																

1) All contracted production work (original, new and growth) has been satisfactorily reviewed, accurate and complete. All non-conformances have been corrected and corrective action request (CAR) are at an acceptable level of completion.

RESULTS/STATUS:

- Complete
- Complete w/ Discrepancies
- Incomplete

Note: If work is incomplete or complete with discrepancies, supporting rational and impact statement with recovery plan in the Comments block below.

Comments: _____

Print and Sign

Name: _____ Date: _____

Position and Responsibility: _____

2) All Tests and Inspections have been completed satisfactorily reviewed, accurate, complete and properly documented in the T&I Plan.

RESULTS/STATUS:

- Complete
- Complete w/ Discrepancies
- Incomplete

Note: If work is incomplete or complete with discrepancies, supporting rational and impact statement with recovery plan in the Comments block below.

Comments: _____

Print and Sign

Name: _____ Date: _____

Position and
Responsibility: _____

3) All required reports and all accompanying required data have been submitted, reviewed, accurate, complete and satisfactory.

RESULTS/STATUS:

- Complete
- Complete w/ Discrepancies
- Incomplete

Note: If work is incomplete or complete with discrepancies, supporting rational and impact statement with recovery plan in the Comments block below.

Comments: _____

Print and Sign

Name: _____ Date: _____

Position and
Responsibility: _____
