

NAVSEA
STANDARD ITEM

FY-20 **CH-1**

ITEM NO:	009-04
DATE:	08 APR 2019
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. ***The calibration laboratory's scope must include the parameters required to execute the calibration at the appropriate ranges and tolerances.***

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 **prior to commencing the specific requirements in a paragraph annotated with the symbol (G), during normal day shift working hours with at least 2 hours, but not more than one-day notice. Following the required notification, the requirements in the paragraph annotated with the symbol (G) may proceed prior to the scheduled time as approved by the SUPERVISOR.** 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 **normal work** day when tests or inspections following a (G) Point are scheduled after normal day shift working hours, on a weekend, or on a federal holiday. **Following the required notification, the requirements in the paragraph annotated with the symbol (G) may proceed prior to the scheduled time as approved by the SUPERVISOR. Notify the SUPERVISOR to cancel a scheduled test or inspection as soon as known, but no later than one hour prior to the scheduled event.**

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. **Following the required notification, the requirements in the paragraph annotated with the symbol (G) may proceed prior to the scheduled time as approved by the SUPERVISOR. Notify the SUPERVISOR to cancel a scheduled test or inspection as soon as known, but no later than one hour 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).

4.8 Scope: The official and detailed statement of the calibration services for which the laboratory is accredited. Alternative terms include scope of accreditation, scope of competency, and scope of calibrations.

Attachment A
Work Completion Certification

SHIP'S NAME :	HULL NO.:
WORK ITEM NO:	SSP NO.:
<div style="display: flex;"><div style="flex: 1;"><p>KEY EVENT:</p><p><input type="checkbox"/> Undocking (UD)</p><p><input type="checkbox"/> Production Completion Date (PCD)</p><p><input type="checkbox"/> Dock Trials (DT)</p><p><input type="checkbox"/> Fast Cruise (FC)</p><p><input type="checkbox"/> Sea Trials (ST)</p><p><input type="checkbox"/> Availability Completion (AC)</p><p><input type="checkbox"/> Command, Control, Communications, Computer, Combat Systems, and Intelligence Light-Off (C5ILO)</p><p><input type="checkbox"/> Other _____</p></div><div style="flex: 1;"></div></div>	

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: _____

CONTRACTOR QMS MANUAL REVIEW CHECKLIST				
Company's Name:		Document's Date of Submission:		
Reviewer's Name:		Checklist Completion Date:		
(1) Support				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
1.1	NSI 009-04 Para 3.2	Requirement: Does the organization's Quality Management System (QMS) Manual address all elements of ISO 9001:2015?		
		Comments:		
	NSI 009-04 Para 3.2.5	Requirement: Does the documented QMS include a matrix listing the correlation between 2.2 (ISO 9001:2015), 3.2 (A written QMS Manual), and other submitted documents?		
		Comments:		
Item	ISO 9001:2015 Para 7.1.5 NSI 009-04	Monitoring and Measuring Resources		
1.2	ISO 9001:2015 Para 7.1.5.1	Requirement: Does the organization have a documented procedure to determine and provide the resources needed to ensure valid and reliable results, when monitoring or measuring is used to verify the conformity of products and services to requirements?		
		Comments:		
		Requirement: Does the documented procedure ensure that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken?		
		Comments:		

(1) Support				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
1.2	ISO 9001:2015 Para 7.1.5.1	Requirement: Does the documented procedure ensure that the resources provided are maintained to ensure their continuing fitness for their purpose?		
		Comments:		
	ISO 9001:2015 Para 7.1.5.1	Requirement: Does the organization retain appropriate documented calibration information as evidence of fitness for purpose of the monitoring and measuring equipment?		
		Comments:		
1.3	ISO 9001:2015 Para 7.1.5.2 NSI 009-04 Para 3.2.1.1	Requirement: Does the documented procedure ensure monitoring and measuring equipment is calibrated against devices traceable to international or national measurement standards? (See NSI 009-04 Para 3.2.1.1 for accreditation requirements). When no such standards exist, the basis used for calibration or verification shall be retained as documented information.		
		Comments:		
	ISO 9001:2015 Para 7.1.5.2 NSI 009-04 Para 3.2.1.2	Requirement: Does the documented procedure ensure calibration intervals are assigned to Measuring and Test Equipment used for acceptance testing, meet the requirements of the NAVSEA Metrology Requirements List (METRL), unless alternate calibration intervals were established IAW ANSI/NCSL Z540-3, Requirements for the Calibration of Measuring and Test Equipment?		
		Comments:		
	ISO 9001:2015 Para 7.1.5.2.b	Requirement: Does the documented procedure ensure devices are identified (i.e. tagged with stickers showing calibration status and due date)?		
		Comments:		

(1) Support				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
1.3	ISO 9001:2015 Para 7.1.5.2.c	Requirement: Does the documented procedure ensure all devices are safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results?		
		Comments:		
	ISO 9001:2015 Para 7.1.5.2	Requirement: Does the documented procedure direct and describe how previous measurement results will be validated, if measuring equipment is found to be unfit for intended purposes, and direct appropriate necessary actions?		
		Comments:		
Item	ISO 9001:2015 Para 7.2	Competence		
1.4	ISO 9001:2015 Para 7.2.a	Requirement: Does the organization have a documented procedure to determine the necessary competence of person(s) doing work under its control, that affects the performance and effectiveness of the QMS?		
		Comments:		
	ISO 9001:2015 Para 7.2.b	Requirement: Does the organization have a documented procedure in place to ensure that persons are competent on the basis of appropriate education, training, or experience?		
		Comments:		
	ISO 9001:2015 Para 7.2.c	Requirement: Does the organization have a documented procedure to take actions to acquire the necessary competence? If so, does the organization have a procedure to evaluate the effectiveness of those actions taken?		
		Comments:		

(1) Support				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
1.4	ISO 9001:2015 Para 7.2.d	Requirement: Does the organization have a documented procedure to retain appropriate personnel records (i.e. education, training, skills, and experience) as evidence of competence?		
		Comments:		
Item	ISO 9001:2015 Para 7.5 NSI 009-04	QMS Documented Information		
1.5	ISO 9001:2015 Para 7.5.2.a	Requirement: When creating and updating documented procedures, does the organization have a documented procedure to ensure appropriate: a) identification and description?		
		Comments:		
1.5	ISO 9001:2015 Para 7.5.2.b	Requirement: b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic)?		
		Comments:		
	ISO 9001:2015 Para 7.5.2.c	Requirement: c) review and approval for suitability and adequacy of documented information (i.e. procedures and records)?		
		Comments:		
	ISO 9001:2015 Para 7.5.3.1	Requirement: Does the organization have a documented procedure to control documented information to ensure its protection (e.g. from loss of confidentiality, improper use, or loss of integrity) and availability at locations essential to the effectiveness of the QMS?		
		Comments:		

(1) Support				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
1.6	ISO 9001:2015 Para 7.5.3.2.a	Requirement: Does the organization's document control procedure: a) address distribution, access, retrieval, and use of documented information?		
		Comments:		
	ISO 9001:2015 Para 7.5.3.2.b	Requirement: b) ensure adequate storage and preservation (including preservation of legibility) of documented information?		
		Comments:		
	ISO 9001:2015 Para 7.5.3.2.c	Requirement: c) control of changes (e.g. version control)?		
		Comments:		
	ISO 9001:2015 Para 7.5.3.2.d	Requirement: d) retention and disposition of documents? Are obsolete documents prevented from unintended use IAW the approved procedure?		
		Comments:		
	ISO 9001:2015 Para 7.5.3.2	Requirement: Does the organization's document control procedure ensure that documents of external origin determined by the organization to be necessary for the planning and execution of the QMS, are identified and controlled?		
		Comments:		

(1) Support				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
1.6	ISO 9001:2015 Para 7.5.3.2	Requirement: Does the organization's documented procedure ensure documented information is retained as evidence of conformity and the information is protected from unintended alteration?		
		Comments:		

Auditor: _____	Date: _____
<i>Printed Name and Signature</i>	

CONTRACTOR QMS MANUAL REVIEW CHECKLIST			
Company's Name:		Document's Date of Submission:	
Reviewer's Name:		Checklist Completion Date:	
(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
Item	ISO 9001:2015 Para 8.2	Requirements for Products and Services	
2.1	ISO 9001:2015 Para 8.2.1	Requirement: Does the organization have a documented procedure for customer communication that: a) provides information related to products and services?	
		Comments:	
		Requirement: b) identifies and implements arrangements for inquiries, contracts, and orders, including changes?	
		Comments:	
		Requirement: c) provides for customer feedback relating to products and services, including complaints?	
		Comments:	
		Requirement: d) addresses handling or controlling customer property	
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.1	ISO 9001:2015 Para 8.2.1	Requirement: e) establishes specific requirements for contingency actions, when relevant?	
		Comments:	
2.2	ISO 9001:2015 Para 8.2.2	Requirement: When determining the requirements for the products and services to be offered to customers, does the organization's documented procedure ensure requirements for products and services offered are defined, including: a) applicable statutory and regulatory requirements and those considered necessary by the organization?	
		Comments:	
	ISO 9001:2015 Para 8.2.3.1	Requirement: b) meeting claims for the products and services it offers?	
		Comments:	
		Requirement: Does the organization's documented procedure direct a review prior to the commitment of the services and products offered to ensure they meet the requirements of the customer, including: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities	
		Comments:	
		Requirement: b) requirements not stated by the customer, but necessary for the specified or intended use, when known?	
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.2	ISO 9001:2015 Para 8.2.3.1	Requirement: c) requirements specified by the organization?	
		Comments:	
		Requirement: d/e) statutory and regulatory requirements applicable to the products and services and contract or order requirements differing from those previously expressed?	
		Comments:	
		Requirement: f) confirmation that contract or order requirements differing from those previously defined are resolved?	
		Comments:	
	ISO 9001:2015 Para 8.2.3.1	Requirement: g) confirmation by the organization before acceptance, when the customer does not provide a documented statement of their requirements?	
		Comments:	
	ISO 9001:2015 Para 8.2.3.2	Requirement: Does the organization's documented procedure ensure the results of the review for products and services and any new requirements for products and services are documented?	
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.2	ISO 9001:2015 Para 8.2.4	Requirement: Does the organization's documented procedure ensure that relevant documented information is amended and relevant persons are made aware of the changed requirements when customer requirements for products and services change? Comments:	
Item	ISO 9001:2015 Para 8.4, NSI 009-04	Control of Externally Provided Processes, Products, and Services	
2.3	ISO 9001:2015 Para 8.4.1	Requirement: Does the organization's documented procedure ensure that externally provided processes, products, and service conform to requirements and determine the controls to be applied to externally provided processes, products, and services when: a) products and services from external providers are intended for incorporation into the organization's own products and services? Comments:	
		Requirement: b) products and services are provided directly to the customer(s) by external providers on behalf of the organization? Comments:	
		Requirement: c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization? Comments:	
		Requirement: Does the organization's documented procedure determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements? Does the organization retain documented information of	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
		products and services in accordance with requirements. Does the organization retain documented information of external providers and any necessary actions arising from the evaluations?	
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.4	ISO 9001:2015 Para 8.4.2	Requirement: Does the organization's documented procedure ensure that externally provided processes, products, and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers? The procedure shall: a) ensure that externally provided processes are controlled by their QMS?	
		Comments:	
		Requirement: b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output?	
		Comments:	
		Requirement: c.1) take into consideration potential impact of the externally provided processes, products, and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements?	
		Comments:	
		Requirement: c.2) take into consideration the effectiveness of the controls applied by the external provider?	
		Comments:	
		Requirement: determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and service meet requirements?	
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.4	NISI 009-04 Para 3.2.2.2	Requirement: Does the organization have a process for Receipt Inspection of CFM based on supplier performance history and one or more of the following: certificate of compliance, vendor material test certification data, manufacturer's MIL certificate, or testing using sampling techniques?	
		Comments:	
2.5	ISO 9001:2015 Para 8.4.3	Requirement: Does the organization's documented procedure ensure the adequacy of requirements prior to their communication to the external provider? The procedures shall communicate to external providers it's requirements for: a) the processes, products, and services to be provided	
		Comments:	
	ISO 9001:2015 Para 8.4.3	Requirement: b) the approval of: 1. products and services 2. methods, processes, and equipment 3. the release of products and services	
		Comments:	
	ISO 9001:2015 Para 8.4.3	Requirement: c) competence including any required qualification of persons	
		Comments:	
	ISO 9001:2015 Para 8.4.3	Requirement: d) the external provider's interactions with the organization	
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.5	ISO 9001:2015 Para 8.4.3	Requirement: e) control and monitoring of the external provider's performance to be applied by the organization	
		Comments:	
	ISO 9001:2015 Para 8.4.3	Requirement: f) the verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.	
		Comments:	
	NSI 009-04 Para 3.2.2.1	Requirement: The organization's documented procedure identifies, in purchasing documents, verification arrangements at the SKTR/vendor location/premises IAW NSI 009-04 Para 3.2.2.1?	
		Comments:	
Item	ISO 9001:2015 Para 8.5	Production and Service Provision	
2.6	ISO 9001:2015 Para 8.5.1	Requirement: Does the organization's documented procedure implement production and service provision under controlled conditions? Controlled conditions include: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved	
		Comments:	
		Requirement: b) the availability and use of suitable monitoring and measuring resources	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.6	ISO 9001:2015 Para 8.5.1	Requirement: c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met	
		Comments:	
		Requirement: d) the use of suitable infrastructure and environment for the operation of processes	
		Comments:	
		Requirement: e) the appointment of competent persons, including any required qualification	
		Comments:	
		Requirement: f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement	
		Comments:	
		Requirement: g) the implementation of actions to prevent human error	
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.6	ISO 9001:2015 Para 8.5.1	Requirement: h) the implementation of release, delivery, and post-delivery activities	
		Comments:	
2.7	ISO 9001:2015 Para 8.5.2	Requirement: Does the organization's documented procedure specify suitable means to identify outputs, when necessary, to ensure the conformity of products and services?	
		Comments:	
		Requirement: Does the organization's documented procedure identify the status of outputs, with respect to monitoring and measurement requirements throughout production and service provision?	
		Comments:	
		Requirement: When traceability is a requirement, does the organization's documented procedure control and record the unique identification of the product?	
		Comments:	
2.8	ISO 9001:2015 Para 8.5.3	Requirement: For property belonging to customers or external providers, does the organization's documented procedure ensure: a) the exercise of care with property belonging to customers or external providers while it is under the organization's control or being used by the organization?	
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.8	ISO 9001:2015 Para 8.5.3	Requirement: b) the identification, verification, protection, and safeguarding of customers' or external providers' property provided for use or incorporation into the products and services?	
		Comments:	
		Requirement: c) that when the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, the organization reports this to the customer or external provider and retain documented information on what has occurred?	
	ISO 9001:2015 Para 8.5.4	Comments:	
		Requirement: Does the organization's documented procedure preserve the outputs during production and service provision, to the extent necessary to ensure conformity of product with customer requirements?	
	ISO 9001:2015 Para 8.5.5	Comments:	
		Requirement: Does the organization's documented procedure have a process to meet post-delivery activities associated with the products and services? The organization shall consider: a) statutory and regulatory requirements	
		Comments:	
		Requirement: b) the potential undesired consequences associated with its products and services	
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.8	ISO 9001:2015 Para 8.5.5	Requirement: c) the nature, use, and intended lifetime of its products and services;	
		Comments:	
		Requirement: d) customer requirements	
		Comments:	
	ISO 9001:2015 Para 8.5.6	Requirement: e) customer feedback.	
		Comments:	
Item	ISO 9001:2015 Para 8.6	Release of Products and Services	
		Requirement: Does the organization's documented procedure implement planned arrangements at appropriate stages, to verify product and service requirements are met?	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.9	ISO 9001:2015 Para 8.6		
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.9	ISO 9001:2015 Para 8.6	Requirement: Does the organization's documented procedure ensure the release of products and services to the customer proceed only after the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer?	
		Comments:	
		Requirement: Does the organization's documented procedure require the retention of relevant documented information, including the evidence of conformity with the acceptance criteria, and traceability to the person(s) authorizing the release?	
		Comments:	
Item	ISO 9001:2015 Para 8.7	Control of Nonconforming Outputs	
2.10	ISO 9001:2015 Para 8.7.1	Requirement: Does the organization's documented procedure ensure that nonconforming outputs are identified and controlled to prevent their unintended use or delivery?	
		Comments:	
		Requirement: Does the organization's documented procedure deal with nonconforming outputs in one or more of the following ways, based on the nature of the nonconformity and its effect on the conformity of products and services (this shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services): a) correction	
		Comments:	
		Requirement: b) segregation, containment, return, or suspension of provision of products and services	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.10	ISO 9001:2015 Para 8.7.1	Requirement: c) informing the customer	
		Comments:	
		Requirement: d) and/or obtaining authorization for acceptance under concession?	
		Comments:	
		Requirement: Does the organization's documented procedure ensure verification of conformity to the requirements, when nonconforming outputs have been corrected?	
		Comments:	
		Requirement: Does the organization's documented procedure require retention of documented information that: a) describes the nonconformance?	
		Comments:	
		Requirement: b) describes actions taken?	
		Comments:	

(2) Operation			
Item	Reference Paragraph	Requirement/Audit Question	Compliant?
2.10	ISO 9001:2015 Para 8.7.1	Requirement: c) describes concessions obtained?	
		Comments:	
		Requirement: d) identifies the authority deciding the action in respect to the nonconformity?	
		Comments:	
Auditor: _____		Date: _____	
<i>Printed Name and Signature</i>			

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CONTRACTOR QMS MANUAL REVIEW CHECKLIST				
Company's Name:		Document's Date of Submission:		
Reviewer's Name:		Checklist Completion Date:		
(3) Performance Evaluation & Improvement				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
Item	ISO 9001:2015 Para 9.2	Internal Audit		
3.1	ISO 9001:2015 Para 9.2.1	Requirement: Does the organization's documented procedure require internal quality audits be performed at planned intervals to ensure the QMS: a) conforms to: 1. the organization's own requirements for its QMS? 2. the requirements of ISO 9001:2015? 3. the requirements of NSI 009-04?		
		Comments:		
		Requirement: b) is effectively implemented and maintained?		
		Comments:		
	ISO 9001:2015 Para 9.2.2	Requirement: Does the organization's documented procedure: a) plan, establish, implement, and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits?		
		Comments:		
		Requirement: b) define the audit criteria and scope for each audit?		
		Comments:		

(3) Performance Evaluation & Improvement				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
3.1	ISO 9001:2015 Para 9.2.2	Requirement: c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process?		
		Comments:		
		Requirement: d) ensure that the results of the audits are reported to relevant management?		
		Comments:		
		Requirement: e) take appropriate correction and corrective actions without undue delay?		
		Comments:		
		Requirement: f) retain documented information as evidence of the implementation of the audit program and the comments?		
		Comments:		
Item	ISO 9001:2015 Para 9.3	Management Review		
3.2	ISO 9901:2015 Para 9.3.1	Requirement: Does the organization's documented procedure require top management to review the organization's QMS at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization?		
		Comments:		

(3) Performance Evaluation & Improvement				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
3.2	ISO 9001:2015 Para 9.3.2	Requirement: Is the organization's management review documented procedure planned and carried out taking into consideration: a) the status of actions from previous management reviews		
		Comments:		
		Requirement: b) changes in external and internal issues that are relevant to the QMS;		
		Comments:		
		Requirement: c) information on the performance and effectiveness of the QMS, including trends in: 1) customer satisfaction and feedback from relevant interested parties 2) the extent to which quality objectives have been met 3) process performance and conformity of products and services 4) nonconformities and corrective actions 5) monitoring and measurement results 6) audit results 7) the performance of external providers		
		Comments:		
		Requirement: d) the adequacy of resources		
		Comments:		
		Requirement: e) the effectiveness of actions taken to address risks and opportunities (see 6.1 of ISO 9001:2015)		
		Comments:		

(3) Performance Evaluation & Improvement				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
3.2	ISO 9001:2015 Para 9.3.2	Requirement: f) opportunities for improvement?		
		Comments:		
	ISO 9001:2015 Para 9.3.3	Requirement: Does the organization's management review documented procedure include decisions and actions related to: a) opportunities for improvement?		
		Comments:		
		Requirement: b) any need for changes to the QMS?		
		Comments:		
		Requirement: c) resource needs?		
		Comments:		
		Requirement: Does the organization's documented procedure require retention of the results of the management reviews?		
		Comments:		

(3) Performance Evaluation & Improvement				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
Item	ISO 9001:2015 Para 10.2	Nonconformance and Corrective Action		
3.3	ISO 9001:2015 Para 10.2.1	Requirement: Does the organization's documented procedure require, when a nonconformance occurs, including any arising from complaints, the organization to: a) react to the nonconformity and, as applicable: 1) take action to control and correct it 2) deal with the consequences?		
		Comments:		
		Requirement: b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1) reviewing and analyzing the nonconformity; 2) determining the causes of the nonconformity; 3) determining if similar nonconformities exist or could potentially occur?		
		Comments:		
		Requirement: c) implement any action needed?		
		Comments:		
		Requirement: d) review the effectiveness of any corrective action taken?		
		Comments:		
		Requirement: e) update risks and opportunities determined during planning, if necessary?		
		Comments:		

(3) Performance Evaluation & Improvement				
Item	Reference Paragraph	Requirement/Audit Question	Compliant?	Noncompliant?
3.3	ISO 9001:2015 Para 10.2.1	Requirement: f) make changes to the QMS, if necessary?		
		Comments:		
		Requirement: Does the documented procedure require that the Corrective Actions are appropriate to the effects of the nonconformities encountered?		
		Comments:		
	ISO 9001:2015 Para 10.2.2	Requirement: Does the organization's documented procedure require retention of documented information about: a) the nonconformance and corrective action taken?		
		Comments:		
		Requirement: b) results of the corrective actions?		
		Comments:		
Auditor: _____		Date: _____		
<i>Printed Name and Signature</i>				