NUCLEAR PROCUREMENT ISSUES COMMITTEE AUDIT CHECKLIST

SUMMARY SHEET

SUPPLIER INFORMATION		
SUPPLIER NAME:		NUPIC SUPPLIER NO.:
PRIMARY ADDRESS:		
CITY:	STATE:	ZIP CODE:
ADDITIONAL LOCATIONS:		
PRIMARY TELEPHONE NO:	WEB ADDRESS:	
PRODUCT/SERVICE:		
ASME CODE STAMP, AUTHORIZATIONS, AND EXPIRATION DATES:		

QUALITY PROGRAM COMMITMENTS

☐ 10CFR50 Appendix B	☐ ANSI/ASME NQA-1 (Yr) _____	☐ ASME SECTION XI	☐ IEEE (specify) _____
☐ 10CFR21	☐ ANSI N45.2	☐ ASME NCA 3800	☐ SNT-TC-1A
☐ 10CFR (other) _____	☐ ANSI (other) _____	☐ ASME NCA 4000	☐ CP-189
			☐ Other _____

SUPPLIER CONTACTS:		
SENIOR COMPANY OFFICER:	TITLE:	PHONE:
SENIOR QA OFFICER:	TITLE:	PHONE:
	E-MAIL:	

AUDIT INFORMATION		
MEMBER AUDIT ID NO.:	NUPIC AUDIT ID NO.:	AUDIT DATES:

AUDIT TEAM INFORMATION

AUDIT TEAM	NAME/NUPIC MEMBER DESIGNATOR	PHONE	EMAIL:	CHECKLIST SECTIONS AUDITED
TEAM LEADER				
TEAM MEMBER				
TEAM MEMBER				
TEAM MEMBER				
TEAM MEMBER				
TECHNICAL SPECIALIST (Specify Discipline)				

Audit Team Leader: _____ Date: _____

NUPIC Representative: _____ Date: _____

NUCLEAR PROCUREMENT ISSUES COMMITTEE AUDIT CHECKLIST

SUMMARY SHEET

Supplier Quality Manual: Revision: Date:

Audit Section	Section Description	E	F	Previous Audit Finding Reference	Section Status	Comments/Findings
1	Contract Review	√	√			
2	Design	√				
3	Commercial Grade Dedication	√				
4	Software Quality Assurance	√	√			
5	Procurement	√	√			
6	Fabrication/Assembly Activities, Material Control and Handling, Storage and Shipping		√			
7	Special Processes		√			
8	Tests, Inspections, and Calibration		√			
9	Document Control/Adequacy	√	√			
10	Organization/Program	√	√			
11	Nonconforming Items/Part 21	√	√			
12	Internal Audit	√				
13	Corrective Action	√	√			
14	Training/Certification	√	√			
15	Field Services	√	√			
16	Records	√	√			

SECTION STATUS KEY

S – SATISFACTORY U – UNSATISFACTORY N/A – NOT APPLICABLE (document basis)

E – Recommended for Engineering Service Suppliers F – Recommended for Field Service Suppliers

NOTE: An audit section status identified as “U” only indicates that one or more attributes in this checklist section were found to be unacceptable and may not suggest that the entire section was found to be unsatisfactory.

SECTION 1 – CONTRACT REVIEW

METHOD OF VERIFICATION	
1.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
1.2	**Verify that measures are established and implemented for the translation of customer purchase order/contract technical and quality requirements into the supplier's control documents.** **Objective Evidence required for Figure 1:** • Customer PO/Contract and date • Item/service description and part number • Supplier control document and verification (Yes/No) of translation from customer PO/Contract • Customer approval of exceptions (Yes/No) **Implementation Information:** Technical and quality requirements may include description, part numbers, tests/inspections, documentation, C of C, packaging/shipping, hold points, materials, etc. Supplier control documents may include order review forms, travelers, shop work orders, work tracking documents, etc. **References :** Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III NQA-1 Supplement 3S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide the measures for translation of purchase order/contract technical and quality requirements into supplier's control documents:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (identify and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for translating customer purchase order/contract requirements, including:

1. Correct translation of technical and quality requirements into the control documents.

SECTION 1 – CONTRACT REVIEW

2. Documentation, customer notification, and customer approval of any exceptions to the purchase order/contract technical and quality requirements, including design changes.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION	
1.3	**Verify that measures are established and implemented for control of items returned from the customer for repair/rework.**
	Implementation Information: Returns may refer to previously purchased items which require repair/refurbishment due to age/use and are typically requested by the normal purchase order/contract process. This question refers to items returned due to non-conformances at customer's receipt inspection, infantile failures, etc., and are typically requested by Return Material Authorization (RMA) or equivalent. **Checklist Interface:** Provide any related supplier nonconformance information to the audit team member evaluating checklist Section 11. **References:** Appendix B/ANSI N45.2 Ref. (15/16) ASME Section III NQA-1 Supplement 15S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide the measures for control of items returned from the customer for repair/rework:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 1 – CONTRACT REVIEW

b. Describe implementation of the supplier's measures (who, what, how) for return of items to be repaired/reworked:

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION	
1.4	**Verify that measures are established and implemented to ensure that final record packages, including Certificates of Compliance/Conformance, demonstrate that purchase order/contract technical and quality requirements were satisfied.** **Implementation Information:** Records must accurately describe the delivered products, including the "as-built" of the item or component, and should include documentation such as material certifications/test data, reports of inspections/examinations/tests, drawings, specifications, procedures, instructions, and non-conformances including the resolution. **References:** Appendix B/ANSI N45.2 Ref: (6/7) (17/18) ASME Section III NQA-1 Supplement 17S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide measures to ensure that final record packages demonstrate that purchase order/contract technical and quality requirements were satisfied:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to ensure that final record packages demonstrate that purchase order/contract technical and quality requirements were satisfied:

Are procedural controls adequately implemented?

SECTION 1 – CONTRACT REVIEW

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 1 – CONTRACT REVIEW

(FIGURE 1)

CUSTOMER P.O. **or** CONTRACT NUMBER **and** DATE * 1.2	ITEM/SERVICE DESCRIPTION **and** PART NUMBER (as applicable) * 1.2	SUPPLIER CONTROL DOCUMENTS (work orders, travelers, drawings, etc.) **and** CORRECT TRANSLATION TO SUPPLIER CONTROL DOCUMENTS (Yes/No) * 1.2	CUSTOMER APPROVAL OF P.O. / CONTRACT EXCEPTIONS (Yes/No) * 1.2

* Refers to applicable question

SECTION 2 – DESIGN

METHOD OF VERIFICATION	
2.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
2.2	**Verify that measures are established and implemented to control the translation of design requirements into design documents.** **Objective Evidence required for Figure 2:** • Member/Supplier Design Input and Bases • Supplier Design Document • Design Inputs Correctly Incorporated (Yes/No) **Implementation Information:** Design requirements (inputs) may be specified by the customer as technical and quality requirements in the purchase order/contract or may originate from the supplier. These include information such as design bases, regulatory requirements, codes, standards, EQ/seismic reports, etc. Design bases is information which identifies the specific functions to be performed and specific values/ranges of values for controlling parameters, chosen as reference bounds for design. **Checklist Interface:** Identify any software used in design to the audit team members evaluating Checklist Section 3 (purchased commercially and dedicated), Section 4, and Section 5 (purchased safety related). Identify any qualified / certified design specialists (i.e., ASME Code design personnel to ASME Section III) to the audit team member evaluating Checklist Section 14. **References :** Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III NQA-1 Supplement 3S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide the measures for translation of design requirements into design documents.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

SECTION 2 – DESIGN

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for translating design requirements into design documents:

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION	
2.3	**Verify that measures are established and implemented for the selection, and review for suitability of application, of materials, parts, equipment and processes that are essential to the safety related function of the product.** **Implementation Information:** If safety related components contain parts identified as non-safety related, a documented evaluation process should exist to provide a basis for the non-safety related classification. This evaluation process should consider the functional application of the part and a failure modes analysis to verify that the part failure would not prevent the parent component from performing its safety related function. **References:** Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III NQA-1 Supplement 3S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide the measures for the selection, and review for suitability of application, of materials, parts, equipment and processes essential to the safety related function.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 2 – DESIGN

b. Describe implementation of the supplier's measures (who, what, how) for the selection, and review for suitability of application, of materials, parts, equipment and processes essential to the safety related function.

1. If the supplier's safety related components have parts classified as non-safety related, describe the measures in use which provide the basis for the non-safety related classification.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION
2.4 **Verify that measures are established and implemented for the identification and control of design interfaces.** **Implementation Information**: Design activities may require interface between design groups within the same company, subcontracted design service suppliers, Code agencies such as ASME, and customer design organizations. These interfaces require establishment of procedures among participating design organizations (internal/external) for the review, approval, release, distribution, and revision of design documents. **Checklist Interface:** Identify any subcontracted design service suppliers to the audit team member evaluating Checklist Section 5. **References:** Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III NQA-1 Supplement 3S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide the measures for the identification and control of design interfaces.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

SECTION 2 – DESIGN

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for the identification and control of design interfaces.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION
2.5 **Verify that measures are established and implemented for the verification of design adequacy**. **Objective Evidence required for Figure 2:** • Method of Design Verification **References:** Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III NQA-1 Supplement 3S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide the measures for the verification of design adequacy.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for the verification of design adequacy.

1. Assure the verification method is identified (design review, alternate calculations or test) and that the verification is performed by individuals or groups other than those who performed the original design, but who may be from the same organization.

SECTION 2 – DESIGN

2. Verify that the design is supported by engineering data (i.e., calculations, performance test, etc.), including verification that design inputs are satisfied.
3. When the verification method used is qualification test, verify that a prototype unit is tested under the most adverse design conditions including design basis event service conditions.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION	
2.6	**Verify that measures are established and implemented to control design changes including changes for spare/replacement parts.** **Objective Evidence required for Figure 2:** • Design Change Control and Revision and/or Date **References:** Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III NQA-1 Supplement 3S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to control design changes including changes for spare/replacement parts.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to control design changes including changes for spare/replacement parts.

1. Review revised design documents, (e.g., calculations, drawings, stress reports), to verify that design changes are made by the same organization as originally reviewed and approved, or by other knowledgeable, qualified and designated organizations.
2. Ensure design control measures are equal to those of the original design.

SECTION 2 – DESIGN

3. Ensure that design changes have been adequately evaluated to assure that the impact of the change or cumulative effect of multiple changes are carefully considered (i.e. material substitutions, performance, interchangeability, EQ/seismic, test and equipment qualification).

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 2 – DESIGN

(FIGURE 2)

CUSTOMER/SUPPLIER DESIGN INPUT **and** BASES * 2.2	SUPPLIER DESIGN DOCUMENT * 2.2	DESIGN INPUTS CORRECTLY INCORPORATED (Yes / No) * 2.2	METHOD OF DESIGN VERIFICATION * 2.5	DESIGN CHANGE CONTROL **and** REV / DATE * 2.6

* Refers to applicable question.

SECTION 3 – COMMERCIAL GRADE DEDICATION

METHOD OF VERIFICATION	
3.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
3.2	**Verify that measures are established and implemented for the dedication of purchased Commercial Grade Items and services.** **Objective Evidence required for Figure 3A:** • Item Description, P/N, S/N, Model No., Software Name/ID, No., etc. • Critical Characteristics and Method(s) of Dedication **Implementation Information:** This question applies to Commercial Grade Item's dedicated by the supplier for customer procurement as basic components, or for the supplier's use in safety-related parts/services (e.g. software, consumables, fasteners, elastomers etc.). As a minimum, the process should include documented controls which define the dedication process including a documented technical evaluation that establishes requirements providing reasonable assurance the item/service will perform its intended safety function (or meet design requirements), identification of critical characteristics, and selection of acceptance method(s) for each critical characteristic identified. If the design criteria for the commercial grade item are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific safety function. In this case, consideration of failure modes is not required and the item's design parameters and allowables become the critical characteristics and acceptance criteria. In this instance, the design requirements become the critical characteristics requiring verification. For items that are seismically/environmentally qualified (e.g., relays, switches, nonmetallic items, etc.), appropriate critical characteristics should be verified that ensures the seismic/environmental qualification of the item has been maintained. **Note 1:** For suppliers who are unable to determine the items/materials safety function or end use (i.e., material suppliers, QSC Certificate holders, etc.), characteristics identified in the material specification, which are applicable to the finished product (i.e., chemical, physical, hydro, etc.), must be verified as critical characteristics. **References:** Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III NQA-1 Supplement 7S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide the measures for dedication of purchased Commercial Grade Items and services.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

SECTION 3 – COMMERCIAL GRADE DEDICATION

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for the dedication of purchased Commercial Grade Items and services, including:

1. A documented technical evaluation, performed by the responsible engineering organization that establishes requirements that will provide reasonable assurance the item/service will perform its intended safety related function (see Note 1). The Technical evaluation should include identification of safety function, critical characteristics and acceptance methods. Determination of the safety function for the item/service intended end use should include review of documents associated with the technical evaluation, such as:
   - Classification of the item
   - Item equivalency evaluations
   - Consideration of credible failure modes (See Implementation **Note 1**)

2. Measures for the selection of the acceptance method(s) of dedication, for each identified critical characteristic:

   Method 1 – Inspection, and Test

   Method 2 – Commercial Grade Item Surveys

   Method 3 – Source Verification

   Method 4 – Supplier/Performance history in conjunction with Methods 1, 2, or 3, above.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION	
3.3	**Verify that measures are established and implemented for the acceptance of purchased commercial grade items and services by Method 1 dedication**. **Objective Evidence required for Figure 3A:** • Inspection/ Test Procedure and Rev./Date • Inspector/ Tester Name/ Stamp • ID Number of M&TE used • Results SAT or UNSAT (record NCR No. if UNSAT) **Implementation Information:**

SECTION 3 – COMMERCIAL GRADE DEDICATION

Special tests/inspections supporting Method 1 Dedication are different from receipt inspection. When used as the Dedication Method, tests/inspections selected must be appropriate to verify each critical characteristic **after receipt**.

Checklist Interface:

Identify the Inspector/Tester to the audit team member evaluating Checklist Section 14.

Identify the M&TE used to the audit team member evaluating Checklist Section 8.

References:

Appendix B/ANSI N45.2 Ref: (10, 11/11, 12)

ASME Section III

NQA-1 Supplement 10S-1, 11S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide the measures for the acceptance of purchased Commercial Grade Items and services by Method 1 dedications.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for the acceptance of purchased Commercial Grade Items and services by Method 1 dedications, including:

1. Verify that the tests and inspections specified for the acceptance of commercial grade items adequately verified the identified critical characteristics.
2. Verify that the tests and inspections specified for the acceptance of commercial grade items incorporate and implement sampling plans which are controlled and their technical basis (homogeneity, item complexity, lot/batch control, heat traceability, supplier controls (survey), supplier performance, etc.) established and documented.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 3 – COMMERCIAL GRADE DEDICATION

METHOD OF VERIFICATION

3.4 **Verify that measures are established and implemented for the acceptance of purchased commercial grade items and services by Method 2 and Method 3 dedication.**

Objective Evidence required for Figure 3B:

- Commercial Grade Item (CGI) Supplier Name and Location and Date(s) Survey/Source Performed
- Commercial Grade Survey (Method 2) or Source Verification (Method 3)
- Scope of Supply To Be Dedicated
- Auditors (Method 2) Auditor and/or Inspectors (Method 3)
- Critical Characteristics (CCs) Verified and SAT or UNSAT
- CCs Verified Match Those Specified (Yes/No)

Implementation Information:

Surveys should be performed by personnel trained (qualified) in auditing and knowledgeable in operation of the item(s) being dedicated and critical characteristics being verified.

Source verifications should be performed by technically competent personnel, knowledgeable in operation of the item(s) being dedicated and critical characteristics being verified.

Checklist Interface:

Identify the Auditors or Inspectors (Source) to the audit team member evaluating Checklist Section 14.

References:

Appendix B/ANSI N45.2 Ref: (10, 11/11, 12)

ASME Section III

NQA-1 Supplement 10S-1, 11S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide the measures for the acceptance of purchased Commercial Grade Items and services by Method 2 and Method 3 dedication.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 3 – COMMERCIAL GRADE DEDICATION

b. Describe implementation of the supplier's measures (who, what, how) for the acceptance of purchased Commercial Grade Items and services by Method 2 and Method 3 dedication.

1. Verify, as applicable, that the commercial grade survey or source verification used for the acceptance of commercial grade items:

   i. Is performed in accordance with a procedure describing the applicable commercial grade survey or source verification process.

   ii. Are conducted by appropriately trained/qualified personnel.

   iii. Documents the procedure/instruction/program controls in place which control the identified critical characteristics

   iv. Demonstrates that the identified critical characteristics are controlled.

   v. Identifies compensatory or corrective actions proposed/completed for critical characteristics found to be inadequately controlled.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

3.5 **Verify the following measures have been established and implemented if the ILAC process is used in lieu of commercial grade survey for the verification of the critical characteristics for calibration and/or test laboratories.**

Objective Evidence required for Figure 3B:

- CGI Supplier Name, Location, AB Name, ILAC Certificate Number and Expiration Date (column 1)
- Identify as ILAC Accreditation (column 2)
- Scope of Supply To Be Dedicated (column 3)
- Critical Characteristics (CCs) Verified and SAT or UNSAT

Implementation Information:

The process for accepting accreditation to ISO/IEC 17025:2005 by an acceptable Accreditation Body (AB) must be proceduralized, including reference to the NRC APS SER and/or NEI 14-05A as applicable. If the NRC APS SER is utilized, acceptance of laboratory services is limited to domestic calibration laboratories that are accredited to by either NVLAP, A2LA, ACLASS, L-A-B, IAS, or PJLA. If NEI 14-05A is utilized, both calibration and test laboratories are acceptable provided the laboratory is accredited by an Accreditation Body which is a signatory to the ILAC MRA. This includes both domestic and international laboratories.

A technical evaluation must be documented that identifies the safety function and critical characteristics of the service.

For implementation of the NRC APS SER:

A documented evaluation must be performed by the supplier for the following requirements:

SECTION 3 – COMMERCIAL GRADE DEDICATION

1. Sub-supplier has accreditation to ISO/IEC 17025:2005.
2. Accreditation is issued by NVLAP, A2LA, ACLASS, LAB, IAS, or PJLA.
3. Sub-Supplier is a commercial grade, domestic (US) calibration laboratory.
4. The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.
5. Receipt inspection is performed which includes a review of the certification documentation supplied by the laboratory to verify the certification documentation includes the laboratory's name, location, Accreditation Body (AB) name and logo, certificate number, accreditation was current (not expired) at the time of calibration, certification indicates that the services were performed in accordance with the laboratory's accredited ISO/IEC 17025:2005 program and accredited scope, and a statement certifying that the purchase order requirements were met.

For implementation of NEI 14-05A:

A documented evaluation must be performed by the supplier for the following requirements:

1. The calibration or test laboratory holds accreditation by an Accreditation Body (AB) recognized by the ILAC MRA. The accreditation encompasses ISO/IEC 17025:2005.
2. For procurement of **calibration services**, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
3. For procurement of **testing services**, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
4. Receipt inspection is performed which includes a review of the certification documentation supplied by the laboratory to verify the certification documentation includes the laboratory's name, location, Accreditation Body (AB) name and logo, certificate number, accreditation was current (not expired) at the time of calibration, certification indicates that the services were performed in accordance with the laboratory's accredited ISO/IEC 17025:2005 program and accredited scope, and a statement certifying that the purchase order requirements were met.

NOTE 1: Implementation of the requirements listed in either Implementation option (APS/NEI), respectively, is considered to be acceptable for use of the ILAC process to accept commercial grade calibration services.

Checklist Interface:

Identify the use of the ILAC process to the audit team member evaluating Checklist Section 5.

References:

Appendix B/ANSI N45.2 Ref: (3, 10, 11/ 4, 11, 12)

ASME Section III

NQA-1 Supplement 3S-1,10S-1, 11S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide measures for use of the ILAC process in lieu of commercial grade survey for the verification of the critical characteristics for calibration and/or test laboratories.

SECTION 3 – COMMERCIAL GRADE DEDICATION

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for use of the ILAC process in lieu of commercial grade survey for the verification of the critical characteristics for calibration and/or test laboratories.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 3 – COMMERCIAL GRADE DEDICATION

(FIGURE 3A)

COMMERCIAL GRADE ITEMS / METHOD 1 ACCEPTANCE					
ITEM DESCRIPTION P/N, S/N, MODEL NO., SOFTWARE NAME/ID, NO., ETC. (All Methods) * 3.2, 3.3, 3.4, 4.5	CRITICAL CHARACTERISTICS **and** METHOD(s) OF DEDICATION FOR EACH (All Methods) * 3.2, 3.3, 3.4, 4.5	INSPECTION/ TEST PROCEDURE **and** REV / DATE (Method 1 only) * 3.3, 4.5	INSPECTOR/ TESTER NAME / STAMP (Method 1 only) * 3.3, 4.5	ID NUMBER OF M&TE USED (Method 1 only) * 3.3, 4.5	RESULTS SAT **or** UNSAT (record NCR No. if UNSAT) (Method 1 only) * 3.3, 4.5

* Refers to applicable question.

SECTION 3 – COMMERCIAL GRADE DEDICATION

(FIGURE 3B)

SURVEYS / SOURCE VERIFICATION / ILAC ACCREDITATION – METHODS 2, 3 or ACCREDITATION ACCEPTANCE					
CGI SUPPLIER NAME, LOCATION, DATE(S) PERFORMED **or**	COMMERCIAL GRADE SURVEY (METHOD 2) SOURCE VERIFICATION (METHOD 3) **or**	SCOPE OF SUPPLY TO BE DEDICATED	AUDITORS (Method 2) **and/or** INSPECTORS (Method 3)	CRITICAL CHARACTERISTICS (CC) VERIFIED **and** SAT or UNSAT	DO CCs VERIFIED MATCH THOSE SPECIFIED (Yes/No)
CGI SUPPLIER NAME, LOCATION, AB NAME, ILAC CERTIFICATE NUMBER and EXPIRATION DATE. * 3.4, 3.5, 4.5	ILAC ACCREDITATION * 3.4, 3.5, 4.5	* 3.4, 3.5, 4.5	N/A for ILAC Accreditation * 3.4, 4.5	* 3.4, 3.5, 4.5	N/A for ILAC Accreditation * 3.4, 4.5
* Refers to applicable question.					

SECTION 4 – SOFTWARE

METHOD OF VERIFICATION	
4.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
4.2	**Verify documented measures (plans, policies, procedures) are established and implemented to control the quality of software (including firmware).** **Objective Evidence required for Figure 4:** • Software Program (Name, Number, Revision and/or Date) **Implementation Information:** A "plan" for software quality is required at the start of software lifecycle for developed software or upon entry into the purchaser's organization for procured software. "Plans" may be unique to each project, may exist as a generic document (procedure), or may be incorporated into the overall QA program. "Plans" identify: • The software product • Responsible organizations, tasks, and responsibilities • Documentation requirements • Standards , conventions, techniques, methodologies applied to the development • Review requirements • Error reporting/corrective action methods A software lifecycle includes activities such as requirements phase, design phase, implementation phase, testing phase, installation and checkout phase, operations and maintenance phase, and retirement phase. The number of phases, and emphasis placed on each, is dependent on nature and complexity of the software. **References:** Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III NQA-1-1994 Basic Requirements 3, 11 and 17, Supplement 3S-1, 11S-2, 17S-1 and Subpart 2.7

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to control the development or procurement of safety related software (including firmware).

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

SECTION 4 – SOFTWARE

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for the development or procurement of safety related software (including firmware).

b) Verify that a "plan" exists for assuring software quality.

c) Verify that lifecycle activities are identified and reviewed, as applicable to the nature and complexity of the software.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

4.3 **Verify that measures are established and implemented to assure that software acceptance testing (verification and validation) is planned and performed to demonstrate that software adequately and correctly performs all intended functions (i.e., specified software design requirements) and does not perform any unintended function.**

Objective Evidence required for Figure 4:

- "Method of Acceptance" Testing and Date

Implementation Information:

Software verification, performed during development, ensures that results of a given lifecycle phase meet requirements of the previous phase/phases (i.e., design phase satisfies requirements phase, etc.).

Software validation, performed at the conclusion of the implementation phase, ensures that the code satisfies the requirements by development and execution of test plans and test cases. To evaluate technical adequacy, test case results can be compared to alternative "Methods of Acceptance" such as:

- hand calculations
- other validated computer program
- experiments/tests
- standard problems with known solutions
- confirmed published data and correlations

Identify the software acceptance testing, listed on Figure 4, which was observed in progress versus reviewed in completed documentation.

References:

Appendix B/ANSI N45.2 Ref: (4/5, 7/8)

ASME Section III

NQA-1-1994 Basic Requirement 11, Supplement 11S-2 and Subpart 2.7

SECTION 4 – SOFTWARE

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to control software acceptance testing

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for software acceptance testing.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

4.4 **Verify that measures are established and implemented to assure that software configuration is maintained and the changes to software are formally documented.**

Objective Evidence required for Figure 4:

- Software Program (Name, Number, Revision and/or Date)

Implementation Information:

Changes to software require formal documentation identifying:

- description of the change
- rationale for the change
- identification of affected baselines (e.g. Requirements documentation, Design documentation)

A configuration baseline defines completion of each major phase of software development. Approved changes added to the baseline define the current approved software configuration. Configuration management includes documentation of the approved configuration, the status of proposed changes to the configuration and the status of approved changes to the configuration.

Note: Configuration management also applies to backups, maintenance, disaster recovery, and virus protection.

SECTION 4 – SOFTWARE

References:

Appendix B/ANSI N45.2 Ref: (3/4)

ASME Section III

NQA-1-1994 Basic Requirement 3, Supplement 3S-1 and Subpart 2.7

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to control software changes and configuration.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for software change and configuration management including:

1. Evaluation and approval of software changes by the organization responsible for the original software development.
2. Software verification, to ensure the change is reflected in traceable software documentation, and software validation, as necessary.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

4.5 **Verify measures are established and implemented for the procurement of software (safety related or commercial grade).**

Objective Evidence required (as appropriate to the software classification):

- Commercial Grade: Figures 3A and 3B (as appropriate to the methods of Dedication)
- Safety Related: Figures 5A and 5B

Implementation Information:

SECTION 4 – SOFTWARE

Safety Related software procurement requires purchaser controls (i.e. acceptable supplier qualification, procurement practices and receipt inspection) to ensure that the software supplier is providing software that meets the technical and quality requirements specified in the purchase order. The purchaser's audit of the software supplier ensures that the software was developed and maintained in accordance with software quality assurance program requirements identified in this Checklist Section (4).

Procurement of commercial grade (commercial) software for use in safety related applications requires Commercial Grade Item Dedication per Checklist Section 3. Dedication activities should establish configuration control and ensure, as a minimum, that application requirements are identified, test plans/test cases to validate software acceptability are performed and user documentation is generated (input/output specifications, system limitations, etc.).

Procured software typically enters the purchaser's organization at the start of the lifecycle installation and checkout phase. This phase includes software verification and validation activities which consist of testing for installation and integration and documentation of software approval for operational use. The purchaser's software quality plan should address applicable lifecycle activities (i.e. installation and checkout, operations and maintenance, retirement), once the software has entered the purchaser's organization

Checklist Interface:

Safety Related software procurement: Interface with, and identify the software supplier and software to, the auditor responsible for evaluating Checklist Section 5.

Commercial grade (commercial) software procurement: Interface with, and identify the software supplier and software to, the auditor responsible for evaluating Checklist Section 3.

References:

Appendix B/ANSI N45.2 Ref: (3/4, 4/5, 7/8)

ASME Section III

NQA-1-1994 Basic Requirements 4, 7, 11, Supplements 4S-1, 7S-1, 11S-2 and Subpart 2.7

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to control the procurement of software (safety related or commercial grade).

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for procurement of software (safety related or commercial grade).

Are procedural controls adequately implemented?

SECTION 4 – SOFTWARE

YES ☐ ***or***
NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION	
4.6	**Verify that problem reporting measures are established and implemented to assure that software errors and failures from <u>both</u> internal and external sources are identified, documented, evaluated, resolved, and assessed for impact on past and present applications.** **Objective Evidence required for Figure 4:** • Error Notice Date and Status (OPEN / CLOSED) **References:** Appendix B/ANSI N45.2 Ref: (15/16) ASME Section III NQA-1-1994 Basic Requirement 16 and Subpart 2.7

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to control problem reporting.

Are procedures listed the current revision?
YES ☐ ***or***
NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?
YES ☐ ***or***
NO ☐ (describe the inadequacy)

b. Describe <u>implementation</u> of the supplier's measures (who, what, how) for control of problem reporting including:

1. Methods of notification consistent with those identified in the problem reporting system.
2. Problem classification with defined criteria based on impact of software output.
3. Problems and their significance promptly reported to affected organizations.

Are procedural controls adequately implemented?
YES ☐ ***or***
NO ☐ (describe the inadequacy)

SECTION 4 – SOFTWARE

METHOD OF VERIFICATION	
4.7	**Verify measures are established and implemented to assure that software is adequately packaged, marked, stored, and shipped.** **References:** Appendix B/ANSI N45.2 Ref: (13, 14/14, 15) ASME Section III NQA-1-1994 Basic Requirement 13 and Supplement 13S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to control software packaging, marking, storage, and shipment.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for control software packaging, marking, storage, and shipment.

1. Verify when duplicate copies are generated, that methods are in place to ensure exact duplication.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 4 – SOFTWARE

(FIGURE 4)

SOFTWARE PROGRAM (NAME, NO., REV / DATE) * 4.2, 4.4	METHOD OF ACCEPTANCE TESTING **and** DATE * 4.3	PROBLEM REPORT No. DATE **and** STATUS (OPEN / CLOSED) * 4.6

* Refers to applicable question.

SECTION 5 – PROCUREMENT

METHOD OF VERIFICATION	
5.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
5.2	**Verify that measures are established and implemented for the control and release of procurement documents, including changes.**

Objective Evidence required for Figure 5A:

- ITEM DESCRIPTION NAME (PART NUMBER, SERIAL NUMBER, MODEL NUMBER, SOFTWARE NAME)
- SUPPLIER **and** LOCATION
- P.O. NUMBER **and** DATE

Implementation Information:

As applicable, supplier procurement processes should ensure the following requirements are identified in procurement documents and procurement document changes, for items and services:

- Scope of work
- Technical requirements (by reference to specific drawings, codes, specifications)
- Documented Quality Assurance program
- Right of access for source inspection/audit
- Document submittals for approval
- Deliverable records
- Reporting and approving nonconformance dispositions
- Records availability, retention and disposition
- Extending Technical and QA requirements to lower tier suppliers
- 10CFR21 applicability

Note 1:

If the supplier utilizes NEI 14-05A, in lieu of commercial grade surveys, for acceptance of domestic and international commercial calibration and testing sub-supplier services from laboratories accredited to ISO/IEC 17025 that are a signatory to the ILAC MRA, procurement document requirements must include:

1. The service must be provided in accordance with their accredited ISO/IEC 17025:2005 program and scope of accreditation.
2. As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance ***(for calibration services only)***.
3. The equipment/standards used to perform the calibration must be identified in the certificate of calibration ***(for calibration services only)***.
4. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
5. Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

Note 2:

SECTION 5 – PROCUREMENT

If the supplier utilizes the NRC APS SER, in lieu of commercial grade surveys, for acceptance of domestic commercial calibration sub-supplier services from laboratories accredited to ISO/IEC 17025 by NVLAP, A2LA, ACLASS, L-A-B, IAS, or PJLA, procurement document requirements must include:

1. Requirement for reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
2. Requirement that calibration reports include identification of the laboratory equipment/standards used.
3. Additional technical and administrative requirements, as necessary, to satisfy the supplier's QA program and technical requirements.

Note 3:

Implementation of the requirements listed in either Note 1 or Note 2, respectively, is considered to be acceptable for use of ILAC process to accept commercial grade calibration services.

Checklist Interface:

Identify any procurement, based on use of the ILAC process, to the audit team member evaluating Checklist Section 3.

References:

Appendix B/ANSI N45.2 Ref: (4/5) ASME Section III

NQA-1 Supplement 4S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to control and release procurement documents, including changes.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to control, release, and change procurement documents, including:

3. Consistent inclusion of applicable requirements.
4. Consistent inclusion of applicable requirements for accredited domestic and international commercial calibration and testing laboratory services.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 5 – PROCUREMENT

METHOD OF VERIFICATION

5.3 **Verify that measures are established and implemented for the evaluation, selection and assessment of sub-suppliers including distributors, services (calibration, NDE, testing, heat treatment, etc) and software.**

Objective Evidence required for Figure 5A:

- ITEM DESCRIPTION NAME (PART NUMBER, SERIAL NUMBER, MODEL NUMBER, SOFTWARE NAME)
- SUPPLIER **and** LOCATION
- P.O. NUMBER **and** DATE
- METHOD **and** DATE OF SUPPLIER EVALUATION
- SCOPE OF SUPPLIER APPROVAL

Implementation Information:

As applicable to sub-suppliers in use, the supplier's quality program must address audits of Appendix B sub-suppliers, commercial grade surveys of commercial grade sub-suppliers and, if applicable, the use of accreditation in lieu of commercial grade surveys for domestic and international commercial calibration and testing laboratory services. .

- Evaluation of the sub-supplier must be performed prior to award of the purchase order/contract, and periodically thereafter.
- Sub-suppliers must be "approved" for use as indicated by an approved/qualified suppliers list or equivalent.
- The sub-supplier scope of approval must encompass the items/services identified in the procurement documents.

Note 1:

Content of CGI surveys is addressed in Checklist Question 3.4.

Note 2:

Evaluation of suppliers using ILAC accreditation in lieu of commercial grade surveys, for acceptance of domestic and international commercial calibration and testing laboratory services is addressed in Checklist Question 3.5.

Checklist Interface:

Identify any evaluations, based on use of the ILAC process, to the audit team member evaluating Checklist Section 3.

References:

Appendix B/ANSI N45.2 Ref: (7/8)

ASME Section III

NQA-1 Supplement 7S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

SECTION 5 – PROCUREMENT

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established for the evaluation, selection and assessment of sub-suppliers.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for the evaluation, selection and assessment of sub-suppliers.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

5.4 **Verify that measures are established and implemented to ensure a comprehensive system of planned and periodic external audits (including 3rd party audits).**

Objective Evidence required for Figure 5B:

- SUPPLIER NAME, LOCATION **and** DATE(S) PERFORMED
- EVALUATION METHOD (APPENDIX B AUDIT, SOURCE ACTIVITY)
- SCOPE OF SUPPLY
- AUDITORS
- NUMBER OF DEFICIENCIES (OPEN/ CLOSED)
- CORRECTIVE ACTION VERIFICATION METHOD **and** DATE

Implementation Information:

If 3rd party audits (NIAC, Consultant performed) are used as a basis for supplier qualification, the process must be addressed within the supplier's program/procedures. The evaluation of 3rd party audits must be documented and must address:

1. Performance of the audit by qualified personnel.
2. Performance of the evaluation by qualified personnel to ensure the user's program requirements are satisfied.
3. Scope of the audit envelops the current scope of procurement.
4. Applicable regulatory and/or commercial program requirements are adequately addressed in the audit scope.
5. Sufficient objective evidence is available to support conclusions of the audit.

SECTION 5 – PROCUREMENT

Checklist Interface:

Provide auditor names to the audit team member evaluating Checklist Section 14.

References:

Appendix B/ANSI N45.2 Ref: (18/19)

ASME Section III

NQA-1 Supplement 18S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to ensure a comprehensive system of planned and periodic external audits (including 3rd party audits).

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to ensure a comprehensive system of planned and periodic external audits (including 3rd party audits).

1. Verify that the audits were conducted by qualified personnel and are of sufficient depth and scope to ensure adequacy and effectiveness of the sub-suppliers program.
2. Verify that checklists or procedures were used with sufficient objective evidence documented and that follow-up action is taken where needed.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

5.5 **Verify that measures are established and implemented for acceptance of safety related material from an ASME sub-supplier, based on ASME certification (including materials supplied under provisions of NX2610).**

References:

SECTION 5 – PROCUREMENT

Appendix B/ANSI N45.2 Ref: (7/8)

IE Notice 86-21 including supplements

NQA-1 Supplement 7S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established for acceptance of safety related material from an ASME sub-supplier, based on ASME certification.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for acceptance of safety related material from an ASME sub-supplier, based on ASME certification.

1. Verify that the certification is validated via surveillance, audit and/or independent test.
2. If validation of the certification is based on independent test, in lieu of auditing, and end use is not known, ensure the test encompasses all characteristics of the material specification (i.e., chemical, physical, hydro, etc.).

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 5 – PROCUREMENT

(FIGURE 5A)

ITEM DESCRIPTION NAME (P/N, S/N, MODEL NO., SOFTWARE NAME) * 4.5, 5.2, 5.3	SUPPLIER **and** LOCATION * 4.5, 5.2, 5.3	P.O. NUMBER **and** DATE * 4.5, 5.2, 5.3	METHOD **and** DATE OF SUPPLIER EVALUATION * 4.5, 5.3, 5.4	SCOPE OF SUPPLIER APPROVAL * 4.5, 5.3, 5.4
* Refers to applicable question.				

SECTION 5 – PROCUREMENT

(FIGURE 5B AUDITS/SOURCE VERIFICATION)

SUPPLIER NAME, LOCATION **and** DATE(S) PERFORMED * 3.4, 5.4	EVALUATION METHOD (APPENDIX B AUDIT, SOURCE ACTIVITY) * 3.4, 5.4	SCOPE OF SUPPLY * 3.4, 5.4	AUDITORS * 3.4, 5.4	NUMBER OF DEFICIENCIES (OPEN / CLOSED) * 3.4, 5.4	CORRECTIVE ACTION VERIFICATION METHOD **and** DATE * 3.4, 5.4

* Refers to applicable question.

SECTION 6 – FABRICATION/ASSEMBLY ACTIVITIES
MATERIAL CONTROL, HANDLING, SHIPPING AND STORAGE

METHOD OF VERIFICATION

6.1 Within the ASSESSMENT/SUMMARY Section (a) of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.

6.2 **Verify that measures are established and implemented for the control of fabrication/assembly activities.**

Objective Evidence required for Figure 6A:

- ITEM DESCRIPTION
- WORK DOCUMENT
- WORK ACTIVITY
- WORK ACTIVITY PROCEDURE

Implementation Information:

Fabrication/assembly should be controlled by a shop work order/traveler type document identifying a controlled sequence of applicable work activities required for completion. Controls should include provision for rework.

Checklist Interface:

Provide any related supplier test/inspection activity information to the audit team member evaluating Checklist Section 8.

Note: Assessment of software controls relating to the manufacturing processes is to be verified in Section 4.

References:

Appendix B Criteria VIII

ANSI N45.2 Section 9

ASME Section III

NQA-1 Supplement 9S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for control of the fabrication/assembly activities:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 6 – FABRICATION/ASSEMBLY ACTIVITIES
MATERIAL CONTROL, HANDLING, SHIPPING AND STORAGE

b. Describe implementation of the shop work order/traveler type document measures in use (who, what, how) including the applicable information/verifications it provides, such as:

- use of correct parts or materials;
- identification of each work activity;
- instructions, procedures and drawings to be used;
- hold/witness points;
- handling/cleanliness/environmental requirements

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION
6.3 **Verify that measures are established and implemented to assure the identification and traceability of items (i.e., materials, parts, weld filler material, etc.) is maintained throughout processing operations.** **Objective Evidence required for Figure 6B:** • ITEM DESCRIPTION • METHOD OF IDENTIFICATION **AND** TRACEABILITY • INSPECTION STATUS **Implementation Information:** Item status and identification should be evident through fabrication/assembly/storage/etc. Indicators may be marked on items, attached to items, or identified in accompanying documents, as appropriate. Controls should include: • Identification of items as to inspection/test status. • Defined authority for application and removal of identification markings/status indicators. • Item markings are clear and not detrimental. (for example, die stamps, if used, are low stress). • Subdivided items have satisfactory transfer of markings to each item. • Defined shelf-life requirements. Control of item traceability through fabrication/assembly should be provided by a documentation sequence such as serial number/part number to batch/lot/heat number to purchase order number to C of C, etc. **Note:** Figure 6B, column 2, requires **Identification** and **Traceability.** As an example, a tag or stamp (identification) identifying heat number, serial number (traceability). **References:** Appendix B Criteria VIII, XIV

SECTION 6 – FABRICATION/ASSEMBLY ACTIVITIES
MATERIAL CONTROL, HANDLING, SHIPPING AND STORAGE

ANSI N45.2 Section 9, 15

ASME Section III

NQA-1 Basic Requirement 8, Supplement 7S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures to assure the identification and traceability of items is maintained:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the identification and traceability measures(s) in use (who, what, how):

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

6.4 **Verify that measures are established and implemented for the control of storage and shipping activities.**

Objective Evidence required for Figure 6B:

- ITEM DESCRIPTION
- METHOD OF IDENTIFICATION **AND** TRACEABILITY
- INSPECTION STATUS

Implementation Information:

The supplier's program and procedure controls should include typical storage and shipping activities, e. g. packaging practices to prevent damage during transit; marking of pertinent information on the container such as address, purchase order #, etc.; storage pending shipment; status of shipment such as identified on a traveler document, shipping log, etc.

As applicable to the product(s), specific controls should address:

- Handling

SECTION 6 – FABRICATION/ASSEMBLY ACTIVITIES
MATERIAL CONTROL, HANDLING, SHIPPING AND STORAGE

- Cleaning
- Preservation
- Foreign material controls
- Storing including access and environment
- Packaging
- Marking
- Documentation
- Shipment

Note: This question does not apply to software. Shipping of software is addressed in Item 4.7.

References:

Appendix B Criteria XIII

ANSI N45.2 Section 14

ASME Section III

NQA-1 Supplement 13S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for the control of storage and shipping activities:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for the control of storage and shipping activities:

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 6 – FABRICATION/ASSEMBLY ACTIVITIES
MATERIAL CONTROL, HANDLING, SHIPPING AND STORAGE

(FIGURE 6A)

ITEM DESCRIPTION List description of part (name, Part Number, P.O. number, etc.) * 6.2, 6.4	WORK DOCUMENT List Shop Work Order number, Traveler number, etc. * 6.2, 6.4	WORK ACTIVITY List activity (e.g. assembly, welding, packaging etc.) * 6.2, 6.4	WORK ACTIVITY PROCEDURE List the work activity procedure number and revision / date for the work activity observed. * 6.2, 6.4

* Refers to applicable question.

SECTION 6 – FABRICATION/ASSEMBLY ACTIVITIES
MATERIAL CONTROL, HANDLING, SHIPPING AND STORAGE

(FIGURE 6B)

ITEM DESCRIPTION List description of part (Name, Part Number, P.O./Contract Number, etc.) * 6.3, 6.4	METHOD OF IDENTIFICATION AND TRACEABILITY List the method used to identify the item (Heat Number, P.O./Contract number, etc.) * 6.3, 6.4	INSPECTION STATUS Indicate the status of the item (i.e., awaiting inspection, on hold, discrepant, rejected, etc.) * 6.3, 6.4

* Refers to applicable question.

SECTION 7 – SPECIAL PROCESSES

METHOD OF VERIFICATION	
7.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation
7.2	**Verify that measures are established and implemented to control welding.**

Objective Evidence required for Figure 7A:

- ITEM DESCRIPTION
- SPECIAL PROCESS
- PROCEDURE **and** REV / DATE
- QUALIFICATION (personnel, procedures, equipment)

Objective Evidence required for Figure 7B:

- WELDER NAME / STAMP
- CERTIFICATION TYPE (WELD PROCESS **and** POSITIONS)
- CODE QUALIFIED TO
- WELD PROCESS SPECIFICATION (WPS) **and** REV / DATE

Implementation Information:

Qualified personnel:

Nationally recognized standards have been developed for welding, such as ASME IX. The supplier's programmatic controls should follow the requirements and/or recommendations of those programs. Welder qualification is typically documented on a Procedure Qualification Record (PQR). Welders should be qualified for the weld process (e.g. GTAW, etc.), specific material, and position (e.g. overhead, etc.)

Qualified procedures:

There are two types of Procedure Qualification Records (PQR). One is for documenting the welder's qualification;

- The PQR is specific for different types of welding processes and requires maintaining proficiency (proficiency logs). One is for the technical approval of the welding parameters to the Code.
- Procedure Qualification Records contain essential and non-essential variables. It is mandatory that essential variables be followed. PQRs also contain and are not limited to Material (P) numbers, Filler Metal (F) numbers, Voltages and Polarity.

Welding procedures, usually denoted as Welding Procedure Specifications (WPS), are required for each type of welding process being used. WPS's are developed from a Procedure Qualification Record.

Qualified equipment:

Welding equipment requirements and any specific calibration requirements are usually referenced in the controlling procedure. The equipment must meet the parameters required by the procedure.

References:

Appendix B/ANSI N45.2 Ref: (9/10)

ASME Section III

NQA-1 Supplement 9S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

SECTION 7 – SPECIAL PROCESSES

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for control of welding:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to control welding including the use of:

- qualified personnel;
- qualified procedures;
- qualified equipment

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

7.3 **Verify that measures are established and implemented to control Non-Destructive Examination (NDE).**

Note: NDE disciplines include Ultrasonic Testing (UT), Magnetic Particle Testing (MT), Liquid Penetrant Testing (PT), Radiographic Testing (RT), Eddy Current Testing (ET), and Leak Testing (LT). PT, UT and RT may be automated processes, as opposed to being manually performed.

Objective Evidence required for Figure 7A:

- ITEM DESCRIPTION
- SPECIAL PROCESS
- PROCEDURE **and** REV / DATE
- QUALIFICATION (personnel, procedures, equipment)

Implementation Information:

Qualified personnel:

SECTION 7 – SPECIAL PROCESSES

Nationally recognized standards have been developed for NDE, such as SNT-TC-1A and CP-189. The supplier's programmatic controls should follow the requirements and/or recommendations of those programs. Personnel are usually qualified to a "written practice" which identifies education, training and experience requirements for certification.

Qualified procedures:

NDE procedures should contain the requirements outlined in the referenced standards (e.g. ASTM standards for Nondestructive Testing).

Qualified equipment:

NDE equipment requirements and any specific calibration requirements are usually referenced in the controlling procedure.

Checklist Interface:

Identify any M&TE used to the audit team member evaluating Checklist Section 8.

References:

Appendix B/ANSI N45.2 Ref: (9/10, 10/11)

ASME Section III

NQA-1 Supplement 9S-1, 10S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for control of Nondestructive Examination (NDE):

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to control NDE including the use of:

- qualified personnel;
- qualified procedures;
- qualified equipment

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 7 – SPECIAL PROCESSES

METHOD OF VERIFICATION
7.4 **Verify that measures are established and implemented to control other special processes (e.g., heat treating, soldering, painting, etc.)**

Objective Evidence required for Figure 7A:

- ITEM DESCRIPTION
- SPECIAL PROCESS
- PROCEDURE **and** REV./DATE
- QUALIFICATION (personnel, procedures, equipment)

Implementation Information:

Qualified personnel:

Personnel qualification requirements for heat treatment, soldering, and painting are usually based on the supplier's experience but may have a basis in a standard (ASTM, SSPC, IPC, etc.). Any requirements for personnel qualification should be identified in the controlling procedure.

Qualified procedures:

As applicable, procedures should contain the requirements outlined in any referenced standards (e.g. ASTM standards for heat treating / coatings, SSPC standards for coatings, IPC standards for soldering, etc.).

Qualified equipment:

Equipment requirements and any specific calibration requirements are usually referenced in the controlling procedure.

Checklist Interface:

Identify any M&TE used to the audit team member evaluating Checklist Section 8.

References:

Appendix B/ANSI N45.2 Ref: (9/10)

ASME Section III

NQA-1 Supplement 9S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for control of other special processes (e.g., heat treating, soldering, painting, etc.):

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

SECTION 7 – SPECIAL PROCESSES

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to control other special processes (e.g., heat treating, soldering, painting, etc.) including the use of:

- qualified personnel;
- qualified procedures;
- qualified equipment

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 7 – SPECIAL PROCESSES

(FIGURE 7A)

ITEM DESCRIPTION (NAME, P/N, S/N, MODEL NO.) * 7.2	SPECIAL PROCESS * 7.2	PROCEDURE **and** REV / DATE * 7.2	QUALIFICATION		
			PERSONNEL AND LEVEL * 7.2	PROCEDURE * 7.2	EQUIPMENT * 7.2

* Refers to applicable question.

SECTION 7 – SPECIAL PROCESSES

(FIGURE 7B WELDER/WELD OPERATOR)

WELDER (NAME / STAMP) * 7.2	CERT. TYPE (PROCESS & POSITIONS) * 7.2	CODE QUALIFIED TO * 7.2	WELD PROCESS SPECIFICATION (WPS) AND REV / DATE * 7.2	MAINTENANCE OF QUALIFICATION * 7.2

* Refers to applicable question.

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

METHOD OF VERIFICATION

8.1 Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation

8.2 **Verify that adequate measures are established and implemented for the inspection (receipt, in-process, and final) and testing of materials, components and parts.**

Objective Evidence required for Figure 8:

- ITEM DESCRIPTION (NAME, P/N, S/N, ETC.)
- TEST/INSPECTION ACTIVITY TYPE **and** DATE
- TEST/INSPECTION DOCUMENT TITLE/NUMBER **and** REV./DATE
- INSPECTOR/ TESTER NAME/STAMP
- ID NUMBER OF M&TE USED **and** CALIBRATION CURRENT (Yes / No)
- SAT OR UNSAT **and** NCR NO. IF UNSAT

Implementation Information:

Inspection/testing activities and resultant documentation must provide applicable information which verifies conformance to specified requirements/demonstrates acceptability for service of materials, components and parts.

The Test/Inspection to be performed must be clearly identified in a shop work order/traveler type document (e.g. in-process, final) and/or administrative procedure which must identify/provide the procedures, specifications, work instructions, drawings, etc., which control performance of the test/inspection.

Documentation should identify:

- Procedures, specifications, work instructions, drawings, etc., which control performance of the test/inspection, including revision;
- Hold or witness points;
- Test/inspection prerequisites identified and met;
- Characteristics to be inspected;
- Appropriate Inspection equipment, tools, gages, and instrumentation (correct type, range and accuracy).
- Acceptance criteria (from applicable design documents);
- Test/inspection personnel
- Results (approved by responsible authority)
- Action taken relative to any non-conformances/deficiencies identified.

Identify Inspection/testing activities, listed on Figure 8, which were observed in progress versus reviewed in completed documentation.

Checklist Interface:

Provide inspection/test personnel names to the audit team member evaluating Checklist Section 14.

References:

Appendix B/ANSI N45.2 Ref: (7/8, 10/11, 11/12)

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

ASME Section III

NQA-1 Supplement 7S-1, 10S-1, 11S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for the inspection (receipt, in-process, and final) and testing of materials, components and parts:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the inspection and test measures in use (who, what, how) including the applicable information/verifications they provide:

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

8.3 **Verify that measures are established and implemented to assure that purchased material, items, equipment, software, services (including engineering services, studies, and evaluations) conform to the procurement documents (i.e., receipt inspection, source inspection, post installation testing).**

Objective Evidence required for Figure 8:

- ITEM DESCRIPTION (NAME, P/N, S/N, ETC.)
- TEST/INSPECTION ACTIVITY TYPE **and** DATE
- TEST/INSPECTION DOCUMENT TITLE/NUMBER **and** REV / DATE
- INSPECTOR/ TESTER NAME/STAMP
- ID NUMBER OF M&TE USED **and** CALIBRATION CURRENT (Yes / No)
- SAT OR UNSAT **and** NCR NO. IF UNSAT

Implementation Information:

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

Appendix B and ANSI N45.2 (references below) address the requirement to establish and implement measures to assure that purchased items and services conform to procurement documents. Relative to inspection activities, the measures specifically identified include source inspection and receiving inspection. NQA-1 (reference below) adds post installation testing.

While most material, items, equipment, software are adaptable to inspection/test, some services (e.g. engineering, auditing, inspection services, etc.) do not provide measureable attributes such as dimensions, configuration, etc. verifiable by inspection/test. In these instances, assurance methods may include review of associated documentation (e.g. certifications), technical evaluation of data, and oversight of the service activity.

Checklist Interface:

Provide inspection/test personnel names to the audit team member evaluating Checklist Section 14.

References:

Appendix B/ANSI N45.2 Ref: (7/8)

ASME Section III

NQA-1 Supplement 7S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for the inspection (receipt, in-process, and final) and testing of materials, components and parts:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the inspection and test measures in use (who, what, how) including the applicable information/verifications they provide:

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

8.4 **Assess the adequacy of inspection/testing processes (such as those used during receipt/in-process/final inspection and/or testing) for identifying suspect/counterfeit/fraudulent material, items or components that may not be equivalent to those ordered.**

Implementation Information:

Appendix B, ANSI N45.2, NQA-1 (references below) address the requirement to establish and implement measures to assure that purchased items and services conform to procurement documents. With the global economy, opportunities for the introduction of suspect/counterfeit/fraudulent material, items or components into the supply chain have increased. As such, specific measures for the detection of suspect/counterfeit/fraudulent material, items or components should be an integral part of ensuring that purchased items and services conform to procurement documents, commensurate with the complexity of the items/services provided.

Suspect/counterfeit/fraudulent indications may include:

- Altered manufacturer's name, logo, serial number, manufacturing date
- Items differing in configuration, dimensions, fit, finish, color, or other attributes from that expected
- Markings on items or documentation are missing, unusual, altered, or inconsistent with that expected
- Markings or documentation from country other than that of the sub-supplier
- Items, sold as new, exhibiting evidence of prior use
- Performance inconsistent with specifications, certification, or test data furnished
- Documentation that appears altered, incomplete, or lacks expected traceability, UL or manufacturer's markings

References:

Appendix B/ANSI N45.2 Ref: (7/8, 10/11, 11/12)

ASME Section III

NQA-1 Supplement 7S-1, 10S-1, 11S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for identifying suspect/counterfeit/fraudulent material, items or components that may not be equivalent to those ordered.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for identifying suspect/counterfeit/fraudulent material, items or components that may not be equivalent to those ordered.

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

- Assess whether responsible personnel are aware of suspect/counterfeit/fraudulent indications.
- Assess if measures established are commensurate with the complexity of the items/services provided.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION	
8.5	**Verify that measures are established and implemented for the use of sampling plans, in lieu of 100% inspection, during receipt/in-process/final inspection.** **Note:** Sampling plans used for commercial grade dedication are addressed in Checklist Section 3. **Implementation Information:** Sampling used to verify acceptability of multiple identical items requires procedure controls based on recognized industry standard sampling practices. The procedures that implement the receipt/in-process/final inspection activities should identify the sampling criteria and associated standard, or reference a procedure, which identifies the sampling criteria and associated standard. **References:** Appendix B/ANSI N45.2 Ref: (10/11) ASME Section III NQA-1 Supplement 10S-1, 11S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for sampling during inspection (receipt, in-process, and final) of materials, components and parts:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for sampling during inspection (receipt, in-process, and final) of materials, components and parts:

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

8.6 **Verify that measures are established and implemented for the control of measuring and test equipment (M&TE).**

Objective Evidence required for Figure 8:

- ID NUMBER OF M&TE USED **and** CALIBRATION CURRENT (Yes / No)

Implementation Information:

Appendix B, ANSI, and NQA-1 references below require control, periodic calibration, and adjustment (as necessary) of M&TE to maintain accuracy. Controls include:

- Labeling/identification of M&TE to ensure the device and calibration status are readily identifiable;
- Calibration of M&TE and standards at periodic (recall) intervals;
- Adequacy of standards to assure accuracy, stability, range, and resolution required for their intended use;
- Traceability of reference (primary) and working (secondary) standards used to the National Institute of Standards and Technology (NIST), other recognized standards, or natural law;
- Documentation of As Found/As Left information;
- Maintenance of Calibration History - dates calibrated, by whom/supplier, results, due date, primary standard, and P.O. No. (if applicable);
- Control of M&TE found to be “out-of tolerance”, “out of calibration”, and/or past due for calibration, including evaluation of past use of affected M&TE and customer notification where appropriate
- Calibration performed by the supplier in an environment that is controlled to the extent necessary to assure required accuracy.

Checklist Interface:

M&TE data from Sections 3 and 7 to be obtained from the responsible auditor(s) for those sections.

Identify any sub-suppliers providing calibration services to the audit team member(s) evaluating Checklist Sections 3 and 5.

Note:

If required by P.O./Contract, standards must have a nominal accuracy of four times the nominal accuracy of the measuring and test equipment being calibrated. If a 4:1 ratio is not possible, a documented (and authorized) basis of acceptance must be provided.

References:

Appendix B/ANSI N45.2 Ref: (12/13)

ASME Section III

NQA-1 Supplement 12S-1

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for the control of measuring and test equipment (M&TE).

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for the control of measuring and test equipment (M&TE).

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

(FIGURE 8)

ITEM DESCRIPTION (NAME, P/N, S/N, ETC.) * 8.2, 8.3	TEST/INSPECTION ACTIVITY TYPE **and** DATE * 8.2, 8.3	TEST/INSPECTION PROCEDURE (TITLE/NUMBER) **and** REV / DATE * 8.2, 8.3	INSPECTOR/ TESTER (NAME/STAMP) * 8.2, 8.3	ID NUMBER OF M&TE **and** CALIBRATION CURRENT (Yes / No) * 8.2, 8.3	SAT OR UNSAT **and** NCR NO. IF UNSAT * 8.2, 8.3

* Refers to applicable question.

SECTION 9 – DOCUMENT CONTROL/ADEQUACY

METHOD OF VERIFICATION	
9.1	Within the assessment/summary section of this checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
9.2	**Verify that measures are established and implemented to control the preparation, review/approval, and issue of documents (i.e., procedures, instructions, drawings, work orders, etc.) including changes.**

Implementation Information:

Measures to control the issue of documents include the following :

- Documented review for adequacy;
- Approved for release by authorized personnel;
- Distributed to applicable workstation;
- Adequate controls if maintained electronically.

Objective evidence can be obtained by comparing the supplier's master procedure listing to a sample of controlled documents from workstations, verifying that required documents are available at the work stations, are the latest reviewed/approved revision, and are legible. In addition, audit team members will provide reference to documents (with revisions) that were found while auditing their assigned checklist sections and will verify the document and revision numbers they reviewed are current as compared to the supplier's master procedure listing.

Documents may also be available in electronic form at work stations. If provided electronically at work stations, also verify there is sufficient control to prevent unauthorized changes to the electronic documents (read only).

Checklist Interface:

Query other audit team members regarding the verification of document and revision numbers they reviewed. Checklist questions in Section 1-8 and 10-16 require the following determination:

Are procedures listed the current revision?

YES or NO (provide information to the audit team member evaluating checklist Section 9.)

References:

Appendix B/ANSI N45.2 Ref: (5, 6/6, 7)

ASME Section III

NQA-1 Supplement 6S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide measures to control the preparation, review/approval, and issue of documents (i.e., procedures, instructions, drawings, work orders, etc.) including changes.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document)

SECTION 9 – DOCUMENT CONTROL/ADEQUACY

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to control the preparation, review/approval, and issue of documents (i.e., procedures, instructions, drawings, work orders, etc.) including changes.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 10 – ORGANIZATION/PROGRAM

METHOD OF VERIFICATION	
10.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
10.2	**Verify that adequate measures are established and implemented for management, direction, and execution of the Quality Assurance Program.** **Implementation Information:** The supplier's Quality Assurance Program must: • define the organizational structure (typically by an organizational chart depicting reporting relationships between management, production, engineering, quality positions, etc.); • define individual responsibilities (An individual/organization responsible for defining/measuring the overall effectiveness of the QA Program must be designated, e.g. QA Manager/QA Department); • provide quality organizational authority, independence, and freedom to identify problems, recommend solutions, control non-conformances (The organization chart and defined responsibilities for Quality personnel should clearly indicate sufficient independence from production and direct access to management levels having authority to ensure appropriate actions are taken); • assure that management regularly reviews the effectiveness of the QA program (typically an annual review presented by the QA Manager to senior management including such items as non-conformances, corrective actions, internal audit results, customer returns, etc.. An effective management review process would result in additional corrective actions for areas found to be unsatisfactory as a result of the review.) **References:** Appendix B/ANSI N45.2 Ref: (1-3) ASME Section III NQA-1 Supplement 1S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) which provide the measures for management, direction, and execution of the Quality Assurance Program.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 10 – ORGANIZATION/PROGRAM

b. Describe implementation of the supplier's measures for management, direction, and execution of the Quality Assurance Program (who, what, how) including:

1. Designation of an individual/organization responsible for defining/measuring the overall effectiveness of the QA Program;
2. Adequacy of the authority, independence and organizational freedom of personnel performing verification activities;
3. Regular supplier management review of the status and effectiveness of the Quality Assurance Program including corrective actions for areas found to be unsatisfactory as a result of the review.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 11 – NONCONFORMING ITEMS/PART 21

METHOD OF VERIFICATION	
11.1	Within the assessment/summary section of this checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
11.2	**Verify that measures are established and implemented to control items which do not conform to requirements:** **Implementation Information:** Nonconforming items must be clearly recognizable as nonconforming by marking/tagging of the item or segregation in a clearly marked (as nonconforming) container, area, etc. Nonconforming items must be identified on nonconformance documents and assigned a unique identification number which is logged and tracked. This process, in conjunction with marking, tagging, segregation, controls further processing, delivery and installation of items until disposition is completed. **References:** Appendix B/ANSI N45.2 Ref: (15/16) ASME Section III NQA-1 Supplement 15S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide the measures for control of items which do not conform to requirements:

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) for control of items which do not conform to requirements:

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

SECTION 11 – NONCONFORMING ITEMS/PART 21

11.3 **Verify that measures are established and implemented to disposition items which do not conform to requirements:**

Objective Evidence Required:

Document NCR Numbers reviewed under the Assessment/Summary.

Implementation Information:

Review a sample of Nonconformance documents. Select sample from:

- Actual nonconforming items observed during the audit by the audit team. Verify that these items are entered into the nonconformance process. (This will verify that a nonconformance which occurred was entered into the QA program);
- References in quality documentation being reviewed by the audit team to a nonconforming condition and resulting nonconformance report number;
- Select additional sample as needed from the supplier's nonconformance records (logs or electronic database files).

The selected disposition, such as use-as-is, reject, repair, rework, must be identified and documented, typically on the "nonconformance" document.

- Authority and responsibility for personnel performing the review/disposition must be defined.
- Documented justification must be provided verifying the acceptability of the nonconforming items which are dispositioned as repair or use-as-is.

  Note: Customer approval of use-as-is and repair dispositions is necessary when required by customer purchase order.
- Procedures or instructions for repair and rework must be provided.
- Repaired and reworked items must be re-inspected.

A clear connection between the nonconformance process and the Part 21 procedure must exist such that a mechanism exists to identify and elevate conditions requiring 10CFR21 evaluation.

- The nonconformance process should clearly interface and direct users to the 10CFR 21 evaluation process such that conditions adverse to quality are evaluated for 10CFR 21 reportability.

Note : If the supplier uses a Material Review Committee or similar organization, review a sample of the meeting minutes of this organization to verify follow through on any commitments from the meeting pertaining to significant conditions adverse to quality.

References:

Appendix B/ANSI N45.2 Ref: (15/16)

ASME Section III

NQA-1 Supplement 15S-1 (paragraph 4.1)

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to disposition items which do not conform to requirements.

SECTION 11 – NONCONFORMING ITEMS/PART 21

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to disposition items which do not conform to requirements including:

1. Documented disposition by authorized personnel.
2. Justification for repair and use-as-is dispositions including customer notification when required.
3. Identification of procedures/instructions for rework.
4. Re-inspection of repaired/reworked items.
5. Evaluation for 10CFR 21 reportability.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

11.4 **Verify that measures are established and implemented to address posting, evaluation, notification, and reporting requirements of 10CFR21.**

Objective Evidence Required:

Document NCR/CAR Numbers associated with 10CFR21 evaluations reviewed in the Assessment/Summary.

Document any NRC inspections performed since the previous NUPIC audit which identify noncompliance to 10CFR21 requirements.

Implementation Information:

Posting:

Appropriate documents are required to be posted per 10CFR21.6(a) **OR** (b) :

10CFR21.6(a)

- 10CFR21 regulations, and
- Section 206 of the Energy Reorganization Act of 1974, and
- Procedures adopted pursuant to the 10CFR21 regulations.

SECTION 11 – NONCONFORMING ITEMS/PART 21

10CFR21.6(b)

- Section 206 of the Energy Reorganization Act of 1974, and
- Notice describing regulations/procedures.

Evaluation:

Procedures are required to provide criteria (10CFR21.21(a)) for evaluation/determination, within 60 days of discovery of the deviation, if a defect or failure to comply exists under 10CFR21.3; or an Interim Report submitted within 60 days of discovery of the deviation.

Obtain a sample of Nonconformance Reports (Checklist Section 11) and Corrective Action Reports (Checklist Section 13) which have been screened for reportability and determined to be potentially reportable, requiring 10CFR 21 evaluation.

Review a sample of 10CFR21 evaluations performed to verify procedure implementation for conditions determined to be potentially reportable.

Notification:

Procedures are required to establish notification timeframes consistent with 10CFR21.21(a), (b) and (d):

- Purchaser/affected licensee within 5 working days of the determination of inability to perform the evaluation?
- Director or responsible officer within 5 working days after evaluation completion?
- Initial NRC notification by facsimile or telephone within 2 days of informing the responsible officer of a defect or failure to comply?
- Written NRC notification within 30 days of informing the responsible officer of a defect or failure to comply?

Reporting:

10CFR21 notifications must include (10CFR21.21(d)):

- Name/address of individual providing the report,
- Identification of facility/activity/basic component failing to comply or containing a defect,
- Identification of constructor/supplier,
- Nature of defect/failure to comply and safety hazard,
- Date information was obtained,
- Number and location of components in use/supplied/being supplied,
- Corrective actions, responsible entity, and time to complete,
- Advice related to the defect/failure to comply.

Review any NRC inspections performed since the previous NUPIC audit which identify noncompliance to 10CFR21 requirements (10CFR21.41). Verify that any NRC inspection issues, related to 10CFR 21 compliance, were corrected. If no NRC inspections of 10CFR 21 requirements were performed, state this.

References:

10CFR21.3, 10CFR21.6, 10CFR21.21, 10CFR21.41

SECTION 11 – NONCONFORMING ITEMS/PART 21

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to address posting, evaluation, notification, and reporting requirements of 10CFR21.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating Checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to address posting, evaluation, notification, and reporting requirements of 10CFR21 including:

1. Posted documents per 10CFR21.6(a) or 10CFR21.6(b).
2. Evaluation/Notification timeframes per 10CFR21.21(a), (b) and (d).
3. Reporting content per 10CFR21.21(d)

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 12 – INTERNAL AUDITS

METHOD OF VERIFICATION	
12.1	Within the assessment/summary section of this checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
12.2	**Verify that measures are established and implemented to ensure a comprehensive system of planned and periodic internal audits.**

Objective Evidence required for Figure 12:

- AUDIT SCOPE **and** DATE
- AUDITOR(S)
- NUMBER OF DEFICIENCIES **and S**TATUS (OPEN/CLOSED)
- CORRECTIVE ACTION VERIFICATION METHOD (document review, follow-up audit, surveillance, etc.)

Checklist Interface:

Identify any corrective actions resulting from the audits to the audit team member evaluating Checklist Section 13.

Identify the Auditors to the audit team member evaluating Checklist Section 14.

Implementation Information:

The supplier's current audit schedule and a sample of audits conducted since the last NUPIC audit will identify objective evidence for Figure 12. The audit planning/scheduling process should ensure that the audits are comprehensive (i.e. cover all aspects of the quality program) and that the frequency of the audits is defined, tracked, and met.

To ensure auditor independence, an auditor, directly employed by the supplier, cannot assess work in an area for which they have responsibilities as part of their position. Any auditor, direct employee or contracted, cannot assess any work which they previously performed (i.e. assessing the internal audit program if they performed the previous internal audit).

Audit results (conclusions) must be clearly documented, including a statement of "effectiveness". Checklists and/or procedures must contain adequate objective evidence to support the conclusions. Audit results must be reviewed by responsible management in area(s) audited and the overall "effectiveness" of the QA program communicated to upper management.

The process should include follow-up on issues from previous audits and verification of continued corrective action effectiveness, as documented in the audits reviewed.

References:

Appendix B/ANSI N45.2 Ref: (18/19)

ASME Section III

NQA-1 Supplement 18S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to ensure a comprehensive system of planned and periodic internal audits.

Are procedures listed the current revision?

SECTION 12 – INTERNAL AUDITS

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to ensure a comprehensive system of planned and periodic internal audits including.

5. Planning/scheduling
6. Auditor independence
7. Adequate objective evidence to support the conclusions
8. Management review of audit results
9. Evaluation of corrective action effectiveness from previous audits

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION	
12.3	**Assess the overall effectiveness of the internal audit process by review of previous internal audits and comparison of the results/issues identified in these audits with those identified by this NUPIC audit.** **Implementation Information:** The supplier QA program implementation should encourage self identification and effective resolution of quality issues. If effectively implemented, it would be expected that the NUPIC audit would not identify any significant QA program implementation issues, process gaps, or recurrence of issues previously identified by the supplier. For non-significant issues, some variations in quantity and subject of audit issues identified may occur, dependent on scopes, team sizes, performance timeframes, objective evidence selected, etc. However, the NUPIC results should generally validate the supplier's previous results, e.g. if NUPIC is identifying issues, the previous supplier audits would be expected to also be identifying and correcting issues. **References:** Appendix B/ANSI N45.2 Ref: (18/19) ASME Section III NQA-1 Basic Requirement 18S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

SECTION 12 – INTERNAL AUDITS

ASSESSMENT/SUMMARY: Describe the comparison of previous supplier internal audit results/issues with those identified by this NUPIC audit.

Has the internal audit process been effective, overall?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 12 – INTERNAL AUDITS

(Figure 12)

AUDIT SCOPE **and** DATE(s) * 12.2	AUDITOR(S) * 12.2	NUMBER OF DEFICIENCIES **and** STATUS (OPEN / CLOSED) * 12.2	CORRECTIVE ACTION VERIFICATION METHOD (document review, follow-up audit, surveillance, etc.) * 12.2

* Refers to applicable question.

SECTION 13 – CORRECTIVE ACTION

METHOD OF VERIFICATION	
13.1	Within the assessment/summary section of this checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
13.2	**Verify that measures are established and implemented to assure that conditions adverse to quality are promptly identified and corrected.**

Objective Evidence Required:

Document CAR Numbers reviewed under the Assessment/Summary.

Implementation Information:

Review a sample of corrective action documents selected from sources such as:

- Actual conditions adverse to quality identified during the audit by the NUPIC audit team. Verify that these conditions are entered into the supplier corrective action process. (This will verify that a condition discovered was entered into the supplier's corrective action program.)
- References in quality documentation, such as audits, to conditions adverse to quality and resulting corrective action report numbers.
- Select additional sample as needed from the supplier's corrective action program records (logs or electronic database files).

Note:

The supplier's program should define "significant" conditions adverse to quality.

If the supplier uses a Corrective Action Review Board or similar organization, review a sample of the meeting minutes of this organization to verify follow through on any commitments from the meeting pertaining to significant conditions adverse to quality.

As a minimum, measures to control conditions adverse to quality must include the following:

- Identification and description of the condition adverse to quality;
- Determination of the cause and actions taken to prevent recurrence and notification to appropriate levels of management for significant conditions adverse to quality;
- Review and approval by responsible authority (programmatically defined) on the adequacy of the corrective action;
- Review of corrective actions for timeliness and effectiveness;
- A clear connection between the corrective action process and the Part 21 procedure such that a mechanism exists to identify and elevate conditions requiring 10CFR21 evaluation;
- Follow-up actions verifying that the corrective actions are scheduled and/or have taken place.

References:

Appendix B/ANSI N45.2 Ref: (16/17)

ASME Section III

NQA-1 Basic Requirement 16

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

SECTION 13 – CORRECTIVE ACTION

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide measures to assure that conditions adverse to quality are promptly identified and corrected.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to assure that conditions adverse to quality are promptly identified and corrected.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION	
13.3	**Verify that deficiencies identified/reported by customers, to the supplier, (e.g., receipt inspection rejections, source verification rejections, return material authorizations, site nonconformances, etc.) are adequately evaluated and entered into the supplier's nonconformance or corrective action program, as applicable.** **Objective Evidence Required:** Document NCR and/or CAR Numbers reviewed under the Assessment/Summary. Appendix B/ANSI N45.2 Ref: (16/17) ASME Section III NQA-1 Basic Requirement 16

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to provide measures to assure that deficiencies identified/reported by customers, to the supplier, are entered into the supplier's nonconformance or corrective action program, as applicable, and adequately evaluated.

Are procedures listed the current revision?

YES ☐ ***or***

SECTION 13 – CORRECTIVE ACTION

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to assure that deficiencies identified/reported by customers, to the supplier, are adequately evaluated and entered into the supplier's nonconformance or corrective action program, as applicable.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

METHOD OF VERIFICATION

13.4 **Verify the overall effectiveness of the corrective action process**.

Objective Evidence Required:

Document CAR Numbers reviewed under the Assessment/Summary.

Implementation Information:

- Evaluate the adequacy of actions taken to prevent recurrence for any significant conditions adverse to quality.
- Review the adequacy of corrective actions taken as a result of the issues identified during previous supplier internal audits (if applicable) to determine if there were any repeat issues.
- ***** Review the adequacy of corrective actions taken as a result of the issues identified during the last NUPIC audit (if applicable) to determine if there are any repeat issues.

Checklist Interface:

***** Adequacy of corrective actions taken, as a result of the issues identified during the last NUPIC audit, will be provided by audit team members assigned to the checklist sections which identified the previous issues.

References:

Appendix B/ANSI N45.2 Ref: (16/17)

ASME Section III

NQA-1 Basic Requirement 16

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

SECTION 13 – CORRECTIVE ACTION

ASSESSMENT/SUMMARY: Describe the adequacy of the corrective action process in preventing recurrence of previously identified issues.

Has the corrective action process been effective, overall?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 14 - TRAINING/CERTIFICATION

METHOD OF VERIFICATION	
14.1	Within the assessment/summary section of this checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
14.2	**Verify that measures are established and implemented to ensure quality program indoctrination and training of personnel who perform activities affecting quality.** **Objective Evidence required for Figure 14:** • NAME a**nd** JOB TITLE • INDOCTRINATION AND TRAINING COMPLETED (Yes / No) **Implementation Information:** Any individuals performing functions described in the Quality Program require quality program indoctrination and training. Obtain a sample of personnel from those observed, interviewed, or whose quality related work was reviewed, during the audit and verify they received quality program indoctrination and training. **References:** Appendix B/ANSI N45.2 Ref: (2/2) ASME Section III NQA-1 Supplement 2S-4

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to ensure quality program indoctrination and training of personnel who perform activities affecting quality.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to ensure quality program indoctrination and training of personnel who perform activities affecting quality.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 14 - TRAINING/CERTIFICATION

METHOD OF VERIFICATION	
14.3	**Verify that inspection/test personnel, auditors, calibration, repair personnel and similar specialists (i.e., ASME Code design personnel to ASME Section III) are qualified and have certifications on file.** **Objective Evidence required for Figure 14:** • NAME **and** JOB TITLE • INDOCTRINATION AND TRAINING COMPLETED (Yes/No) • QUALIFICATION / CERTIFICATION TYPE **and** LEVEL **Implementation Information:** Obtain a sample of personnel from Checklist Sections 2 (Design), 3 (Commercial Grade Dedication), 5 (Procurement), 8 (Tests/Inspections/Calibrations), and 12 (Internal Audits) and verify these personnel were properly qualified and/or certified for the activities they performed by review of supporting documents on file (qualification, certification and training records). **Note:** Special process personnel Qualification / Certification is addressed in Checklist Section 7. **References:** Appendix B/ANSI N45.2 Ref: (2, 9, 10, 11, 18/2, 10, 11, 12, 19) ASME Section III NQA-1 Supplement 2S-1, 2S-2, 2S-3

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESSMENT/SUMMARY: a. List the Vendor Quality Manual reference and implementing procedure(s) established to ensure that inspection/test personnel, auditors, calibration, repair personnel and similar specialists are qualified and have certifications on file.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 14 - TRAINING/CERTIFICATION

b. Describe implementation of the supplier's measures (who, what, how) to ensure that inspection/test personnel, auditors, calibration, repair personnel and similar specialists are qualified and have certifications on file.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

SECTION 14 – TRAINING/CERTIFICATION

(FIGURE 14 PERSONNEL INDOCTRINATION/TRAINING/QUALIFICATION)

NAME **and** JOB TITLE * 14.2, 14.3	INDOCTRINATION AND TRAINING COMPLETED (Yes / No) * 14.2, 14.3	QUALIFICATION / CERTIFICATION TYPE **and** LEVEL * 14.3

* Refers to applicable question.

SECTION 15 – FIELD SERVICES

METHOD OF VERIFICATION
15.1 **Verify that measures are established and implemented to control field services.** **Implementation Information:** Each checklist section must be evaluated to determine if Field Services should be addressed. If applicable, each checklist section assessment should clearly address the adequacy of controls for this area as it applies to Field Services. If the supplier controls Field Services under the same quality program which is implemented for the control of in-house activities, examples of the adequacy and implementation of the controls must be documented in each applicable section of the checklist. If the supplier has a separate quality program for Field Services, examples of the adequacy and implementation of the controls prescribed by the separate quality program should be evaluated and addressed in the applicable sections of the checklist in addition to the other (in-house) quality program requirements. **Checklist Interface:** Query the audit team members regarding applicability of field services to their assigned checklist sections. **References:** Appendix B/ANSI N45.2 Ref: 2/2 ASME Section III NQA-1 Basic Requirement 2

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

ASSESMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established to control field services.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) to control field services.

1. Verify the controls for these services have been evaluated in the appropriate sections of the checklist and list the checklist sections determined to be applicable.

Are procedural controls adequately implemented?

YES ☐ ***or***

SECTION 15 – FIELD SERVICES

NO ☐ (describe the inadequacy)

SECTION 16 – RECORDS

METHOD OF VERIFICATION	
16.1	Within the assessment/summary section of this checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
16.2	**Verify that adequate measures are established and implemented to ensure that all QA records not transferred to the member are maintained in facilities that provide storage, retention requirements and protection against environmental effects, damage and loss.**

Implementation Information:

Record storage standards recognize differing extent of storage requirements, dependent on single or dual storage. Record storage must provide protections to ensure that records are legible, identifiable, and retrievable. These protections should include environmental hazards (fire, moisture, sunlight, etc.) and controlled access.

Methods of obtaining objective evidence include:

- Query the audit team regarding the condition of any quality records which they have reviewed.
- Request the supplier to demonstrate ability to retrieve quality records from storage.
- Tour the records storage facility and sample records in storage.

10CFR21.51, "Reporting of Defects And Noncompliance – Maintenance and Inspection of Records", provides specific retention requirements for associated records:

- Evaluation of deviations and failures to comply retained a minimum of 5 years after the date of the evaluation.
- Notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification.
- Record of purchases of basic components retained for 10 years after the delivery of the basic component or service associated with a basic component.

For 10CFR52 licensed plants, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants", 10CFR21.51 requires:

- Notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of notification.
- Record of purchases purchasers for 15 years after delivery of design which is the subject of the design certification rule or service associated with the design. This pertains to applicants for standard design certification, typically NSSS suppliers (e.g. Westinghouse, AREVA, GE) and Engineering-Procurement-Construction contractors (e.g. Shaw).

Checklist Interface:

Query the audit team regarding the condition of any quality records which they have reviewed.

References:

Appendix B/ANSI N45.2 Ref: (17/18)

10 CFR 21.51

10 CFR 52

ASME Section III

NQA-1 Supplement 17S-1, 6S-1

RESULTS: ***SAT*** ☐ ***or UNSAT*** ☐ Finding(s) # _____

SECTION 16 – RECORDS

ASSESSMENT/SUMMARY:

a. List the Vendor Quality Manual reference and implementing procedure(s) established **to** ensure that all QA records not transferred to the member are maintained in facilities that provide storage, retention requirements and protection against environmental effects, damage and loss.

Are procedures listed the current revision?

YES ☐ ***or***

NO ☐ (document and provide information to the audit team member evaluating checklist Section 9.)

Are procedural controls adequate?

YES ☐ ***or***

NO ☐ (describe the inadequacy)

b. Describe implementation of the supplier's measures (who, what, how) **to** ensure that all QA records not transferred to the member are maintained in facilities that provide storage, retention requirements and protection against environmental effects, damage and loss including:

1. Records are legible, identifiable, and retrievable.
2. Records are retained and maintained per 10CFR21.51 including those for 10CFR52 licensed plants.

Are procedural controls adequately implemented?

YES ☐ ***or***

NO ☐ (describe the inadequacy)