NUCLEAR PROCUREMENT ISSUES CORPORATION (NUPIC)

NUPIC DOCUMENT NO. 11

NUPIC Joint Audit Checklist Implementation Guideline

REVISION 27

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Roger Mills Chairman

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JOINT AUDIT & CHECKLIST IMPLEMENTATION GUIDELINE

OVERVIEW:

This guideline has been developed to assist audit teams in the use of the NUPIC Audit Checklist. The checklist utilizes the philosophy and principles of EPRI NP-6630 - "Guideline for Performance-Based Supplier Audits (NCIG-16)." Each audit team member is required to thoroughly understand and adopt the NUPIC philosophy for conducting Performance Based Supplier Audits.

A performance-based audit examines both the technical and quality elements of a supplier's manufacturing/service processes to assess both the adequacy and effectiveness of the vendor's quality program. The NUPIC Audit Checklist encourages auditing effort concentrating on performance-based observations and reviews of processes and resultant objective evidence. Implementing procedures should be requested and reviewed to verify compliance to the applicable Regulations, endorsed by the supplier's QA Program, prior to the audit.

The NUPIC Audit Checklist identifies processes to be examined within each checklist section which, in total, represent an evaluation of the supplier's Quality Program adequacy and implementation. Within each checklist section are individual questions relative to the applicable processes to be evaluated. Each question provides the following tools to assist the auditor and promote performance-based auditing techniques:

- Provides a clear statement of the process to be evaluated for adequacy/implementation.
- Identifies Objective Evidence required for the corresponding Figure, when applicable.
- Provides basic implementation information, from this document.
- Identifies checklist interfaces with other audit team members to ensure information transfer, when applicable.
- Provides a standard format for the Results and Assessment/Summary sections.
- Enables working in the Results and Assessment/Summary sections without continually scrolling back to the question.

Addressing the Checklist Questions:

Review the checklist question and supporting information as provided.

- Notes
- Checklist interface

Review, prior to the audit when possible, Implementing Procedures to verify that, if implemented, they provide compliance to the applicable Regulations endorsed by the supplier's QA Program.

Note that the following information is to be placed only in the "WHITE" text box areas provided which will expand as you enter information.

"RESULTS" section:

Identify in the "RESULTS" section, the results of your evaluation (Satisfactory, Finding(s)/Deficiency(s), or Not Applicable), by clicking (double click) on the appropriate checkbox and selecting "checked" under the Default Field Value option. If checklist section is "Not Applicable", please provide the N/A basis in the "Findings/Deficiencies (current) section text box.

"FINDINGS/DEFICIENCIES (current)" section text box:

If Finding(s)/Deficiency(s) are identified within the checklist section, please provide the description of each finding/deficiency write-up. List finding(s) write-up first, then deficiency(s) write-up after.

"FINDINGS/DEFICIENCIES (previous)" section text box:

If the previous NUPIC Audit identified Finding(s)/Deficiency(s) in the checklist section, please provide the description of each finding/deficiency write-up. List finding(s) write-up first, then deficiency(s) write-up after.

"ASSESSMENT/SUMMARY" section text boxes:

a. List the Vendor Quality Manual reference and implementing procedures reviewed for the checklist section. Implementing procedures should include revision/date and follow after the Quality Manual reference.

b. Describe implementation of the supplier's measures being evaluated (who, what, how), including any specific (numbered/bulleted) items listed under "Describe implementation". Implementation description should include observation of processes as they are being performed and/or observations of completed documentation resulting from performance of those processes. Completed documentation review should be accompanied by interview of those responsible for producing the documentation.

c. Indicate (YES/NO) if the procedural controls are adequate (i.e. provide compliance to the applicable Regulations, endorsed by the supplier's QA Program, if implemented) and are the current revision, by clicking (double click) on the appropriate checkbox and selecting "checked" under the Default Field Value option. If, "NO" is selected describe in "Finding(s)/Deficiency(s) current" section text box.

d. Indicate (YES/NO) if procedural controls are adequately implemented by clicking (double click) on the appropriate checkbox and selecting "checked" under the Default Field Value option. If, "NO" is selected describe in "Finding(s)/Deficiency(s) current" section text box. If implementation of the procedure/program controls has not occurred since the previous audit, check the "N/A" box and provide this basis in section "b." of the Assessment/Summary regarding implementation of these controls.

Complete each checklist section as described on the previous two pages.

RESULTS:	SAT ☐	FINDING(s)/DEFICIENCY(s) ☐	N/A ☐ Describe basis in box below.
FINDINGS/DEFICIENCIES: *(current)*			
FINDINGS/DEFICIENCIES: *(previous)*			
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:	
	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 2. Documentation, customer notification, and customer approval of any exceptions to the purchase order/contract technical and quality requirements, including design changes.	
	c.	Are procedural controls adequate and procedure revision current? *YES* ☐ *or NO* ☐ (describe in Findings/Deficiencies current section above)	
	d.	Are procedural controls adequately implemented? *YES* ☐ *or NO* ☐ (describe in Findings/Deficiencies current section above) *or N/A* ☐	

Provide any checklist objective evidence interface information to the appropriate audit team member(s).

Checklist "Do's" and "Do Not's":

- Do request and review, prior to the audit when possible, Implementing Procedures to verify that, if implemented, they provide compliance to the applicable Regulations endorsed bythe supplier's QA Program.

- Do describe implementation of the supplier's measures (who, what, how), for the process being evaluated. The Assessment/ Summary should describe observations of processes as they are being performed and/or observations of completed documentation resulting from performance of those processes. Both direct observation and documentation review are considered performance-based auditing techniques, but must be biased to the nature of products/services being provided. Direct observation is preferable for products being manufactured, assembled, tested, calibrated, etc., while documentation review may be more appropriate for products which are documentation, such as engineering services. Documentation review should be accompanied by interview of those responsible for producing the documentation.

- Do Not copy the Supplier's implementing procedure requirements into the Assessment/Summary. The commentary should describe the implementation of those requirements.

- Do ensure that any NO ☒ or N/A ☒ checkbox is accompanied by additional information/findings/deficiencies/etc.

- Do Not remove or revise any existing checklist text. Information is to be placed only in "WHITE" text box areas provided.

Objective Evidence Documentation:

Figures for documentation of objective evidence do not exist for every checklist question. Any objective evidence reviewed which is not identified on Figures must be documented, with appropriate examples, in the Assessment/Summary sections of the checklist questions.

Not-Applicable Checklist Sections – Summary Sheet:

Audit Checklist sections (including Figures), determined to be "not applicable", are not required to be included in the final audit package provided the section non-applicability justificationbasis is clearly documented on Page 2 of the checklist Summary Sheet. The following examples illustrate the correct and incorrect application of this requirement.

Correct:

The supplier's scope of work may not include Design, Software Quality Assurance or Field Services. On the appropriate row/column for these sections on Page 2 of the Checklist Summary Sheet enter a comment such as:

"N/A – The supplier's scope of work does not include this activity. Therefore, this section has been eliminated from the checklist."

Incorrect:

"N/A – The supplier has not performed any of these activities since the previous audit."

If this is determined to be the case, the appropriate controls for those applicable activities must still be addressed to show that an adequate program is in place should the occasion arise when these activities require implementation.

Addressing Field Services:

If Field Services are within the supplier's scope of supply (i.e., the supplier performs services at the customer's facility under the supplier's Quality Program controls), each checklist section must also address the adequacy of controls as they apply to Field Services.

If the supplier has a separate Quality Program for Field Services, the controls provided by the separate Quality Program should be evaluated and addressed in the applicable sections of the checklist, in addition to the primary Quality Programcontrols.

Checklist question 15.1 is intended to document a description of the Field Services provided by the supplier and an overall assessment verifying that the applicable sections of the checklist adequately evaluate Field Services. The assessment should also list the checklist sections determined to be applicable to the Field Services provided by the supplier.

Other Considerations:

- The sequence in which the Audit Checklist is executed may be varied and is to be determined by the Audit Team Leader.
- The use of the symbol "/" in the Audit Checklist signifies an "and/or" statement.
- All Figures must be annotated; blanks are not acceptable.
- Figures requiring a “Yes or No” to be entered should include an explanation when “No” is entered.
- As applicable to the observation, review, etc., include a description of the sample size chosen (a small sample size may be warranted but may need to be qualified) and make a reference to the checklist Figure where the objective evidence isrecorded.

Guideline Applicability:

The remainder of this guideline provides supplementary guidance information based on complexity of each checklist question and availability of existing Industry guidance (EPRI, NEI, etc.).

The detail of information provided is intended for understanding by a qualified NUPIC audit team member with lead auditor qualification and basic experience.

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.** **References:** Appendix B/ANSI N45.2 - (3/4) ASME Section III NQA-1 Requirement 3

SUPPLEMENTARY GUIDANCE:

Objective evidence can be obtained through a sample of utility customer purchase orders since the last NUPIC audit identifying specific contract technical and quality requirements. After these requirements are identified, review the supplier's corresponding control documents to assure these requirements have been incorporated.

If the supplier has taken any exceptions with the utilities' purchase order requirements, describe how this was communicated to, and approved by, the utility.

Objective Evidence required for Figure 1:

- Customer Purchase Order/Contract Number and Date
- Item/Service Description and Part number (as applicable)
- Supplier Control Documents (work orders, travelers, drawings, etc.) and verification (Yes/No) of translation from Customer Purchase Order/Contract Number
- Customer Approval of Exceptions (Yes/No)

Implementation Information:

Technical and quality requirements may include description, part numbers, tests/inspections, documentation, CofC, packaging/shipping, hold points, materials, etc.

Supplier control documents may include order review forms, travelers, shop work orders, work tracking documents, etc.

METHOD OF VERIFICATION	
1.3	**Verify that measures are established and implemented for control of items returned from the customer for repair/rework.** **Checklist Interface:** Provide any related supplier nonconformance information to the audit team member evaluating checklist Section 11. **References:** Appendix B/ANSI N45.2 - (15/16) ASME Section III NQA-1 Requirement 15

SUPPLEMENTARY GUIDANCE:

Objective evidence can be obtained through a sample of items returned by the utility customer since the last NUPIC audit verifying these items are being controlled in accordance with the supplier's process.

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.

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.** **References:** Appendix B/ANSI N45.2 - (6/7) (17/18) ASME Section III NQA-1 Requirement 17

SUPPLEMENTARY GUIDANCE:

For the utility customer purchase orders reviewed in checklist questions 1.2 & 1.3, objective evidence can be obtained through review of the final document packages to assure the utilities' specific documentation requirements have been met by the supplier. This could vary from a simple verification of the Certificate of Conformance to a complex data package review, dependent on utility requirements.

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 nonconformances including the resolution.

SECTION 1 – CONTRACT REVIEW (FIGURE 1)

SECTION 1 – CONTRACT REVIEW
(FIGURE 1)

CUSTOMER P.O. CONTRACT NUMBER **and** DATE	ITEM/SERVICE DESCRIPTION **and** PART NUMBER (as applicable)	SUPPLIER CONTROL DOCUMENTS (work orders, travelers, drawings, etc.) **and** CORRECT TRANSLATION TO SUPPLIER CONTROL DOCUMENTS (Yes/No)	CUSTOMER APPROVAL OF P.O. / CONTRACT EXCEPTIONS (Yes/No/N/A)
* 1.2	* 1.2	* 1.2	* 1.2
List: Member Utility Name, Purchase Order or Contract Number, and date PO was generated	List: Product description parameters which describe the product or services and part number.	List: The supplier's documents that translate the requirements. State: If Purchase Order/Contract Requirements were translated correctly by stating Yes or No.	Answer Yes: If there were exceptions and these were documented and approved by the utility. Answer No: If there were exceptions and these were not approved by the utility. Assure this is documented in attribute 1.2(b) and action taken by the team. Answer N/A: If there were no exceptions taken.
* 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.** **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 - (3/4) ASME Section III NQA-1 Requirement 3

SUPPLEMENTARY GUIDANCE:

In many instances, the design requirements do not come from the utility customer but reside with the supplier. Any utility specified design requirements are typically identified or referenced in the utility purchase orders. Dependent on the nature of the product/service requested, the utility purchase order may not include detailed design input, such as with purchasing a replacement part/component of a legacy design which may only be identified in the utility purchase order by brief description and part number associated with the supplier's design. More extensive utility design inputs would be anticipated in purchase orders to suppliers such as engineering service providers supporting utility design change packages, component obsolescence, etc.

Objective evidence can be obtained by requesting design documentation from the supplier, relative to items identified in utility customer purchase orders, and/or any utility customer design requirements identified in the utility purchase orders.

Objective Evidence required for Figure 2:

- Customer/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 information which identifies the specific functions to be performed and specific values/ranges of values for controlling parameters, chosen as reference bounds of design.

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.** **References:** Appendix B/ANSI N45.2 - (3/4) ASME Section III NQA-1 Requirement 3		
RESULTS:	***SAT*** ☐	***FINDING(s)/DEFICIENCY(s)*** ☐	***N/A*** ☐ Describe basis in box below.

SUPPLEMENTARY GUIDANCE:

Any “processes” should undergo a controlled qualification for use in safety related applications. 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.

METHOD OF VERIFICATION	
2.4	**Verify that measures are established and implemented for the identification and control of design interfaces.** **Checklist Interface:** Identify any subcontracted design service suppliers to the audit team member evaluating Checklist Section 5. **References:** Appendix B/ANSI N45.2 - (3/4) ASME Section III NQA-1 Requirement 3

SUPPLEMENTARY GUIDANCE:

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.

METHOD OF VERIFICATION	
2.5	**Verify that measures are established and implemented for the verification of design adequacy**. **References:** Appendix B/ANSI N45.2 - (3/4) ASME Section III NQA-1 Requirement 3

SUPPLEMENTARY GUIDANCE:

If design verification was performed by qualification testing, verify the prototype was tested under the most adverse conditions required by the design, such as, normal/abnormal service conditions and design basis events service conditions.

Objective Evidence required for Figure 2:

- Method of Design Verification

METHOD OF VERIFICATION	
2.6	**Verify that measures are established and implemented to control design changes including changes for spare/replacement parts.** **References:** Appendix B/ANSI N45.2 - (3/4) ASME Section III NQA-1 Requirement 3

SUPPLEMENTARY GUIDANCE:

Controls must ensure that any environmental/seismic qualification, which served as a basis for the original design, remains valid for the design change or is re-performed. Design change packages should include this documentation.

Objective Evidence required for Figure 2:

- Design Change Control and Revision and/or Date

SECTION 2 – DESIGN (FIGURE 2)

CUSTOMER/SUPPLIER DESIGN INPUT **and** BASES	SUPPLIER DESIGN DOCUMENT	DESIGN INPUTS CORRECTLY INCORPORATED (Yes/No)	METHOD OF DESIGN VERIFICATION	DESIGN CHANGE CONTROL **and** REV / DATE
* 2.2	* 2.2	* 2.2	* 2.5	* 2.6
Record the source (Utility/Supplier) and design bases identified that apply (i.e. Codes/code requirements, calculations, EQ qualifications report, Seismic Report, etc.	Record the document (e.g., drawings, specification, calculations, etc.) used to translate design requirements.	Indicate by Yes/No if inputs are incorporated. Explain any "No" answer.	Record the Method of design verification (i.e., design review, alternate calculation, or test).	Record change document used (i.e., EC"s, customer approvals, drawings, etc.) and revision/date.
Example Below				
ASME Section III, 1980 Edition including Winter Addenda, Class 2 per ANSI B16.34 1977 Special Class FP&L Design PV-156, Rev. 0 Reference PO XXXX	Drawing D-123789 Rev. 2 Pneumatic Valve, Plug Type, Globe Pattern, 5/16 Dia. Orifice, ANSI 1500 SPL, Bellows Seal, Air to Open Operator	Yes	Design Review and Test	ECN No. 01 dated 01/04/03
* 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.** **Note:** 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 - (3/4) ASME Section III NQA-1 Requirement 7

SUPPLEMENTARY GUIDANCE:

When the accepting entity has access to and sufficient knowledge of the design requirements, they can accept commercial grade items with no dedication by ensuring (through the use of traditional quality activities included in 10CFR50, Appendix B) that the item they are accepting for use/designating as a basic component meets the design requirements.

The accepting entity may also use an integrated approach to accept commercial grade items. In this situation, the accepting entity has access to and sufficient knowledge of the design requirements. However, instead of accepting the item by ensuring the item meets design requirements through the use of traditional quality activities included in 10CFR50 Appendix B, dedication methodology is used to accept the item as follows:

The dedicating entity uses commercial grade dedication to ensure that the item meets design requirements by documenting the design requirements as the critical characteristics in a technical evaluation which does not require identification of safety function(s).

or

In lieu of using the design requirements as critical characteristics, the dedicating entity identifies critical characteristics based upon identifying safety function(s) and performing a failure modes and effects analysis (FMEA).

Failure modes and effects analysis (FMEA) is not required when the dedicating entity has access to and sufficient knowledge of the design requirements and is utilizing the design requirements as the critical characteristics for verification to ensure the item will meet design and thereby perform its intended safety function.

The basis for the selection of critical characteristics be documented in the technical evaluation. The technical evaluation needs to document how the critical characteristics selected will provide reasonable assurance that the item will perform its intended safety function(s) when verified. This is especially important in order to verify that adequate critical characteristics have been selected to address each credible failure mode identified in the technical evaluation.

Commercial material (unqualified source material) that has been previously upgraded as ASME material per the requirements of ASME Section III NCA-3855.1 (ASME Section III NCA-4255.1 for the 2017 Code edition) but will be used in non-ASME safety related applications does not require a documented technical evaluation as a commercial grade dedication. The commercial material has already been accepted using controls applicable to 10CFR50 Appendix B to verify the design (i.e., material specification) requirements for the material that was upgraded.

Additional guidance on commercial grade dedication may be obtained from EPRI 3002002982, “Acceptance of Commercial Grade Items for use in Nuclear Safety-Related Applications”.

Objective Evidence required for Figure 3A:

- Item Description, P/N, S/N, Model No., Software Name/ID, No., etc. (List items/services dedicated using Method 1 only or in combination with Methods 2, 3, 4.)
- 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 must 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 must be verified that ensures the seismic/environmental qualification of the item has been maintained.

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**. **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 - (10, 11/11, 12) ASME Section III NQA-1 Requirement 10, 11

SUPPLEMENTARY GUIDANCE:

The technical basis for the selection of sample plans used to verify critical characteristics should be documented describing the rationale used to conclude that the sample plan selected would ensure that the sample size is appropriate for and representative of the quantity/lot of the items being dedicated. The technical basis must be more than a simple statement such as "… the sample plan used is based on the Normal sample plan contained in EPRI TR-017218-R1." Such statements just identify the sample plan that will be used but provides no justification as to why that sample size selected is acceptable for verifying the critical characteristics of the lot/batch of items being dedicated. For example, lot formation/homogeneity are important aspects when determining appropriate sample size and should be included in the basis of the sample plan selection. Confidence in lot homogeneity can be directly related to how the lot is formed. For instance, if production traceability exists for a given lot size, a high degree of lot homogeneity would be expected. However, if the lot is only traceable to a specific purchase order line item and different product manufacturers might have produced the items; there would be reduced confidence in lot homogeneity.

Where there is reduced confidence in lot homogeneity, larger sample sizes should be considered. This is just an example of one thought process that supplier's should be utilizing and documenting in their technical basis when selecting sample plans for verification of critical characteristics. Other considerations include procurement of the items from OEMs vs distributors, onsite assessments of sub-tier supplier material controls, item performance history, and safety significance/complexity of the item. These considerations should be included in the technical basis as appropriate to support the selection of the sample plan.

Additional guidance on commercial grade dedication may be obtained from EPRI 3002002982 "Acceptance of Commercial Grade Items for use in Nuclear Safety-Related Applications."

Objective Evidence required for Figure 3A:

- Inspection/Test Procedure and Revision and/or Date
- Inspector/Tester Name/Stamp
- ID Number of M&TE used
- Results SAT or UNSAT (record NCR No. if UNSAT)

Implementation Information:

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.

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.** **Checklist Interface:** Identify the Auditors or Inspectors (Source) to the audit team member evaluating Checklist Section 14. **References:** Appendix B/ANSI N45.2 - (10, 11/11, 12) ASME Section III NQA-1 Requirement 10, 11

SUPPLEMENTARY GUIDANCE:

Additional guidance on commercial grade dedication may be obtained from EPRI 3002002982 “Acceptance of Commercial Grade Items for use in Nuclear Safety-Related Applications”.

Objective Evidence required for Figure 3B:

- Scope of Item/Service Requiring Dedication
- CGI Supplier Name and Location
- Commercial Grade Survey (Method 2) or Source Verification (Method 3) and Date(s) Performed
- 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.

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.** **Note:** Only implementation of the requirements listed in NEI 14-05-A, Revision 1 are considered acceptable for use of the ILAC accreditation process to accept commercial grade calibration and testing services. The APS SER is no longer usable and NEI 14-05A, Revision 0 are no longer valid. **Checklist Interface:** Coordinate with the audit team member evaluating Checklist Section 5 to review purchase orders issued by the supplier for accredited calibration and testing services. **References:** Appendix B/ANSI N45.2 - (3, 10, 11/ 4, 11, 12) ASME Section III NQA-1 Requirement 3, 10, 11

SUPPLEMENTARY GUIDANCE:

NEI 14-05-A, Revision 1 provides the NRC recognized methodology for implementation of the ILAC Accreditation Process. NEI 14-05-A, Revision 1 supersedes NEI 14-05A, Revision 0 effective June 2, 2021.

If it is determined that a supplier is still implementing the APS SER a discussion should be held with the supplier to explain why implementing the APS SER is no longer acceptable. While an audit deficiency or finding may not be necessary, the supplier's continued use of the APS SER must be clearly communicated to the NUPIC Membership in the associated audit report. This communication is needed so that Member Utilities can make the use of NEI 14-05-A, Revision 1 (and the associated caveats) special procurement requirements/ conditions. It is recommended that the "Unique Order Entry Requirement" Section of the Audit Report is utilized to communicate the supplier's continued use of the APS SER along with a recommendation for utilities to invoke use of NEI 14-05-A, Revision 1 in their purchase orders to the supplier.

Suppliers can implement NEI 14-05-A, Revision 1 provided the appropriate QA manual and/or procedures are changed. The methodology of using accreditation in lieu of performing a commercial-grade survey must be documented in a supplier's QA program prior to use. For most suppliers, this methodology could be documented in their QA manual and/or applicable procedures. However, suppliers that have a topical report that is reviewed and approved by the NRC (such as Nuclear Steam Supply Services (NSSS) and Engineering Procurement and Construction (EPC) Suppliers) must have the methodology prescribed in their topical report similar to licensees. NEI 14-05-A, Revision 1, Appendix A provides acceptable wording which can be inserted in a supplier's QA manual and/or procedures as appropriate. Under NEI 14-05-A, Revision 1, the accrediting body that accredits a given laboratory to ISO/IEC 17025:2017 must be an Accreditation Body (AB) that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). A list of Accreditation Bodies that are signatories to the ILAC MRA is posted on the NUPIC website under the Supplier Information

– Hot Topics Tab.

If a supplier is utilizing accreditation for acceptance of commercial grade calibration or testing services based on NEI 14-05-A, Revision 1, the process for using these services via accreditation must be documented as a commercial grade dedication. The supplier must have a technical evaluation documented which includes the safety function and critical characteristics of calibration and testing services. NEI 14-05-A, Revision 1 identifies the critical characteristics for calibration and testing services. The use of a supplier's accreditation is essentially being used as the method of verifying a supplier satisfactorily controls the critical characteristics. NEI 14-05- A, Revision 1 includes a sample technical evaluation/commercial grade dedication plan for commercial grade calibration services and one for commercial grade testing services. While use of these templates are not required, the templates do present acceptable technical evaluations for the dedication of these services.

Objective Evidence required for Figure 3C:

- CGI Supplier Name and Location
- Accrediting Body Name, Certificate Number and Expiration Date
- Scope of Accreditation (Calibration or Testing Service)
- Dedication Technical Evaluation Completed and Satisfactory (Yes/No)
- Documented Review of Accreditation Completed and Satisfactory (Yes/No)
- Receipt Inspection of Accredited Calibrations Satisfactory (Yes/No) NOTE: ASME

Nuclear Suppliers, NCA-3300 and NCA-4000 Programs

The ASME Code includes ISO17025 accreditation language. NCA-3126/NCA-3127 and NCA- 4255.3 both 2019 and 2021 editions contain the requirements for alternate use of ISO17025 accreditation alternate to audits or surveys of calibration/testing suppliers. Neither mentions CGID or the terms technical evaluation. Be aware of the differences and ensure that the suppliers that have used the ASME Code process have incorporated all the NRC required elements as well. Refer to the current revision to NEI 14-05A.

Implementation Information:

The process for accepting accreditation to ISO/IEC 17025:2017 by an acceptable Accreditation Body (AB) must be proceduralized including reference to NEI 14-05-A, Revision 1. This process can be used for accepting both calibration and testing services provided the laboratory is accredited by an Accreditation Body which is signatory to the ILAC MRA. This includes both domestic and international laboratories. The process cannot be used to dedicate Non-destructive Examination (NDE) services. In addition, subcontracting of accredited services is prohibited. The laboratory that is contracted to perform the required accredited calibration or testing must perform the service and cannot subcontract the services to another accredited laboratory.

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

Implementation of the process must include the following:

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 17025:2017.

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. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

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, Accreditation Body (AB) name and logo (when required by accrediting body), 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 17025:2017 program and accredited scope, and a statement certifying that the purchase order requirements were met.

SECTION 3 – COMMERCIAL GRADE DEDICATION (FIGURE 3A)

COMMERCIAL GRADE ITEMS / METHOD 1 ACCEPTANCE					
ITEM/SERVICE DESCRIPTION P/N, S/N, MODEL #, SOFTWARE NAME/ID #, ETC. (Note 1)	CRITICAL CHARACTERISTICS **and** METHOD(s) OF DEDICATION FOR EACH (Note 1)	INSPECTION/ TEST PROCEDURE **and** REV / DATE (Method 1 only)	INSPECTOR/ TESTER NAME / STAMP (Method 1 only)	ID # OF M&TE USED (Method 1 only)	RESULTS SAT or UNSAT (record NCR # if UNSAT) (Method 1 only)
* 3.2, 3.3, 3.4, 4.5	* 3.2, 3.3, 3.4, 4.5	* 3.3, 4.5	* 3.3, 4.5	* 3.3, 4.5	* 3.3, 4.5
Enter description and, as applicable, Software Name/ID number, etc., part number, serial number, model number, etc. of the item evaluated	List the critical characteristics identified by the supplier. Report method used for dedication of critical characteristics (i.e., test and inspection, CG survey, source verification, etc.)	List procedure number, revision and or date used to perform activities.	List inspection/test personnel that performed the activity.	Record the ID number of the M&TE used.	Enter SAT or UNSAT for results. If UNSAT, record NCR number if applicable.
Note: These attributes are to be addressed only for Method 1. When Method 2 or 3 is employed, Checklist Attribute 3.4 and Figure 3B are to be completed. Use of ILAC accreditation for dedication of calibration and/or testing services is evaluated in Checklist Attribute 3.5 and Figure 3C only.					
* Refers to applicable question Note 1: List items/services dedicated using Method 1 only or in combination with Methods 2, 3, 4.					

SECTION 3 – COMMERCIAL GRADE DEDICATION (FIGURE 3B)

SURVEYS / SOURCE VERIFICATION – METHODS 2 AND 3					
SCOPE OF ITEM/SERVICE REQUIRING DEDICATION (Note 1)	CGI SUPPLIER NAME **and** LOCATION	COMMERCIAL GRADE SURVEY (Method 2) **or** SOURCE VERIFICATION (Method 3) **and** DATE(s) PERFORMED	AUITORS (Method 2) **and/or** INSPECTORS (Method 3)	CRITICAL CHARACTERISTICS (CC) VERIFIED (Note 2)	DO CC(s) VERIFIED MATCH THOSE SPECIFIED IN TECHNICAL EVALUATION/ DEDICATION PLAN (Yes/No)
* 3.4, 4.5	* 3.4, 4.5	* 3.4, 4.5	* 3.4, 4.5	* 3.4, 4.5	* 3.4, 4.5
List the scope of supply for which the supplier was evaluated (i.e. what component, part, material or service is being supplied).	List the name, city and state of the supplier.	List the evaluation Method, Commercial Grade Survey or Source Verification number and the date(s) the activities were performed.	List the auditor(s) that performed the survey. If source verification was used, list the title or function of personnel performing the verification activity (e.g. inspector, engineer, etc.)	List the specified critical characteristics which were verified by the Method 2 or 3 verification activity.	Does the CCs verified by the CG Survey, or source verification match those specified to be verified by these Methods in the Technical Evaluation and Dedication Plan? Enter Yes or No. If No, explain in the Assessment Summary section of Attribute 3.4.

* Refers to applicable question

Note 1: List Items/Services being dedicated using Method 2 or 3.

Note 2: Critical characteristics, listed on this figure, should match those verified using Method 2 or 3, as listed on Figure 3A, when the item/service is being dedicated using Method 1 in combination with Methods 2 or 3.

SECTION 3 – COMMERCIAL GRADE DEDICATION (FIGURE 3C)

ILAC ACCREDITATION ACCEPTANCE					
CGI SUPPLIER NAME **and** LOCATION	ACCREDITING BODY NAME CERTIFICATE # **and** EXPIRATION DATE	SCOPE OF ACCREDITATION (Calibration or Testing Service)	DEDICATION TECHNICAL EVALUATION COMPLETED **and** SATISFACTORY (Yes/No)	DOCUMENTED REVIEW OF ACCREDITATION COMPLETED **and** SATISFACTORY (Yes/No)	RECEIPT INSPECTION OF ACCREDITED CALIBRATIONS SATISFACTORY (Yes/No)
* 3.5	* 3.5	* 3.5	* 3.5	* 3.5	* 3.5
List the name, city, and state of supplier.	List the Accrediting Body name, certificate number and expiration date.	List the scope of accreditation for type of service provided by the supplier (i.e. Calibration or Testing Service).	Indicate by Yes/No if the dedication of the technical evaluation was completed and satisfactory by the supplier. Explain if No.	Indicate by Yes/No if a documented review of Accreditation was completed and satisfactory by the supplier. Explain if No.	Indicate by Yes/No if the receipt inspection of Accredited Calibrations were completed and satisfactory by the supplier. Explain if No.
* 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, and procedures) are established and implemented to control the quality of software (including firmware).** **References:** Appendix B/ANSI N45.2 - (3/4) ASME Section III NQA-1 Requirement 3, 11, 17 and Subpart 2.7

SUPPLEMENTARY GUIDANCE:

This question evaluates the overall adequacy and implementation of the supplier's quality program for the control of safety-related software (i.e., software, firmware, digital, etc.). The scope of question 4.2 is intended to be broad. The question is used to determine if the supplier has a software quality program and what activities of the software lifecycle process are involved. First, identify the supplier's software applications, which may include digital control components, and their origin (purchased or developed in-house). The extent of controls should be explained in this question and is dependent on the nature and complexity of the software application and how it supports the supplier's products or services. As examples:

A software development firm that is providing nuclear safety-related software applications should have an established program that meets the necessary requirements of 10CFR50, Appendix B and provides a complete life cycle model that includes requirements phase, design phase through retirement phase.

A component or service supplier that utilizes software (i.e., pump manufacturer for flow calculations or engineering firm for design) should have a program in place to address how software is used. This may not include lifecycle phases such as design of software but may include acceptance testing, configuration management, operation, and retirement.

The complexity and whether the supplier is a purchaser or developer of the software dictates how much of the software life cycle is involved.

Determine if the supplier has developed a "Plan" for software quality appropriate to the software applications identified. As described in the checklist question, "Plans" may be unique to each project, may exist as a generic document (procedure), or may be incorporated into the overall QA program. Determine if the lifecycle is identified and is appropriate to the nature and complexity of the software application.

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.). Verify that verification reviews are performed by individuals other than those who designed the software. As described in the checklist question, typical lifecycle activities for developed software include 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. For purchased software, the software typically enters the purchaser's organization at the beginning of the installation and checkout phase but would include acceptance testing.

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.

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.** **References:** Appendix B/ANSI N45.2 - (4/5, 7/8) ASME Section III NQA-1 Requirement 11 and Subpart 2.7

SUPPLEMENTARY GUIDANCE:

This question evaluates the adequacy and implementation of the supplier's quality program for control of acceptance testing of software and firmware. The question applies to software applications developed by the supplier and software applications purchased by the supplier.

Acceptance testing activities should demonstrate that the software application adequately and correctly performs all intended functions. Test plans, test cases, and test results should be documented, reviewed, and approved.

Acceptance testing is the culmination of testing processes which result in documentation of the approval of the software for operational use.

Following is a listing of various test types which may be encountered:

- Independent Testing – Independent testing is the process of using skilled testers who are not part of the application development team to test theapplication.
- Unit Testing - Unit tests are test of individual software components usually conducted with test drivers, which are special code written just to cause the component to execute.
- Integration Testing - Integration testing is the processes of putting the software pieces together and seeing how well they work together.
- System Testing - System testing is the first point in the testing process in which the total software product can be reviewed in a realisticsetting.

Two approaches are permitted for use of software in design:

- "preverified" per NQA-1a-2009,Requirement 3:
- "results verified as part of the report" – per NQA-1a-2009, Requirement 3, Section 401

The processes should be described in governance and not addressed ad-hoc. Results verified puts the burden of software QA activities on the analyst preparing the work and the verifier. Reasonable approach for simple software or software whose results are obvious to verify but not for complex software.

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 correlations

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

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.** **Note:** Configuration management also applies to backups, maintenance, disaster recovery, and virus protection. **References:** Appendix B/ANSI N45.2 - (3/4) ASME Section III NQA-1 Requirement 3 and Subpart 2.7

SUPPLEMENTARY GUIDANCE:

This question evaluates the adequacy and implementation of the supplier's quality program for establishing and maintaining configuration baseline and associated changes to the software product.

These changes would include enhancement requests from the customer, revision to software based on the design requirements, changes to the operating environment, or reported software problems that must be corrected.

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 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 includes documentation of the approved configuration, the status of proposed changes to the configuration and the status of approved changes to the configuration.

METHOD OF VERIFICATION	
4.5	**Verify measures are established and implemented for the procurement or acquisition of software (safety related or commercial grade).** **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 - (3/4, 4/5, 7/8) ASME Section III NQA-1 Requirement 4, 7, 11 and Subpart 2.7

SUPPLEMENTARY GUIDANCE:

This question assures the supplier has developed and implemented a program for purchasing software as safety related or as commercial-off-the-shelf (COTS) to be dedicated as a “basic component” and should be performed in concert with checklist sections 3 and 5. This includes software development tools for software application developers, and software applications for manufacturing and service supplier use.

For commercial-off-the-shelf (COTS) software, original software design requirements are not always available. Acceptance testing, as addressed in checklist question 4.3, should be performed on these applications. This commercial-off-the-shelf (COTS) software also requires procurement control under the commercial grade dedication process. This includes identification of critical characteristics and methods of acceptance described in EPRI NP-5652. Commercial Grade Dedication of software is addressed in section 3 of the checklist.

Otherwise acquired software comes with limited or no contractual obligation therefore the burden to demonstrate suitability through commercial grade dedication remains entirely with the supplier. Acquired software expands the scope of software acquired through procurement agreements to include software provided at no cost to the supplier (regardless or source) and those whose contract terms do not explicitly address the software such as those provided through partnership agreements or group memberships.

Cautionary note, use of commercial grade dedication for process software that or for embedded software may not be permitted. (this is a US NRC note for the endorsement of NQA-1)

Discuss objective evidence identified in this question with audit team members responsible for checklist sections 3 and 5, as applicable.

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

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

Implementation Information:

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.).

Otherwise acquired software – this includes computer programs not obtained using procurement requirements of Part I, such as freeware, shareware, and computer programs from corporate repositories. This is excerpted from ASME NQA-1-2017, Part II, Subpart 2.7, Section 302.

METHOD OF VERIFICATION	
4.6	**Verify that problem reporting measures are established and implemented to assure that software errors and failures from both internal and external sources are identified, documented, evaluated, resolved, and assessed for impact on past and present applications.** **References:** Appendix B/ANSI N45.2 - (15/16) ASME Section III NQA-1 Requirement 16 and Subpart 2.7

SUPPLEMENTARY GUIDANCE:

This question evaluates the adequacy and implementation of the supplier's quality program for documenting software errors/failures and should include Part 21 evaluation for safety related applications. Errors are conditions deviating from an established baseline, including deviations from the current approved application and its baseline requirements.

Objective Evidence required for Figure 4:

- Error Notice Date and Status (Open/Closed)

METHOD OF VERIFICATION	
4.6	**Verify that problem reporting measures are established and implemented to assure that software errors and failures from both internal and external sources are identified, documented, evaluated, resolved, and assessed for impact on past and present applications.** **References:** Appendix B/ANSI N45.2 - (15/16) ASME Section III NQA-1 Requirement 16 and Subpart 2.7

SUPPLEMENTARY GUIDANCE:

This question evaluates the adequacy and implementation of the supplier's quality program for control of software packaging and shipping. These processes are primarily applicable to software developers providing software applications to customers.

Repositories should be backed up to protect from unintentional damage.

Duplication process should be validated to assure the approved application is transferred to the appropriate media. In some cases, a new or upgraded application can be downloaded from a supplier's File Transfer Protocol (FTP) site or Internet web page.

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 - (13, 14/14, 15) ASME Section III NQA-1 Requirement 13

SUPPLEMENTARY GUIDANCE:

This question evaluates the adequacy and implementation of the supplier's quality program for control of software packaging and shipping. These processes are primarily applicable to software developers providing software applications to customers.

Repositories should be backed up to protect from unintentional damage. Duplication process should be validated to assure the approved application is transferred to the appropriate media. In some cases, a new or upgraded application can be downloaded from a supplier's File Transfer Protocol (FTP) site or Internet web page.

SECTION 4 – SOFTWARE (FIGURE 4)

SOFTWARE PROGRAM (NAME, #, REV / DATE)	METHOD OF ACCEPTANCE TESTING **and** DATE	ERROR NOTICE IDENTIFICATION DATE **and** STATUS (OPEN / CLOSED)
* 4.2, 4.4	* 4.2, 4.3	* 4.6
List software by name, number, rev/date.	Identify the method used for acceptance testing of the software (i.e., hand calculation, other programs, etc. including the date of the acceptance testing.	Record error notice ID number and date. Indicate error notice status. (i.e., Open/Closed)
* 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.** **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 17025:2017 by Accreditation Bodies that are a signatory to the ILAC MRA, procurement document requirements must include: • The service must be provided in accordance with their accredited ISO/IEC 17025:2017 program and scope of accreditation. • 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)***. • The equipment/standards used to perform the calibration must be identified in the certificate of calibration ***(for calibration services only)***. • The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation. • 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. • Subcontracting of these accredited services is prohibited. • Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the Accreditation Body within the past 48 months. **Note 2:** The APS SER is no longer usable and NEI 14-05A, Revision 0 are no longer valid. Implementation of the ILAC accreditation process is based on NEI 14-05-A, Revision 1. **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 - (4/5) ASME Section III NQA-1 Requirement 4

SUPPLEMENTARY GUIDANCE:

Obtain a sample of Purchase Orders representing a cross section of products (parts, components, etc.) or services (testing, calibration, etc.), purchased by the supplier, which provide the scope of supply bounded by the NUPIC audit.

If the supplier utilizes accreditation in lieu of commercial grade surveys for domestic and international commercial calibration and testing service from sub-suppliers, procurement documents must include the requirements identified in the applicable Notes within this question.

NOTE: ASME Nuclear Suppliers, NCA-3300 and NCA-4000 Programs

The ASME Code includes ISO17025 accreditation language. NCA-3126/NCA-3127 and NCA- 4255.3 both 2019 and 2021 editions contain the requirements for alternate use of ISO17025 accreditation alternate to audits or surveys of calibration/testing suppliers. Neither mentions CGID or the terms technical evaluation. Be aware of the differences and ensure that the suppliers that have used the ASME Code process have incorporated all the NRC required elements as well. Refer to the current revision to NEI 14-05A.

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
- 10CFR50 Appendix B
- 10CFR21 applicability

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.** **Note:** Content of CGI surveys is addressed in Checklist Question 3.4. 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 - (7/8) ASME Section III NQA-1 Requirement 7

SUPPLEMENTARY GUIDANCE:

Obtain a sample of Purchase Orders representing a cross section of products (parts, components, etc.) or services (testing, calibration, etc.), purchased by the supplier, which provide the scope of supply bounded by the NUPIC audit.

- Ensure the purchase order is listing only those items and services that have been evaluated and approved by the supplier.
- Ensure the methods of evaluation (audit//survey/accreditation) are addressed in the sub- supplier's quality program, as appropriate.

Audits or commercial grade surveys of NIST or other National Metrology Institutes (NMIs) that are signatories to the International Bureau of Weights and Measures (BIPM) Committee for Weights and Measures Mutual Recognition Agreement (CIPM MRA) are not required for procurement of primary reference standards and calibration services from these organizations. However, appropriate technical requirements must still be included in the procurement document and receipt inspections performed to ensure that the procurement document requirements are met.

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 of equivalent.
- The sub-supplier scope of approval must encompass the items/services identified in the procurement documents.

METHOD OF VERIFICATION	
5.4	**Verify that measures are established and implemented to ensure a comprehensive system of planned and periodic external Appendix B audits (including 3rd party audits).** **Checklist Interface:** Provide auditor names to the audit team member evaluating Checklist Section 14. **References:** Appendix B/ANSI N45.2 - (18/19) ASME Section III NQA-1 Requirement 18

SUPPLMENTARY GUIDANCE:

From the sample of purchase orders obtained, request the corresponding Appendix B audits, used to qualify the sub-supplier, for review.

- Ensure the audits cover the time period for which the purchase order(s) were placed.
- Ensure the scope of the audit covers the scope of purchases as identified in the purchase orders.

NOTE: ASME Suppliers

ASME has created Code Case N-915, approval date 05/07/2021 which was issued to allow ASME suppliers to extend internal and supplier audit due dates in exigent conditions. The ASME Code Case has not been approved by the NRC. If the supplier has implemented this Code Case, ensure the following information has also been incorporated into the supplier's program:

- Address the suppliers program continues to meet the requirements of 10CFR50 Appendix B
- Address Commercial Grade Surveys
- Ensue the documented evaluation process includes the following:

  a) A requirement to include a statement of why the audit could not be completed prior to the end of the 90-day grace period,

  b) Address any significant open issues with the NRC, 10CFR Part notifications

c) The standardization of the items being procured

d) Location of the supplier

e) If the supplier is domestic or international Objective

Evidence required for Figure 5B:

- Supplier Name, Location and Audit Date(s) Performed
- 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:

- Performance of the audit by qualified personnel
- Performance of the evaluation by qualified personnel to ensure the user's program requirements are satisfied.
- Scope of audit envelopes the current scope of procurement.
- Applicable regulatory program requirements are adequately addressed in the audit scope.
- Sufficient objective evidence is available to support conclusions of the audit.

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:** Appendix B/ANSI N45.2 - (7/8) IE Notice 86-21 including supplements NQA-1 Requirement 7

SUPPLEMENTARY GUIDANCE:

Information Notice (IN) 86-21 and Supplement 1, states that the NRC's recognition of the ASME Accreditation Program applied only to the programmatic aspects of the QA programs and that holders of operating licenses or construction permits, and their subcontractors, are still responsible for ensuring that the suppliers are effectively implementing their approved QA programs. NRC IN 86-21, Supplement 2, states…"This supplement clarifies that a method, other than auditing, may be used by purchasers of certain ASME Section III Code items to verify that the ASME-accredited suppliers of the items are effectively implementing their quality assurance (QA) program." Other methods of verification, besides auditing, are surveillance and/or independent testing.

The ASME Accreditation Program, as discussed in IN 86-21, Supplement 1, and Supplement 2, applies only to items manufactured in accordance with Section III of the ASME Code and does not apply to non-Code items that may be supplied by ASME certificate holders.

Objective Evidence required for Figure 5A:

- Method and Date of Supplier Evaluation
- Scope of Supplier Approval

METHOD OF VERIFICATION	
5.6	**Verify that measures are established and implemented to control drop shipment activities to third-parties or customers by an ASME sub-supplier, as authorized by ASME Certified Material Organizations and N-Type Certificate Holders.** **(Applies only to audits of Certified Material Organizations and N-Type Certificate Holders)** **References:** Appendix B/ANSI N45.2 - (7/8) ASME Section III, NCA-3842.2(g); NCA-3315.2(g) NQA-1 Requirement 7

SUPPLEMENTARY GUIDANCE:
Objective evidence can be obtained through a sample of items being drop-shipped by a sub-supplier of the ASME Certified Material Organization and/or N-Type Certificate Holder to the utility customer since the last NUPIC audit (if available). Section 5.3 of this checklist may include information on sub-suppliers that are authorized to drop-ship material directly to utility customers. Section 5.4 of this checklist may include external audits of sub-suppliers (including 3rd party audits) that have been evaluated and authorized by the ASME Certified Material Organization and/or N-Type Certificate Holder to drop-ship material directly to utility customers.

Implementation Information:
As noted above, this checklist section applies only to audits of Certified Material Organizations and N-Type Certificate Holders. If the supplier being audited is a NCA-3300 or NCA-3300 Certified Material Organization and/or N-Type Certificate Holder and its scope of activities includes shipment of material directly from sub-suppliers on the supplier's ASL, the auditor would want to confirm that:

- The supplier's QA manual adequately includes controls for shipping activities to allow drop shipments to third parties or customers as established by NCA-3842.2(g) or NCA-3315.2(g). These requirements establish that:

"(g) When the qualified Material Organization's scope of activities includes shipment of material to parties other than the party performing the qualification, control of this activity shall be included in the Quality System Manual and shall be reviewed by the party accepting the Program. During surveys or audits of qualified Material Organizations, the party performing the evaluation shall review objective evidence that the qualified Material Organization's control of shipments is adequate to assure compliance with the applicable material requirements of this Section."

- Review objective evidence of the supplier's measures to control shipping activities including drop shipments to third parties or customers.

Alternatively, the Lead Utility may determine that drop shipping controls implemented by a Certified Material Organization and/or N-Type Certificate Holder will not be assessed during the audit. An "order entry restriction" or "conditional clause" may be developed by the Lead Utility to prevent drop shipments. That action will give other utilities the opportunity to evaluate whether they want to accept drop shipment controls from the supplier.

SECTION 5 – PROCUREMENT (FIGURE 5A)

ITEM DESCRIPTION NAME (P/N, S/N, MODEL #, SOFTWARE NAME)	SUPPLIER **and** LOCATION	P.O. NUMBER **and** DATE (Note 1)	METHOD **and** DATE OF SUPPLIER EVALUATION (Note 1)	SCOPE OF SUPPLIER APPROVAL
* 4.5, 5.2, 5.3	* 4.5, 5.2, 5.3	* 4.5, 5.2, 5.3	* 4.5, 5.3, 5.4, 5.5	* 4.5, 5.3, 5.4, 5.5
Describe the item and provide any part number, serial number, and/or model number. For software, provide the software name and version.	List the supplier's name and location.	List the supplier's purchase order number and date of issue. Ensure the P.O. is listing only those items or services that have been evaluated and approved by the supplier. (Note 1)	Audit, survey, use of accreditation program (for calibration vendors). (Note 1)	List the scope of approval for the sub-supplier.
Examples Below				
Accelerometer/Charge Amplifier, Asset #S1-02262, S/N #538	ABC Company Acme, NY	PO #4500246625 02/22/10	Survey or Accreditation 10/22/08 (for accreditation include the accreditation certificate number)	Calibration Services
10# 3/32" AWS 5.18-93/ER 70S-2 5.02-S Carbon Steel Filler Material for GTAW to be furnished in accordance with the requirements of ASME Section II Part C, SFA 5.18 and ASME Section III Latest Edition	DEF Company Nuclear, IL	PO #G571088-0 11/03/08	Audit 08/22/07	Nuclear Grade Welding Material

* Refers to applicable question

Note 1: The Supplier Evaluation Date must be performed before the issue date of the P.O. to the supplier.

SECTION 5 – PROCUREMENT (FIGURE 5B)

SUPPLIER NAME, LOCATION **and** AUDIT DATE(S) PERFORMED	SCOPE OF SUPPLY	AUDITORS	NUMBER OF DEFICIENCIES (OPEN / CLOSED)	CORRECTIVE ACTION VERIFICATION METHOD **and** DATE
* 5.4	* 5.4	* 5.4	* 5.4	* 5.4
List the supplier's name, location, and the date of the audit that was performed.	List the actual product or service being audited.	List the auditors that participated on the audit.	List the number of deficiencies and their status.	List the corrective action verification method used and the date of the verification.
Example Below				
DEF Company Nuclear, IL 08/22/07 – 08/26/07	Weld Filler Material	JKL Quality Consultants John Doe	0	Not Applicable. No findings were issued.

* Refers to applicable question

Note 1: List Appendix B audits of sub-suppliers only (which includes 3rd party audits).

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

METHOD OF VERIFICATION	
6.1	Within the assessment/summary section 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.** **Note:** Assessment of software controls relating to the manufacturing processes is to be verified in Section 4. **Checklist Interface:** Provide any related supplier test/inspection activity information to the audit team member evaluating Checklist Section 8. **References:** Appendix B Criteria VIII ANSI N45.2 Section 9 ASME Section III NQA-1 Requirement 9

SUPPLEMENTARY GUIDANCE:

Select a sample of active work packages or work packages associated with purchase orders provided as audit input. Verify that a document exists, such as a shop work order/traveler, which provides for fabrication/assembly activities in a controlled sequence.

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.

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.** **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 ANSI N45.2 Section 9, 15 ASME Section III NQA-1 Requirement 8

SUPPLEMENTARY GUIDANCE:

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 accompanyingdocuments, 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 CofC, etc.

METHOD OF VERIFICATION	
6.4	**Verify that measures are established and implemented for the control of storage and shipping activities.** **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 Requirement 13

SUPPLEMENTARY GUIDANCE:

Objective Evidence required for Figure 6A:

- Item Description
- Work Document
- Work Activity
- Work Activity Procedure

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.

- Handling
- Cleaning
- Shelf-Life Requirements
- Preservation
- Foreign material controls
- Storing including access and environment
- Packaging
- Marking
- Documentation
- Shipment

SECTION – FABRICATION/ASSEMBLY ACTIVITIES MATERIAL CONTROL, HANDLING, SHIPPING AND STORAGE
(FIGURE 6A)

ITEM DESCRIPTION List description of part (Name, Part Number, P.O. number, etc.)	WORK DOCUMENT List Shop Work Order number, Traveler number, etc.	WORK ACTIVITY List activity (e.g. assembly, welding, packaging etc.)	WORK ACTIVITY PROCEDURE List the work activity procedure number **and** revision / date for the work activity observed.
* 6.2, 6.4	* 6.2, 6.4	* 6.2, 6.4	* 6.2, 6.4
List description of part (Name, Part Number, PO Number, etc.)	List Shop Work Order Number, Traveler Number, etc.	List activity observed (e.g. assembly, welding, inspection, etc.)	List the work activity procedure number and revision/date for the work activity observed.
Example Below			
Amplifier P/N #10673-001 Supplier/Customer (identify which) PO #100045674, Rev. 1	Traveler #4687	In-Process Test	Test Procedure TP-277656, Rev. 2
* Refers to applicable question			

SECTION – 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.)	METHOD OF IDENTIFICATION **and** TRACEABILITY List the method used to identify the item (Heat Number, P.O./Contract number, etc.)	INSPECTION STATUS Indicate the status of the item (i.e., awaiting inspection, on hold, discrepant, rejected, etc.)
* 6.3, 6.4	* 6.3, 6.4	* 6.3, 6.4
Description of part (Name, Part Number, PO/Contract Number, etc.)	List the method used to identify the item (heat number, PO/Contract Number, etc.)	Indicate the status of the item (i.e., awaiting inspection, on hold, discrepant, rejected, etc.)
* 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.** **References:** Appendix B/ANSI N45.2 - (9/10) ASME Section III NQA-1 Requirement 9

SUPPLEMENTARY GUIDANCE:

Welding Personnel and Procedures are typically qualified to the Code being used. Review a sample qualification and certification records for welding personnel, being utilized by the supplier, and assure the qualification and certification of the individuals is in accordance with the controlling certification procedures. When reviewing Welder qualification requirements, assure the welder was qualified for the process you observed. If he was welding specific material, verify he was qualified for that material. If he was welding in the overhead position, make sure he was qualified to weld in the overhead position. If work is being performed per ASME, the procedures are required to be demonstrated to an Authorized Nuclear Inspector (ANI) prior to first use. Alternatively, the ANI can approve the procedure while the activity is being performed/witnessed simultaneously. Review the procedure qualification records including ANI approval documents. If you are not familiar with what the procedure is required to have, ask for a copy of the relevant code section where the procedure requirements were obtained from.

Review the WPS for the welding processes observed by the audit team and assure the WPS has been developed and approved as required by the referencing Code section (if applicable).

Objective Evidence required for Figure 7A:

- Item Description
- Special Process
- Procedure and Rev/Date
- Equipment In Use / Used
- 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
- Maintenance of Qualification

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.

METHOD OF VERIFICATION	
7.3	**Verify that measures are established and implemented to control Non-Destructive Examination (NDE).** **Note:** NDE disciplines include Visual Testing (VT), 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. **Checklist Interface:** Identify any M&TE used to the audit team member evaluating Checklist Section 8. **References:** Appendix B/ANSI N45.2 - (9/10, 10/11)

SUPPLEMENTARY GUIDANCE:

Review a sample qualification and certification records for Non-Destructive Examination (NDE) personnel, being utilized by the supplier, and assure the qualification and certification of the individuals is in accordance with the controlling certification procedures for the special process(s) being utilized by the supplier.

When reviewing the documentation for NDE personnel, identify the basis for certification and verify the inspector met the education and experience requirements, and has (in their certification file) the required examinations for certification. Ask to review a sample of the certifying examinations and verify these examinations meet the requirements for number and type of questions listed in NDE standards SNT-TC- 1A or CP-189.

ASNT-SNT-TC-1A (synonymous with SNT-TC-1A) is the most recognized certification program. If suppliers are performing work to ASME Section XI, then ANSI/ASNT CP-189 may be required.

Suppliers who provide personnel for In-service Inspection of Nuclear Power Plants are usually required to meet CP-189 requirements. The requirements for CP-189 are more stringent than SNT-TC-1A. There are different years of SNT-TC-1A and CP-189. Verify which year is being used by the supplier and assure this meets the utilities requirements.

Specific requirements for SNT-TC-1A:

- Typical certification levels are Level I, II & III.
- Work experience is usually tracked in months but can be tracked in hours for later edition years.
- General, Specific and Practical examinations are used to certify NDE Levels I & II.
- Basic, Method and Specific examinations are used to certify NDE Level III personnel.
- Level I & II personnel are recertified every 3/5 years and Level III personnel are recertified every 5 years.
- NDE inspectors must be certified by a Level III certified in the respective discipline.
- NDE inspectors are required to have annual vision examinations to verify Near Vision and Color Contrast.

Specific Requirements for CP-189:

- Typical certification levels are Trainee, Level I, II, III and Trainer
- Work experience is tracked in hours and includes specific time in the discipline and total time in NDE General, Specific and Practical examinations are used to certify NDE Levels I & II.
- Basic, Method, Specific, Practical and Demonstration examinations are used to certify NDE Level III personnel. There is a difference in testing between a Field Level III and Administrative Level III.
- Level I & II personnel are recertified every 3 years and Level III personnel are recertified every 5 years.
- NDE inspectors must be certified by a Level III certified in the respective discipline.
- NDE inspectors are required to have annual vision examinations to verify Near Vision and Color Contrast.

NDE procedures should contain the requirements outlined in the referenced code. If work is performed for the ASME Code, basic procedure requirements are referenced in ASME Section V and supplemented with additional (more stringent) requirements in other sections such as III, VIII and XI, depending on the work performed by the supplier. NDE procedures are required to be approved by an NDE Level III. Work performed per ASME, also requires the procedures to be demonstrated to an Authorized Nuclear Inspector (ANI) prior to first use. Review the procedure qualification records including ANI approval documents. If you are not familiar with what the procedure is required to have, ask for a copy of the relevant code section where the procedure requirements were obtained from.

Objective Evidence required for Figure 7A:

- Item Description
- Special Process
- Procedure and Rev/Date
- Equipment In Use / Used
- Qualification (Personnel, Procedures)

Implementation Information:

Qualified personnel:

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.

METHOD OF VERIFICATION	
7.4	**Verify that measures are established and implemented to control other special processes (e.g., heat treating, soldering, painting, etc.)** **Checklist Interface:** Identify any M&TE used to the audit team member evaluating Checklist Section 8. **References:** Appendix B/ANSI N45.2 - (9/10) ASME Section III NQA-1 Requirement 9

SUPPLEMENTARY GUIDANCE:

Objective Evidence required for Figure 7A:

- Item Description
- Special Process
- Procedure and Rev./Date
- Equipment in Use / Used
- Qualification (Personnel, Procedures)

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.

SECTION 7 – SPECIAL PROCESSES (FIGURE 7A)

ITEM DESCRIPTION (NAME, P/N, S/N, MODEL #)	SPECIAL PROCESS	PROCEDURE **and** REV / DATE	EQUIPMENT IN USE / USED	QUALIFICATION	
				PERSONNEL **and** LEVEL	PROCEDURE
* 7.2, 7.3, 7.4	* 7.2, 7.3, 7.4	* 7.2, 7.3, 7.4	* 7.2, 7.3, 7.4	* 7.2, 7.3, 7.4	* 7.2, 7.3, 7.4
List description of item (P/N, S/N, Model Number)	Enter process observed	List Procedure Number and revision/date.	List equipment in use / used including M&TE. If calibration is required, evaluate as part of Checklist Section 8.6.	List person's name, the discipline certified to and if applicable the level of qualification such as MT Level II, RT Level III.	List PQR, or other qualification record.
Examples Below					
1/2 7H FIG Body Item 128812-MAI Job #20121	GTAW	WPS-818 Rev. 3, 03/06/08	Miller Weld Machine #1500-06-WM Due 02/23/09	Joe Best Welder	WPS 820 Rev. 2
Valve Body 3/4" x 1" P/N #N00658-0002 & #-0003 Flat Stock	UT Straight Beam	UIS-20 Rev. 2, 2/9/75	USK 7D #2871 Transducer S/N #14300 UT-Standard Step Wedge Calibration S/N #INSP-6B	John Blind Level II Stamp #12	TP-5908 Rev. 3 9/14/06
Router #182925 Stock Item Body P/N #050BGLZ-9-W Lot #14745	Heat Treatment Stress Relief Step #50	PRO-P-826 Rev. 10	Vacuum Furnace #36101 Controller #G205498	E. Heatman Operator #54	PRO-P-855 Rev. 3, 10/22/10
Valve Stem (Stellite Weld) P/N #X306799	Liquid Penetrant Test (PT)	SS-3070 Rev. K Dated 1/17/08 Liquid Penetrant Inspection	Penetrant SKL-SP1 #07G073 (Shelf life expired 5 years from July 2007) See Checklist Section 5	Randall Mallaber Level II	Procedure #004-120-501 12/13/13 Qualification and Certification of NDE Test Personnel
* Refers to applicable question					

SECTION 7 – SPECIAL PROCESSES (FIGURE 7B)

WELDER (NAME / STAMP)	CERT. TYPE (PROCESS & POSITIONS)	CODE QUALIFIED TO	WELD PROCESS SPECIFICATION (WPS) **and** REV / DATE	MAINTENANCE OF QUALIFICATION
* 7.2	* 7.2	* 7.2	* 7.2	* 7.2
List Welder's Name and Stamp	List Certification Type, Process, and positions.	List ASME Code qualified to.	List the Weld Process Specification (WPS) procedure and revision/date.	List the maintenance of qualification for welder.
Example Below				
John Doe or Stamp #5	GTAW 6G	ASME Section IX	WPS 820 Rev. 2 or Date 10/1/10	Welded within the 6-month time limit.
* 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.** **Checklist Interface:** Provide inspection/test personnel names to the audit team member evaluating Checklist Section 14. **References:** Appendix B/ANSI N45.2 - (7/8, 10/11, 11/12) ASME Section III NQA-1 Requirement 7, 10, 11

SUPPLEMENTARY GUIDANCE:

Tests and inspections supporting Commercial Grade Dedication are addressed in checklist section 3. This checklist section is intended to address acceptance methods for safety related materials, parts, components and additional inspections/tests of those items if additional fabrication, assembly, etc. is required for the completed product.

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 Names/Stamp
- ID Numbers or 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 nonconformances/deficiencies identified.

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

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).** **Checklist Interface:** Provide inspection/test personnel names to the audit team member evaluating Checklist Section 14. **References:** Appendix B/ANSI N45.2 - (7/8) ASME Section III NQA-1 Requirement 7

SUPPLEMENTARY GUIDANCE:

Tests and inspections supporting Commercial Grade Dedication are addressed in checklist section 3. This checklist section is intended to address acceptance methods for safety related materials, parts, components, and services.

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 Names/Stamp
- ID Numbers or M&TE Used and Calibration Current (Yes/No)
- SAT or UNSAT and NCR No. if UNSAT

Implementation Information:

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 measurable 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.

METHOD OF VERIFICATION	
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.** **References:** Appendix B/ANSI N45.2 - (7/8, 10/11, 11/12) ASME Section III NQA-1 Requirement 7, 10, 11

SUPPLEMENTARY GUIDANCE:

Reasonable methods should be implemented to ensure that suspect (including counterfeit/fraudulent) material, items or components are not being accepted. Normally, if there is not a separate procedure to address the methods utilized to detect suspect, counterfeit, or fraudulent material, items or components, it would be addressed in the receiving inspection procedure. If suspect, counterfeit or fraudulent material, items or components are not addressed in any procedure, then a finding should be issued using the criteria stated below:

"10CFR50 Appendix B Criterion V "Instruction, Procedures and Drawings" states that activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining those important activities have been satisfactorily accomplished."

"10CFR50 Appendix B Criterion VII "Control of Purchased Material, Equipment and Services" states that measures shall be established to assure that purchases material, equipment, and services, whether purchased directly or through contractors and sub-contractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery."

See NRC Information Notice IN 2008-04, IN 89-70, IN 89-70 Supplement 1 and Generic Letter 89-02 for additional information associated with the detection of misrepresented products.

Implementation Information:

Appendix B, ANSI N45.2, NQA-1 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

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. **References:** Appendix B/ANSI N45.2 - (10/11) ASME Section III

SUPPLEMENTARY GUIDANCE:

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.

METHOD OF VERIFICATION	
8.6	**Verify that measures are established and implemented for the control of measuring and test equipment (M&TE).** **Note:** If required by P.O./Contract, standards must have 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. **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. **References:** Appendix B/ANSI N45.2 – (12/13) ASME Section III NQA-1 Requirement 12

SUPPLEMENTARY GUIDANCE:

Labeling/identification of M&TE provides, as a minimum, unique identifier and calibration/calibration-due dates which ensure the device and calibration status are “readily identifiable”. Intervals of calibration for each device must be defined, based on the type of equipment stability characteristics, required accuracy, intended use, manufacturer’s recommendation and other conditions affecting measurement control.

Documentation of As Found/As Left information is normally identified on a Calibration Certificate. Each test report or calibration certificate must include the test or calibration results and, where appropriate, the units of measurement. Note that this does not require “As Found” conditions to be recorded, only “As Left” information. Normally, if “As Found” information is required, it should be a condition of the purchase order. Out-of-calibration devices must be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it should be repaired or replaced.

When measuring and test equipment is found to be out of calibration, an evaluation of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested must be performed. Controls must provide for traceability of M&TE use to specific products/customers such that customers can be notified of potential impact on received items.

Maintenance of Calibration History should include dates calibrated, by whom/supplier, results, due date, primary standard, and P.O. No. (if sub-contracted). This information is typically maintained in an electronic database and can be reviewed to determine if M&TE was within calibration at the time of use in the test/inspection activities being reviewed during the audit.

When calibration is performed by the supplier, the calibration must be performed in an environment that is controlled to the extent necessary to assure required accuracy. This includes consideration, and monitoring as applicable, of temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference, and any other factors affecting the results of measurements. When calibration is subcontracted, environmental controls must be validated by audit, survey or accreditation acceptance.

If the auditor determines that a Figure detailing specific calibration criteria observed would be useful, a table similar to the following can be inserted in the Assessment/Summary.

ID NUMBER OF M&TE AND DESCRIPTION (Asset number)	CALIB. PO (if applicable)	CAL PROCEDURE NUMBER Rev./Date	AS FOUND/ AS LEFT INFORMATION Recorded Yes/No	TESTER/ CALIBRATOR NAME	CAL DATE CAL DUE DATE	CAL FREQ.

If the auditor determines that calibration activities are sufficient to warrant additional investigation, the NUPIC Safety Related Calibration Services Supplemental Audit Checklist, NUPIC Document 42.1, can be used at the discretion of the Audit Team Leader.

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 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 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.

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION (FIGURE 8)

ITEM DESCRIPTION (NAME, P/N, S/N, ETC.)	TEST/INSPECTION ACTIVITY TYPE **and** DATE	TEST/INSPECTION PROCEDURE (TITLE/NUMBER) **and** REV / DATE	INSPECTOR/ TESTER (NAME/STAMP)	ID NUMBER OF M&TE **and** CALIBRATION CURRENT (Yes / No)	SAT OR UNSAT **and** NCR NO. IF UNSAT
* 8.2, 8.3	* 8.2, 8.3	* 8.2, 8.3	* 8.2, 8.3	* 8.2, 8.3. 8.6	* 8.2, 8.3
Describe the item by name, part number, serial number, etc.	List the type of test/inspection activity and the date the test/inspection was performed.	List the procedure by title/number and revision/date that controls the test/inspection activity.	List the inspector/tester by name or number that performed the inspection/test.	List any M&TE that was used during the inspection/test. Verify that the M&TE was in calibration at the time of the inspection/test.	Record the results of the inspection/test (SAT or UNSAT) and the NCR number if the inspection/test was UNSAT.
Examples Below					
Company LA 800C Vendor Job #N80448 S/N #R300239G-1 Kewaunee PO #70177689	Refurbishment 1. Receipt of Equipment 2. Incoming Inspection and Testing 3. Cleaning & Inspection of Parts 4. Reassembly 5. Final Testing (8/22/09 – 9/14/09)	QAP 5.8 Company LA Refurbishment Procedure Rev. 2, 7/14/09 QAP 5.8A Company LA Refurbishment Checklist Rev. 2, 7/14/09	John Doe Mark Moe	Biddle 5KV Megger ID #122728 CB Tester ID #116837 Fluke Multimeter ID #122727 Fluke Multimeter ID #123842 YES All items were in calibration	SAT
P/N #13x012780xxxx 303 SS Machine Screw 1/4", 18-8, 5/8" long Lot #73020 for AEP Work Order #1117	Receipt Inspection 100% Inspection (P/N, Dimensions, Thread) 8/24/09	IP 014, Rev. B "Receiving Inspection of Material" Dated 11/2/04	Betty Joe	Scale S/N #246 Yes Ring Thread Gage S/N #409 Yes	SAT
Engineering Change Package ECP-2181 (Brightman Engineering)	Receipt via Owners Acceptance Review	QP-E002, Rev. 1 "Contracted Engineering Services"	Guy Smart	N/A (acceptance of design documentation)	SAT
* Refers to applicable question					

SECTION 9 – DOCUMENT CONTROL

METHOD OF VERIFICATION	
9.1	Within the assessment/summary section of each 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.** **References:** Appendix B/ANSI N45.2 - (5, 6/6, 7) ASME Section III NQA-1 Requirement 6

SUPPLEMENTARY GUIDANCE:

- The auditor should also validate controls of associated electronic data used to control and issue of documents I maintained.
- The auditor should identify reliance on document management software for design information and refer it to the auditor assessing Section 3.

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).

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 procedural controls adequate and procedure revision current? YES or NO (describe in Findings/Deficiencies current section above)

SECTION 10 – ORGANIZATION

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.** **References:** Appendix B/ANSI N45.2 - (1-3) ASME Section III NQA-1 Requirement 1

SUPPLEMENTARY GUIDANCE:

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.)

SECTION 11 – NONCONFORMING ITEMS/PART 21

METHOD OF VERIFICATION	
11.1	Within the assessment/summary section of each 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:** **References:** Appendix B/ANSI N45.2 - (15/16) ASME Section III NQA-1 Requirement 15

SUPPLEMENTARY GUIDANCE:

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.

METHOD OF VERIFICATION	
11.3	**Verify that measures are established and implemented to disposition items which do not conform to requirements:** **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. 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 - (15/16) ASME Section III NQA-1 Requirement 15

SUPPLEMENTARY GUIDANCE:

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.
- 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.

METHOD OF VERIFICATION	
11.4	**Verify that measures are established and implemented to address posting, evaluation, notification, and reporting requirements of 10CFR21.** **References:** 10CFR21.3, 10CFR21.6, 10CFR21.21, 10CFR21.41

SUPPLEMENTARY GUIDANCE:

The NRC website can be reviewed to identify any 10CFR 21 notifications issued by the supplier since the previous NUPIC audit. If any notifications are identified, the entire process/timetable should be verified for the notifications.

https://www.nrc.gov/reading-rm/doc-collections/event-status/part21/index.html

The NRC website can be consulted to identify if the NRC has performed and posted an inspection of this supplier since the last NUPIC audit.

https://www.nrc.gov/reactors/new-reactors/how-we-regulate/oversight/quality- assurance/vendor-insp/insp-reports.html

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.

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.

SECTION 12 – INTERNAL AUDITS

METHOD OF VERIFICATION	
12.1	Within the assessment/summary section of each 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.** **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. **References:** Appendix B/ANSI N45.2 - (18/19) ASME Section III NQA-1 Requirement 18

SUPPLEMENTARY GUIDANCE:

"Explanation of "Independence":

If the ATL/ATM was contracted or performed activities under the suppliers QA program during the period being evaluated, (sub-supplier audit supporting the suppliers ASL, or an audit of the suppliers programs like procurement, design, etc., or performed other functions/responsibilities associated with the actual implementation of the suppliers quality functions, they could not perform the audit of the QA Program (e.g., audit of the auditors/inspectors, same individual assessing implementation of internal audit process). The key aspect is that the individuals have not performed any direct duties or responsibilities under the QA program (performed activities implementing the suppliers QA program in the areas under evaluation.)

Objective Evidence required for Figure 12:

- Audit Scope and Date
- Auditor(s)
- Number of Deficiencies and Status (Open/Closed)
- Corrective Action Verification Method (document review, follow-up audit, surveillance, etc.) 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.

The audit must be performed by individual(s) that are independent from the suppliers QA Program implementation/administration (have not performed internal program audits, supplier audits, or inspections under the suppliers' program). This audit verifies that the activities directly performed by the suppliers QA staff are implemented as required.

In the context of performing an audit of the suppliers QA Program implementation, an auditor independence concern would only occur if the auditor had been responsible for or performed activities that are the responsibility of the QA staff during the scope period. (e.g., Subsequent audits of the design program could be led by the same ATL, provided this individual has not performed any line functions/responsibilities in the design area since the last 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.

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.** **References:** Appendix B/ANSI N45.2 - (18/19) ASME Section III NQA-1 Requirement 18

SUPPLEMENTARY GUIDANCE:

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.

SECTION 12 – INTERNAL AUDITS (FIGURE 12)

AUDIT SCOPE **and** DATE(s)	AUDITOR(s)	NUMBER OF DEFICIENCIES **and** STATUS (OPEN / CLOSED)	CORRECTIVE ACTION VERIFICATION METHOD (document review follow-up audit, surveillance, etc.)
* 12.2	* 12.2	* 12.2	* 12.2
List the scope of the audit and the date(s) that audit was conducted.	List Audit team members and their role. (Audit Team Leader or Auditor).	List the number of deficiencies/findings from the audit and the status as either open or closed. (i.e. 2-Open, 3-Closed, etc.)	List how the corrective action was verified. (verification of completed actions by an individual, document review, follow-up audit, etc.)
* Refers to applicable question			

SECTION 13 – CORRECTIVE ACTION

METHOD OF VERIFICATION	
13.1	Within the assessment/summary section of each 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.** **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. **References:** Appendix B/ANSI N45.2 - (16/17) ASME Section III NQA-1 Requirement 16

SUPPLEMENTARY GUIDANCE:

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).

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 toquality;
- Review of corrective actions for timeliness and effectiveness;
- Review and approval by responsible authority (programmatically defined) on the adequacy of the corrective action;
- 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.

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.** **References:** Appendix B/ANSI N45.2 - (16/17) ASME Section III NQA-1 Requirement 16

SUPPLEMENTARY GUIDANCE:

Deficiencies identified by customers may be identified by utility input to the audit, utility generated supplier corrective action notifications (stop work orders, corrective action orders, etc.), customer service/sales information, and return information.

Objective Evidence Required:

- Document NCR and/or CAR Numbers reviewed under the Assessment/Summary.

METHOD OF VERIFICATION	
13.4	**Verify the overall effectiveness of the corrective action process.** **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 - (16/17) ASME Section III NQA-1 Requirement 16

SUPPLEMENTARY GUIDANCE:

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.

SECTION 14 – TRAINING

METHOD OF VERIFICATION	
14.1	Within the assessment/summary section of each 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.** **References:** Appendix B/ANSI N45.2 - (2/2) ASME Section III NQA-1 Requirement 2

SUPPLEMENTARY GUIDANCE:

Objective Evidence required for Figure 14:

- Name and Job Title
- Indoctrination and Training Completed (Yes/No)
- Qualification/Certification Type and Level

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.

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.** **Note:** Special process personnel Qualification / Certification is addressed in Checklist Section 7. **References:** Appendix B/ANSI N45.2 - (2, 9, 10, 11, 18/2, 10, 11, 12, 19) ASME Section III NQA-1 Requirement 2

SUPPLEMENTARY GUIDANCE:

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).

SECTION 14 – TRAINING (FIGURE 14)

NAME **and** JOB TITLE	INDOCTRINATION **and** TRAINING COMPLETED (Yes / No)	QUALIFICATION / CERTIFICATION TYPE **and** LEVEL
* 14.2, 14.3	* 14.2, 14.3	* 14.2, 14.3
List name of individual, stamp number if applicable, and job title.	Indicate Yes or No whether Indoctrination and Training in the Quality Assurance Program has been completed.	List the type of qualification or certification (i.e. Lead Auditor, Inspector, ASME Professional Engineer, etc.). List the discipline certified to and the level (i.e. Liquid Penetrant Level I, II, or III, Mechanical Level, I, II, or III).
* Refers to applicable question		

SECTION 15 – FIELD SERVICES

METHOD OF VERIFICATION	
15.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
15.2	**Verify that measures are established and implemented to control field services.** **Checklist Interface:** Query the audit team members regarding applicability of field services to their assigned checklist sections. **References:** Appendix B/ANSI N45.2 - 2/2 ASME Section III

SUPPLEMENTARY GUIDANCE:

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.

SECTION 16 – RECORDS

METHOD OF VERIFICATION	
16.1	Within the assessment/summary section of each 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.** **Checklist Interface:** Query the audit team regarding the condition of any quality records which they have reviewed. **References:** Appendix B/ANSI N45.2 - (17/18) 10 CFR 21.51 10 CFR 52 ASME Section III NQA-1 Requirement 17

SUPPLEMENTARY GUIDANCE:

For QA records not transferred to the customer;

- Ensure that there is a process available that includes periodic review of legibility of electronic records.
- Verify by retrieving sample old electronic records to ensure accessibility and retrievability of records including the availability of software and hardware systems to read thedata.

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 purchasers 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 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).