

**NUCLEAR INDUSTRY ASSESSMENT COMMITTEE
AUDIT CHECKLIST**

Revision: 9 Dated: 11/4/10

SUMMARY SHEET

Page 1 of 40

SUPPLIER INFORMATION:				AUDIT SCOPE
SUPPLIER:		SDI #		10CFR50 App. B <input type="checkbox"/>
STREET ADDRESS:				10CFR21 <input type="checkbox"/>
CITY, STATE & ZIP CODE:				ANSI N45.2 <input type="checkbox"/>
TELEPHONE NO.:		FAX NO.:		ASME NQA-1 <input type="checkbox"/>
PRODUCT/SERVICE:				SNT-TC-1A * <input type="checkbox"/>
CODE STAMP(S) AND AUTHORIZATION NUMBER(S):				NCSL Z540-1 * <input type="checkbox"/>
				IEEE 323 * <input type="checkbox"/>
				IEEE 344 * <input type="checkbox"/>
SUPPLIER CONTACTS:				IEEE 383 * <input type="checkbox"/>
SENIOR CO. OFFICER:	TITLE	TELEPHONE AND/OR EMAIL:		ASME NCA 3800 <input type="checkbox"/>
SENIOR QA OFFICER:	TITLE	TELEPHONE AND/OR EMAIL:		ASME NCA 4000 <input type="checkbox"/>
AUDIT CONTACT:	TITLE	TELEPHONE AND/OR EMAIL:		FIELD SERVICES <input type="checkbox"/>
				ENG. SERVICES <input type="checkbox"/>
AUDIT INFORMATION:				10CFR71 Subpart H <input type="checkbox"/>
NAME OF MEMBER CO.:				10CFR72 Subpart G <input type="checkbox"/>
AUDIT NO.:		AUDIT DATES:		
NIAC MEMBERS AUTHORIZED TO SHARE AUDIT:				
AUDIT TEAM	MEMBER CODE	NAME	TELEPHONE NO.	CHECKLIST SECTIONS AUDITED
TEAM LEADER				
TEAM MEMBER				
TECHNICAL SPECIALIST (SPECIFY DISCIPLINE)				* = Additional checklists / questions are included.

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Audit Team Leader: _____ Date: _____ NIAC Member Representative: _____ Date: _____

NIAC AUDIT CHECKLIST

SUPPLIER: _____

Revision: 9 Dated: 11/4/10

AUDIT NO. _____ PAGE 2 OF 40

SUMMARY SHEET

Supplier QA Manual _____ Revision _____ Date _____

AUDIT SEC.	SECTION DESCRIPTION	S	M	E	PROGRAM ELEMENT MEETS REGULATORY REQUIREMENT	QA PROGRAM REFERENCE	IMPLEMENTATION STATUS	COMMENTS / FINDINGS
OE	ORDER ENTRY	✓	✓	✓				
1-A	ORGANIZATION / PROGRAM	✓	✓	✓				
1-B	NONCONFORMING ITEMS / PART 21	✓	✓	✓				
1-C	AUDITS	✓	✓	✓				
1-D	CORRECTIVE ACTION	✓	✓	✓				
1-E	TRAINING / CERTIFICATION	✓	✓	✓				
1-F	RECORDS	✓	✓	✓				
2	DESIGN	✓		✓				
3	PROCUREMENT & UNQUALIFIED SOURCE MATERIAL	✓	✓					
4	DOCUMENT CONTROL	✓						
5	MATERIAL CONTROL, HANDLING, SHIPPING & STORAGE							
6	FABRICATION, ASSEMBLY & SPECIAL PROCESSES							
7	INSPECTION AND TEST							
8	CALIBRATION							
9	SOFTWARE QUALITY ASSURANCE			✓				
10	COMMERCIAL GRADE DEDICATION			✓				

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NOTE: "S" = NQA-1 / 10CFR50/71/72 "M" = MATERIAL ORGANIZATION "E" = ENGINEERING SERVICES

IMPLEMENTATION STATUS KEY

S = SATISFACTORY U = UNSATISFACTORY N/A = NOT APPLICABLE

This checklist is to be used as a guideline in conjunction with specific requirements of the appropriate industry document imposed via procurement documents.

SECTION 1 - PROGRAM COMPLIANCE

INTERNAL LINKS: [SUMMARY OE 1-A](#), [1-B](#), [1-C](#), [1-D](#), [1-E](#), [1-F](#), [2](#), [3](#), [4](#), [5](#), [6](#), [7](#), [8](#), [9](#), [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>1.A.1 Verify that the individual/organization responsible for defining the overall effectiveness of the QA Program:</p> <ul style="list-style-type: none"> a) is designated; (i.e., authority, organizational structure and responsibility is documented); b) is independent of production pressures; c) has direct access to appropriate management levels; d) Regularly reviews, assesses and reports on the applicability, status and effectiveness of the QA Program. <p>Appendix B/ANSI N45.2 Ref: (1-3) 10CFR71 Subpart H 71.103, 71.105/10CFR72 Subpart G 72.142, 72.144 ASME Section III NQA-1 Supplement 1S-1, NCA3851.3 (b) Vendor Program Ref: _____</p>		
<p>1.A.2 Assess whether personnel performing verification activities have the authority, independence, and organizational freedom to:</p> <ul style="list-style-type: none"> a) Identify quality problems; b) Initiate, recommend or provide solutions to problems; c) Verify implementation of solutions; d) Control further processing of nonconformance until proper disposition has occurred. <p>Appendix B/ANSI N45.2 Ref: (1-3) 10CFR71 Subpart H 71.103/10CFR72 Subpart G 72.142 ASME Section III NQA-1 Supplement 1S-1, NCA 3851.3 (c) Vendor Program Ref: _____</p>		
<p>1.A.3 Verify that the supplier has developed a Quality Program which will assure that supplies and/or services provided will conform to Customer P.O. requirements.</p> <ul style="list-style-type: none"> a) Is there supplemental written policies, procedures or instructions to the Quality Program? b) Describe the method the supplier uses to notify the customer in writing of any changes to the Quality Program; c) Are process control procedures an integral part of the suppliers Quality Program when such procedures are a part of the referenced specification or the P.O.? <p>Appendix B/ANSI N45.2 Ref: (1-3) ASME Section III NQA-1 Supplement 2S-1, NCA3851.1 Vendor Program Ref: _____</p>		

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SECTION 1 - PROGRAM COMPLIANCE

INTERNAL LINKS: [SUMMARY OE 1-A](#), [1-B](#), [1-C](#), [1-D](#), [1-E](#), [1-F](#), [2](#), [3](#), [4](#), [5](#), [6](#), [7](#), [8](#), [9](#), [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>1.B.1 Verify that measures are established and implemented to:</p> <ul style="list-style-type: none"> a. Identify nonconforming items; b. Ensure that responsibility and authority for review/disposition is identified; c. Control further processing, delivery and installation of items until disposition is completed; d. Provide notification to the customer of nonconforming conditions when required by member P.O./Contract <p>Appendix B/ANSI N45.2 Ref. (15/16) 10CFR71 Subpart H 71.131/10CFR72 Subpart G 72.170 ASME Section III NQA-1 Supplement 15S-1, NCA3858.5 Vendor Program Ref: _____</p>		
<p>1.B.2 Verify that nonconforming items are reviewed and dispositioned such that:</p> <ul style="list-style-type: none"> a. The disposition is identified; b. Justification is documented for nonconforming items dispositioned repair or use-as-is; c. The disposition/close-out is approved by the responsible authority; d. Procedures or instructions for repair and rework are provided; e. Repaired & reworked items are reinspected. f. Member approval is obtained for use-as-is and repair dispositions when required by PO g. Closeout is adequate <p>Appendix B/ANSI N45.2 Ref. (15/16) 10CFR71 Subpart H 71.131/10CFR72 Subpart G 72.170 ASME Section III NQA-1 Supplement 15S-1, NCA3858.5 Vendor Program Ref: _____</p>		
<p>1.B.3 Verify that a procedure exists for the evaluation and determination if a defect exists under 10CFR Part 21, that it provides for the notification of NRC, the utility and/or customers as follows:</p> <ul style="list-style-type: none"> a. Notify utility or purchaser within 5 working days of determination of inability to perform the evaluation. b. Notification to NRC within 2 days following the identification of a defect or failure to comply. c. Notify NRC within 30 days following identification of a defect or failure to comply. d. Is there a clear connection between the NRC HR process and the Part 21 procedure? <p>10CFR Part 21 paragraphs 21.21(a), 21.21(a)(1), 21.21(a)(3), 21.21(d)(3)(i), 21.21(d)(3)(ii) Vendor Program Ref: _____</p>		

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SECTION 1 - PROGRAM COMPLIANCE

INTERNAL LINKS: [SUMMARY OE 1-A](#), [1-B](#), [1-C](#), [1-D](#), [1-E](#), [1-F](#), [2](#), [3](#), [4](#), [5](#), [6](#), [7](#), [8](#), [9](#), [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p><u>1.C.</u> Verify that measures are established and implemented to ensure that a comprehensive system of planned and periodic Internal Audits are performed including the following:</p> <ul style="list-style-type: none"> a. Verify that the participants have no direct responsibility in the areas audited, b. Verify that procedures and/or checklists were used with objective evidence documented, c. Verify that follow-up action, including re-audit of deficient areas, is taken where needed. <p>NOTE: Document details of the internal audit program here. Document details of the supplier audit program at Question 3.3. Use Table 1-C to record details for both internal and supplier audits.</p> <p>Appendix B/ANSI N45.2 Ref: (18/19) 10CFR71 Subpart H 71.137/10CFR72 Subpart G 72.176 ASME Section III NQA-1 Supplement 18S-1, NCA3859.1 Vendor Program Ref: _____</p>		
<p><u>1.D.</u> Verify that measures are established and implemented to assure that conditions adverse to quality are promptly identified and corrected. These measures shall include as a minimum:</p> <ul style="list-style-type: none"> a. Identification and description of the condition adverse to quality; b. Determination of the cause and actions taken to prevent recurrence for significant conditions adverse to quality; c. Review and approval by responsible authority on the adequacy of the corrective action; d. Follow-up actions for closeout to verify that the corrective action has taken place or is scheduled. <p>Note: Record objective evidence in Section 4B</p> <p>Appendix B/ANSI N45.2 Ref: (16/17) 10CFR71 Subpart H 71.133/10CFR72 Subpart G 72.172 ASME Section III NQA-1 Basic Requirement 16, NCA3859.2 Vendor Program Ref: _____</p>		

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1-C - PROGRAM COMPLIANCE - AUDITS / SURVEILLANCES

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

REPORT ID NUMBER	PERFORMANCE DATE	SCOPE	INTERNAL/ EXTERNAL	ITEMS CONSIDERED AND SUPPLIER PROCESSES EVALUATED (SPECIFY)	AUDITING ORGANIZATION TEAM MEMBERS	NUMBER OF DEFICIENCIES (OPEN/CLOSED)	CORRECTIVE ACTION VERIFICATION DATE AND METHOD USED (SPECIFY)

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SECTION 1 - PROGRAM COMPLIANCE

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>1.E.1 Verify that measures are established and implemented for indoctrination and training of personnel who perform activities affecting quality.</p> <p>NOTE: Evidence to be obtained from Sections 2 through 7.</p> <p>Appendix B/ANSI N45.2 Ref: (2/2) 10CFR71 Subpart H 71.105/10CFR72 Subpart G 72.144 ASME Section III NQA-1 Supplement 2S-4, NCA3852.1 (a) Vendor Program Ref: _____</p>		
<p>1.E.2 Verify that inspection/test personnel, auditors, NDE, Welding and similar specialists (i.e. ASME Code work design personnel to ASME Section III Appendix XXIII) are qualified and have certifications on file in accordance with Industry and/or supplier QA Program requirements.</p> <p>NOTE: Evidence to be obtained from Sections 1, 2, 3, 4, 6, and 7.</p> <p>Appendix B/ANSI N45.2 Ref: (2, 9, 10, 11, 18, 10, 9, 12, 10, 9, 12, 10, 9, 12) 10CFR71 Subpart H 71.105, 71.119, 71.137/10CFR72 Subpart G 72.144, 72.158, 72.176 ASME Section III NQA-1 Supplement 2S-1, 2S-2, 2S-3, NCA3852.1(a), NCA3852.3(a), NCA3852.3(b), NCA3857.3 Vendor Program Ref: _____</p>		

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SECTION 1 - PROGRAM COMPLIANCE

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METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p><u>1.F.1</u> Verify that measures are established and implemented to assure that sufficient records are:</p> <ul style="list-style-type: none"> a) Available to furnish documentary evidence of the quality of delivered items; b) available to furnish documentary evidence of the quality of generic activities affecting the quality program; c) Provided to the customer in accordance with contract / P.O. requirements. d) Only authorized personnel sign Compliance/Conformance Certificates. <p>Appendix B/ANSI N45.2 Ref: (17/18) 10CFR71 Subpart H 71.135/10CFR72 Subpart G 72.174 ASME Section III NQA-1 Supplement 17S-1, 6S-1, 7S-1, NCA3853.4, NCA3853.5 Vendor Program Ref: _____</p>		
<p><u>1.F.2</u> Verify that measures are established and implemented to assure that records are:</p> <ul style="list-style-type: none"> a) Legible; b) Identifiable and retrievable; c) Retained for proper periods of time; d) Stored to provide protection against damage, deterioration or loss. <p>Appendix B/ANSI N45.2 Ref: (17/18) 10CFR71 Subpart H 71.135/10CFR72 Subpart G 72.174 ASME Section III, NCA3853.4 Vendor Program Ref: _____</p>		
<p>(Applies only to NCA3800 Audits of Non QSC Certificate Holders)</p> <p><u>1. F.3</u> Verify CMTRs include actual results of all required permit analysis tests and examinations.</p> <ul style="list-style-type: none"> a) Verify the material identification is described in either a CMTR or a Certificate of Compliance; b) For material 3/4" & less nominal pipe size, and 1" and less bolting, verify that CMTR or C of C is provided with material spec, grade, class, and heat treatment condition (as applicable); c) Verify the Material Organization Quality System Program revision and date are stated on the CMTR or C of C; <p>Appendix B/ANSI N45.2 Ref: (17/18) ASME Section III, NCA3853.4, Vendor Program Ref: _____</p>		

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SECTION 1 - PROGRAM COMPLIANCE

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>(Applies only to NCA3800 Audits of Non QSC Certificate Holders)</p> <p>1.F.4 Review CMTRs or C of C's to verify:</p> <ul style="list-style-type: none"> a) The certification affirms the contents of the report are correct and accurate and that all test results and operations performed by the Material Organization or its subcontractors are in compliance with the material specification and specific applicable material requirements; b) Chemical Analysis, tests examinations and heat treatments required by the material specification that were not preformed are listed on the CMTR of C of C (may be listed as an attachment); c) When the Material Organizations scope of work includes product form conversion, the organization shall also certify that the material conforms to the applicable dimensional requirements; d) Document how the supplier establishes authorized personnel for certifications, and verify Certifications are signed by those authorized personnel. <p>Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III, NCA3861 Vendor Program Ref: _____</p>		<p style="text-align: center; font-size: 2em; transform: rotate(-45deg); opacity: 0.5;"> "This checklist is intended to provide guidance to a suitably qualified and certified lead auditor that is knowledgeable and competent in the quality assurance standards, codes or regulations indicated within. As it is a guide, the lead auditor is responsible for its appropriate use through consideration of all associated requirements, including all interpretations, judgments and conclusions that are made in performance of the assessment." </p>
<p>(Applies only to NCA4000 Audits)</p> <p>1. F.5 Verify the Certificate Holder completes all operations not completed by the Material Organization and provide a CMTR for all operations performed by him or his approved suppliers, or the Certificate Holder may provide a CMTR for operations performed and at least one CMTR for each of its approved suppliers for operations they had performed.</p> <p>Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III, NCA3862.1 Vendor Program Ref: _____</p>		

SECTION 1 - PROGRAM COMPLIANCE

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>(Applies only to 10 CFR 71 Subpart H vendors)</p> <p>1. F.6 Verify records are retained in accordance with the provisions of 10 CFR Part 71. Specifically:</p> <ul style="list-style-type: none"> a) Records of each shipment of licensed material shall be maintained for 3 years minimum after that shipment [10 CFR 71.91(a)]; b) Records providing evidence of packaging quality shall be maintained for 3 years after the life of the packaging [10 CFR 71.91(c)]; c) Records describing activities affecting packaging quality shall be maintained for 3 years after the Quality Assurance Program Approval is terminated [10 CFR 71.135]. <p>NOTE: These requirements may not apply to vendors if the purchaser is retaining the appropriate records for the vendor. The reasoning for this approach is that it is typically not always possible for the vendor to know the life of a particular storage or transportation device. When this is the case, the applicable requirements of the vendor's QA Program or other applicable regulatory requirements shall apply and be verified utilizing Checklist Items 1.F.1 and 1.F.2.</p> <p>10 CFR 71 Subpart H Vendor Program Ref: _____</p>		
<p>(Applies only to 10 CFR 72 Subpart G vendors)</p> <p>1. F.7 Verify records are retained in accordance with the provisions of 10 CFR Part 72. Specifically:</p> <ul style="list-style-type: none"> a) Records that are required must be maintained until the Commission terminates the license [10 CFR 72.80(c)]. <p>NOTE: These requirements may not apply to vendors if the purchaser is retaining the appropriate records for the vendor. The reasoning for this approach is that it is typically not always possible for the vendor to know the life of a particular storage or transportation device. When this is the case, the applicable requirements of the vendor's QA Program or other applicable regulatory requirements shall apply and be verified utilizing Checklist Items 1.F.1 and 1.F.2.</p> <p>10 CFR 72 Subpart G Vendor Program Ref: _____</p>		

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SECTION 2 - DESIGN

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>2.1 Verify that measures to control the translation of design requirements into design documents are implemented.</p> <p>a) Review engineering/production documents for inclusion of applicable technical and quality requirements.</p> <p>b) Verify inclusion of contractually identified design bases, (regulatory requirements, Code requirements, codes, standards, EQ/Seismic report numbers, analyses etc.) in design/quality documents.</p> <p>c) Assure the P.O. requirements that cannot be met by supplier are promptly communicated back to the buyer. This includes notification of design deviations.</p> <p>NOTE: Evidence reviewed to be used in Sections 6 and 9.</p> <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III NQA-1 Supplement 3S-1 Vendor Program Ref: _____</p>		
<p>2.2 Verify that measures are established and implemented for the identification and control of design interfaces.</p> <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III NQA-1 Supplement 3S-1 Vendor Program Ref: _____</p>		
<p>2.3 Verify that measures are established and implemented for the verification of design adequacy.</p> <p>a) Review design records for evidence that the verification is performed by individuals or groups other than those who performed the design.</p> <p>b) Assure that the verification method to be used is identified. (design review, alternate calculations, or tests)</p> <p>c) When the verification method uses qualification test, verify that a prototype unit is tested under the most adverse design conditions.</p> <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III NQA-1 Supplement 3S-1 Vendor Program Ref: _____</p>		

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SECTION 2 - DESIGN

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>2.4 Verify that measures are established and implemented to control design changes, including changes for spare/replacement parts.</p> <ul style="list-style-type: none"> a) Review revised design documents, (e.g. calculations, drawings, stress reports), to verify that design changes are made using design control measures equal to those of the original design. b) Review design changes to verify that they were reviewed and approved by the same organization as originally reviewed and approved the design, or by other knowledgeable, qualified and designated organizations. c) Verify that design changes or the cumulative effect of multiple changes (i.e. in materials substitutions) have been adequately evaluated to assure that performance (i.e. EQ/seismic), interchangeability and qualification (i.e. test and equipment) are not adversely impacted. d) Verify that Design changes for licensed items also trigger 10CFR71 or 10CFR72 license drawing changes. <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III NQA-1 Supplement 3S-1 Vendor Program Ref: _____</p>		<p style="text-align: center; font-size: 1.2em; font-weight: bold; transform: rotate(-45deg);"> "This checklist is intended to provide guidance to a suitably qualified and certified lead auditor that is knowledgeable and competent in the quality assurance standards, codes or regulations indicated within. As it is a guide, the lead auditor is responsible for its appropriate use through consideration of all associated requirements, including all interpretations, judgments and conclusions that are made in performance of the assessment." </p>

SECTION 3 - PROCUREMENT

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>3.1 Verify that measures are established and implemented to assure that applicable requirements are included in documents for procurement of items including spare and replacement parts and services. Procurement documents should include provisions for the following, as applicable:</p> <ul style="list-style-type: none"> a) Statement of the scope of work. b) Technical requirements by reference to specific drawings, codes, specifications. c) Requirement for a documented quality assurance program, implemented, and meeting applicable code/regulatory requirements. d) Requirement for right of access to plant facilities and records for source inspection/audit. e) Identification of document submittals for approval. f) Identification of deliverable records. g) Requirement for reporting and approving disposition of nonconformances. h) Requirements for records availability, retention and disposition. i) Requirements for extending applicable requirements to lower tier suppliers. j) Applicability of 10CFR21. <p>Appendix B/ANSI N45.2 Ref: (4/5) 10CFR71 Subpart H 71.109/10CFR72 Subpart G 72.144 ASME Section III NQA-1 Supplement 4S-1, NCA3855.4 (a) & (b) Vendor Program Ref: _____</p>		
<p>3.2 Verify that measures are established and implemented to assure that:</p> <ul style="list-style-type: none"> a) Procurement documents are reviewed and approved by authorized personnel prior to release. b) Changes/supplements are processed in the same manner as the original. <p>Appendix B/ANSI N45.2 Ref: (4/5) 10CFR71 Subpart H 71.109/10CFR72 Subpart G 72.144 ASME Section III NQA-1 Supplement 4S-1, NCA3855.4 (a) Vendor Program Ref: _____</p>		
<p>3.3 Verify that measures are established and implemented to assure that purchased material, equipment and services conform to the procurement documents (i.e. performance of receipt inspection).</p> <p>Appendix B/ANSI N45.2 Ref: (7/8) 10CFR71 Subpart H 71.115/10CFR72 Subpart G 72.154 ASME Section III NQA-1 Supplement 7S-1, NCA3855.1 Vendor Program Ref: _____</p>		

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SECTION 3 - PROCUREMENT

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>3.4 Verify that measures are established and implemented for the evaluation, selection and assessment of suppliers (including distributors and calibration, NDE, testing lab and other service suppliers) consistent with the importance, complexity and quality of the product or service.</p> <p>a) Verify evaluations are performed 1) prior to award of contract, 2) at the specified frequency, and 3) ensure only approved suppliers are used.</p> <p>b) Verify that checklists or procedures are used for audits/surveys and that sufficient objective is recorded to substantiate the conclusions reached.</p> <p>c) Verify that the scope of approval of the sub-supplier is commensurate with the requirements of the procurement documents.</p> <p>d) Verify measures are established for source inspection or P.O. specific audit, as necessary.</p> <p>e) Verify when 3rd party audits are used as a basis for supplier qualification the evaluation shall be documented and shall include:</p> <p>Performed and evaluated by qualified personnel, evidence of applicable elements adequately addressed. NOTE: Record audit and surveillance data on Table 1-C.</p> <p>NOTE: The following applies to calibration of M&TE only</p> <p>Verify the supplier implements a program for approving subcontractors through the use of audits, commercial-grade surveys, in-process surveillance or an acceptable accreditation organization such as NVLAP/A2LA except when the calibration supplier is NIST. The following must be met for accepting accreditations and be described in the supplier's Manual</p> <ol style="list-style-type: none"> 1) Accreditation is to ANSI/ISO/IEC 17025: 2005 2) Accreditation covers the needed measurements, parameters, ranges, and uncertainties; 3) Procurement documents shall specify that the certificates/reports must include equipment/standards used and any as found and as left data. 4) reviews shall be performed of certification/reports to insure procurement conformance 5) A current copy of the Accreditation Certificate is maintained on file 6) The supplier is listed on the qualified supplier list along with reference to the accreditation body, accreditation certificate number and expiration date <p>Appendix B/ANSI N45.2 Ref: (7/18) 10CFR71 Subpart H 71.137, 71.115/10CFR71 Subpart G 71.176, 72.154 ASME Section III / NCA-3126 NQA-1 Supplement 7S-1 & 18S-1, NCA3855.3(a) Vendor Program Ref: _____</p>		<p style="text-align: center; font-size: 2em; color: gray; opacity: 0.5; transform: rotate(-45deg);"> "This certificate is intended to provide guidance to a suitably qualified and certified lead auditor that if knowledgeable and competent in the quality assurance standards, codes or regulations is indicated within. As it is a guide, the lead auditor is responsible for its appropriate use through consideration of all associated requirements, including all interpretations, judgments and conclusions that are made in performance of the assessment." </p>

SECTION 3 - PROCUREMENT

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>3.5 Verify that where acceptance of material from an ASME Certificate holder or Material Organization is based on certification from sub-supplier, that the supplier validates the certification via surveillance, audit and/or independent tests.</p> <p>Appendix B/ANSI N45.2 Ref: (7/8) IE Notice 86-21 including supplements NQA-1 Supplement 7S-1, NCA3842.2, NCA3855.3 Vendor Program Ref: _____</p>		
<p>3.6 Verify and assess the Material Organization's controls for using Unqualified Source Material including:</p> <ul style="list-style-type: none"> a) Insuring no welding with filler metal was performed b) Performs chemical analysis on each piece c) Performs all other required tests on each piece. <p>Alternately, testing of each heat and lot is acceptable if a CMTR is provided, material is traceable to the CMTR, the traceability system is audited and approved and upon receipt the Material Organization reviews objective evidence to confirm procurement requirements have been met.</p> <p>Note: Record objective evidence in Table 10</p> <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.121, 71.123, 10CFR72 Subpart 72.160, 72.162 ASME Section III NCA 3855.5 Vendor Program Ref: _____</p>		

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SECTION 5 - MATERIAL CONTROL AND HANDLING, SHIPPING & STORAGE

INTERNAL LINKS: [SUMMARY OF 1-A](#), [1-B](#), [1-C](#), [1-D](#), [1-E](#), [1-F](#), [2](#), [3](#), [4](#), [5](#), [6](#), [7](#), [8](#), [9](#), [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>5.1 Verify that measures are established and implemented to assure the traceability of items (i.e., materials, parts, weld filler material, etc.) is maintained throughout all processing operations.</p> <p>Appendix B/ANSI N45.2 Ref: (8/9) 10CFR71 Subpart H 71.117/10CFR72 Subpart G 72.156 ASME Section III NQA-1 Basic Requirement 8, NCA3855.1 (b), NCA3856.2 Vendor Program Ref: _____</p>		
<p>5.2 Verify that measures are established and implemented for the identification and control of items. Verify the following:</p> <ul style="list-style-type: none"> a) Items are adequately identified as to inspection status. b) The authority for application and removal of identification markings/status indicators is defined. c) Storage areas and methods comply with specified requirements and access controls. d) Item markings are clear and not detrimental. e) Subdivided items have satisfactory transfer of markings to each item. f) Shelf-life requirements are defined and implemented. <p>Appendix B/ANSI N45.2 Ref: (8, 13/9, 14) 10CFR71 Subpart H 71.129/10CFR72 Subpart G 72.168 ASME Section III NQA-1 Supplement 8S-1, 13S-1, NCA3856.1, NCA3858.4 Vendor Program Ref: _____</p>		
<p>5.3 Verify that measures are established and implemented for the control of handling, shipping and storage activities. Areas for consideration include cleaning, handling and packaging, preservation, marking, storing and shipping status.</p> <p>Appendix B/ANSI N45.2 Ref: (13, 14/14, 15) 10CFR71 Subpart H 71.127/10CFR72 Subpart G 72.166 ASME Section III NQA-1 Supplement 13S-1, NCA3857.4 Vendor Program Ref: _____</p>		
<p>5.4 Does the supplier's QA Program adequately control shipping activities to the extent necessary to assure compliance with the applicable material requirements and purchase order to allow drop shipments to third parties or customers?</p> <ul style="list-style-type: none"> a) Review objective evidence of the supplier's measures to control shipping activities. <p>Appendix B/ANSI N45.2 Ref: (4, 7) 10CFR71 Subpart H 71.127/10CFR72 Subpart G 72.166 ASME Section III NCA-3842.2 (g) Vendor Program Ref: _____</p>		

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SECTION 6 - FABRICATION, ASSEMBLY & SPECIAL PROCESSES

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>6.1 Verify by record review and observation (if possible) that fabrication and/or assembly activities are controlled by a shop work order / traveler type document or equivalent system. Verify that the controlling work document (and any referenced instructions, procedures, drawings, as applicable):</p> <ul style="list-style-type: none"> a) Is at the location where the work activity is performed; b) Identifies the work activities to be performed; c) Identifies specific instructions, procedures or drawings (with correct revision levels specified) to be used for the work activity; d) Identifies witness / hold points; e) Contain controls to assure the use and tabulation of correct parts or materials. <p>Appendix B/ANSI N45.2 Ref: (5/6) 10CFR71 Subpart H 71.111/10CFR72 Subpart G 72.150 ASME Section III NQA-1 Basic Requirements 5/6, NCA3853.2(a), NCA3853.3, NCA3857.2 Vendor Program Ref: _____</p>		<p><i>"This checklist is intended to provide guidance to a suitably qualified and certified lead auditor that is knowledgeable and competent in the quality assurance standards, codes or regulations indicated within. As it is a guide, the lead auditor is responsible for its appropriate use through consideration of all associated requirements, including all interpretations, judgments and conclusions that are made in performance of the assessment."</i></p>
<p>6.2 Verify that special processes are accomplished utilizing:</p> <ul style="list-style-type: none"> a) Qualified personnel; b) Qualified procedures; c) Qualified equipment, as applicable. <p>Appendix B/ANSI N45.2 Ref: (9/10) 10CFR71 Subpart H 71.119/10CFR72 Subpart G 72.150 ASME Section III NQA-1 Supplement 9S-1, NCA3857.1, NCA3857.2 Vendor Program Ref: _____</p>		

SECTION 6 - FABRICATION, ASSEMBLY & SPECIAL PROCESSES

INTERNAL LINKS: [SUMMARY OE 1-A](#), [1-B 1-C](#), [1-D](#), [1-E 1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>6.3 Verify that controls are established and implemented for Non-destructive Examinations (NDE). Techniques used include, but are not limited to, radiography, ultrasonic, magnetic particle, and liquid penetrant. Verify the following:</p> <ul style="list-style-type: none"> a. NDE procedures used are consistent with applicable standards. b. NDE procedures are qualified as required by applicable standards. c. NDE examinations are implemented in accordance with procedure requirements. d. NDE personnel are qualified / certified in accordance with applicable standards. e. NDE test equipment is qualified / calibrated in accordance with applicable standards. <p>Appendix B/ANSI N45.2 Ref. (4/5/6) 10CFR71 Subpart H 71.119, 10CFR72 Subpart G 72.158 ASME Section III NQA-1 Basic Requirements 4/5/6, NCA3853.2 (a), NCA3853.3, NCA3857.2 Vendor Program Ref: _____</p>		
<p>6.4 Verify that controls are established and implemented for welding operations/equipment. Verify the following:</p> <ul style="list-style-type: none"> a. Welding Procedure Specifications (WPS) have been completed in accordance with applicable standards. b. Procedure Qualification Record (PQR) has been completed in accordance with applicable standards. c. Welder/Welding Operator qualifications have been completed in accordance with applicable standards. d. Welds are completed in accordance with WPSs and PQRs. e. When Code welding is performed, are procedures and personnel qualified in accordance with Section IX? f. Is all Code Welding performed at the location identified on the certificate of authorization? <p>Appendix B/ANSI N45.2 Reference (9/10) ASME Section III, 10CFR71 Subpart H 71.119, 10CFR72 Subpart G 72.158 NQA-1 Supplement 9S-1, NCA3857.1, NCA3857.2 Vendor Program Ref: _____</p>		

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SECTION 7 - INSPECTION AND TEST

INTERNAL LINKS: [SUMMARY OE 1-A](#), [1-B](#) [1-C](#), [1-D](#), [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>7.1 Verify that measures are established and implemented for the inspection and testing of materials, parts and components. Typical inspections and tests include visual, dimensional, electrical, hydrostatic, nondestructive, operational, functional, chemical, mechanical and physical.</p> <p>Appendix B/ANSI N45.2 Ref: (10, 11/11, 12) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III NQA-1 Supplement 10S-1, 11S-1, NCA3858.1 Vendor Program Ref: _____</p>		
<p>7.2 Verify that inspection and test documents include, as applicable, the inspection/test to be performed, characteristics to be inspected, acceptance criteria, M&TE required, test prerequisites, personnel qualification requirements, results reporting and actions to take should deficiencies be found.</p> <p>Appendix B/ANSI N45.2 Ref: (10, 11/11, 12) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III NQA-1 Supplement 10S-1, 11S-1, NCA3858.1 Vendor Program Ref: _____</p>		
<p>7.3 Verify inspections were performed by individuals other than those who performed the activity being inspected.</p> <p>Appendix B/ANSI N45.2 Ref: (10, 11/11, 12) 10CFR71 Subpart H 71.121/10CFR72 Subpart G 72.160 ASME Section III NQA-1 Supplement 10S-1, 11S-1, NCA3858.1 Vendor Program Ref: _____</p>		

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SECTION 7 - INSPECTION AND TEST

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>7.4 Verify and assess the implementation of any sampling procedures used for the dedication of commercial grade items. The sample plans shall be controlled and their technical basis established and documented.</p> <p>a) Verify that the sampling plans include reduced, normal, and tightened plans. b) Verify that the sampling plans call for accept on zero defects; reject on 1 or more defects</p> <p>Proper consideration should be given to:</p> <ul style="list-style-type: none"> - Lot formation / degree of homogeneity / lot traceability - Sample selection - Complexity of the item - Adequacy of the sub supplier controls - Performance history of the sub supplier. <p>Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.162, 72.168 ASME Section III EPRI NP-5652 (NP-7218) NQA-1 Supplement 10S-1, 11S-1, NCA3800 Vendor Program Ref:</p>		
<p>7.5 Verify that sampling plan(s) other than those used for commercial grade dedication (which those used during receipt/in-process/final inspection) are controlled and acceptably implemented.</p> <p>Appendix B/ANSI N45.2 Ref: (10, 11) ASME Section III NQA-1 Supplement 10S-1, 11S-1 Vendor Program Ref:</p>		
<p>7.6 Verify that the Supplier has assessed and described inspection/testing processes (such as those used during receipt/in process/final inspection or testing) for identifying suspect (including counterfeit/fraudulent) material, items or components that may not be those ordered with indications such as:</p> <ul style="list-style-type: none"> • Altered manufacturer's name, logo, serial number, or manufacturing date • Items differing in configuration, dimensions, fit, finish, color, or other attributes from that specified • 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, exhibit evidence of prior use • Performance inconsistent with specifications or verification or test data furnished • Documentation that appears altered, incomplete, or lacks expected traceability, UL, or manufacturer's markings <p>Appendix B/ANSI N45.2 Ref: (7/8, 10/11, 11/12) ASME Section III NQA-1 Supplement 7S-1, 10S-1, 11S-1 Vendor Program Ref:</p>		

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SECTION 8 - CALIBRATION

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>8.1 Review the reference (primary) and working (secondary) standards and verify traceability to NIST or other recognized standards or natural law.</p> <ul style="list-style-type: none"> a) Assess specific M&TE Standards used as to their range and accuracy relative to items calibrated. b) Review calibration/certification documents for NIST or suitable traceability. <p>NOTE: Calibration standards should have a definitive accuracy range, sensitivity and stability for the instrument being calibrated. The standard shall have a nominal accuracy of four times the nominal accuracy of the M&TE being calibrated. If not possible, documented and authorized basis of acceptance shall be provided.</p> <p>Appendix B/ANSI N45.2 Ref: (12/13) 10CFR71 Subpart H 71.125/10CFR72 Subpart G 72.164 ASME Section III NQA-1 Supplement 12S-1, NCA3858.2 Vendor Program Ref: _____</p>		<p><i>This checklist is intended to provide guidance to a suitably qualified and certified lead auditor that is knowledgeable and competent in the quality assurance standards, codes or regulations indicated within. As it is a guide, the lead auditor is responsible for its appropriate use through consideration of all associated requirements, including all interpretations, judgments and conclusions that are made in performance of the assessment.</i></p>
<p>8.2 Verify maintenance of calibrated equipment & records. Review the equipment & records for the following, as a minimum:</p> <ul style="list-style-type: none"> a) Unique identifiers (e.g., I.D., S/N, name, manufacturer); b) Location/person; c) Status indicator; d) Calibration (recall) interval; e) Calibration procedure including revision; f) Calibration History - Dates calibrated, by whom, results, due date, primary standard; g) As-found, as-left data/condition. h) Is calibration of temperature instruments associated with Charpy impact testing calibrated and the results recorded at least once in each 3-month interval? (Applicable to audits for ASME Section III criteria only) <p>Appendix B/ANSI N45.2 Ref: (12/13) 10CFR71 Subpart H 71.125/10CFR72 Subpart G 72.164 ASME Section III NQA-1 Supplement 12S-1, NCA3858.2, NCA3858.1, NCA3860 Vendor Program Ref: _____</p>		
<p>8.3 Verify that:</p> <ul style="list-style-type: none"> a) Calibrations are performed by qualified personnel; b) Calibrations are performed in an environment controlled to the extent necessary to assure required accuracy; c) Measures are established and implemented when the evaluation of M&TE found to be "out-of-tolerance" and notification to affected customers is provided where appropriate. <p>Appendix B/ANSI N45.2 Ref: (12/13) 10CFR71 Subpart H 71.125/10CFR72 Subpart G 72.164 ASME Section III NQA-1 Supplement 12S-1, NCA3858.2 Vendor Program Ref: _____</p>		

SECTION 9 - SOFTWARE QUALITY ASSURANCE

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p><u>9.1</u> Identify in-house developed software used in safety-related applications, (e.g., design, production, calibration, and acceptance). Verify documented measures are established and implemented to control:</p> <ul style="list-style-type: none"> a) Systematic methodology used; b) Inputs to be used as the basis for the software program; c) Development of the computer code; d) Documented interim and final reviews of the software program prior to release; e) Software validation (i.e., the testing and evaluation of the completed software to ensure compliance with software control requirements); f) Software verification (i.e., the process of determining whether or not the product of a given phase of the software development cycle fulfills the requirements imposed by the previous phase); g) Configuration baseline of the software code after review, validation, verification, approval and release for use; h) Changes or revisions to the software code are developed and subjected to the same levels of control as the original code. <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III NQA-1 Supplement 3S-1 Vendor Program Ref:</p>		
<p>9.2 When software is procured from an outside source, verify adequate controls are in place to ensure that the purchased software meets technical and quality requirements.</p> <ul style="list-style-type: none"> a) For software procured safety-related, assure the supplier audit addressed the sub-supplier's software manufacturing program for testing, verification and validation to ensure the software will function as intended. b) For software procured commercial grade, assure that verification activities (such as verification and validation) are performed and documented to ensure the software functions as intended. <p>Appendix B/ANSI N45.2 Ref: (4/5) 10CFR71 Subpart H 71.109/10CFR72 Subpart G 72.148 ASME Section III NQA-1 Supplement 3S-1 (Para 3.1) Vendor Program Ref:</p>		

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SECTION 9 - SOFTWARE QUALITY ASSURANCE

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>9.3 Verify that corrective action measures exist to document software problems from internal and external sources.</p> <p>Appendix B/ANSI N45.2 Ref: (16/17) 10CFR71 Subpart H 71.133/10CFR72 Subpart G 72.172 ASME Section III NQA-1 Basic Requirement 16 Vendor Program Ref: _____</p>		
<p>9.4 Verify that implemented controls exist to ensure that all users (internal and external) that could potentially be impacted are notified of the software problem and corrective actions and the impact of the deficiencies on that customer.</p> <p>Appendix B/ANSI N45.2 Ref: (16/17) 10CFR71 Subpart H 71.131, 71.133/10CFR72 Subpart G 72.170, 72.172 ASME Section III NQA-1 Basic Requirement 16 Vendor Program Ref: _____</p>		
<p>9.5 Verify that measures have been established and implemented to assure the software is adequately marked, stored, packaged, and shipped.</p> <p>NQA-1 Basic Requirement 13 Vendor Program Ref: _____</p>		
<p>9.6 Verify that retirement of software is managed appropriately as part of the cycle management.</p> <p>NQA-1 Subpart 2.7 Vendor Program Ref: _____</p>		

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NIAC AUDIT CHECKLIST

SUPPLIER: _____

Revision: 9 Dated: 11/4/10

AUDIT NO. _____ PAGE 36 OF 40

9 - SOFTWARE QUALITY ASSURANCE

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

SOFTWARE PROGRAM (NAME, NO., REV./DATE)	PROGRAM END USE (E.G. DESIGN, PRODUCTION, CALIBRATION, ACCEPTANCE)	VERIFICATION / VALIDATION	METHOD / PROCEDURE TO CONTROL ISSUANCE OF CHANGES AND/OR ERROR NOTICES

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SECTION 10 – COMMERCIAL GRADE DEDICATION

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>NOTE: All questions within this section apply to Commercial Grade Items (CGI) dedicated by the supplier for delivery to the customer as a basic component or portion thereof. The questions do not apply for items sold by the supplier as CGI which require member company dedication.</p> <p>10.1 Verify and assess the supplier’s controls for dedication of manufactured / purchased commercial grade items. As a minimum, verify that the supplier’s process includes the following:</p> <p>a) Documented controls, which define the dedication process.</p> <p>b) Verify that the dedication process includes:</p> <ul style="list-style-type: none"> - Functional safety classification of the item - Technical evaluation, and - Item equivalency evaluation, if applicable - Failure Mode and Effects Analysis (Optional) - Identification of critical characteristics for acceptance - Methods of acceptance <ol style="list-style-type: none"> 1. Special Test and Inspection 2. Commercial Grade Survey 3. Source Verification 4. Acceptable Supplier/Item Performance Record, in conjunction with successful implementation of methods 1, 2, or 3 above, and objective evidence that the CGI has been performed as designed after installation in its safety-related application(s). <p>Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107, 71.109/10CFR72 Subpart G 72.146, 72.147 10CFR Part 21 NQA-1 Supplement 4S-1, 7S-1, NCA3800 Vendor Program Ref: _____</p>		<p style="text-align: center; font-size: 2em; transform: rotate(-45deg); opacity: 0.5;"> This checklist is intended to provide guidance to a suitably qualified and certified lead auditor that is knowledgeable and competent in the quality assurance standards, codes or regulations indicated within. As it is a guide, the lead auditor is responsible for its appropriate use through consideration of all associated requirements, including all interpretations, judgments and conclusions that are made in performance of the assessment. </p>
<p>10.2 Describe in detail and verify the adequacy of the controls when the CGI method 1 (Special Tests and Inspections) is employed for dedication of commercial grade items.</p> <p>a) Verify that the tests and inspections specified for the acceptance of commercial grade items adequately verify the identified critical characteristics.</p> <p>b) Verify that the acceptance process is not oversimplified by attempting to rely solely on the part number as a means of acceptance.</p> <p>Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III NQA-1 Supplement 7S-1, 10S-1, 11S-1, NCA3800 Vendor Program Ref: _____</p>		

SECTION 10 – COMMERCIAL GRADE DEDICATION

INTERNAL LINKS: [SUMMARY OE 1-A](#) [1-B](#) [1-C](#) [1-D](#) [1-E](#) [1-F](#) [2](#) [3](#) [4](#) [5](#) [6](#) [7](#) [8](#) [9](#) [10](#)

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<p>10.3 Describe in detail and verify the adequacy of the controls when CGI Method 2 (CGI Surveys) is employed for dedication of commercial grade items.</p> <p>a) Verify that the CGI Survey addresses the control of selected critical characteristics.</p> <p>b) Verify that a CGI Survey is not employed as the basis for accepting items from distributors, unless the survey includes the part manufacturer(s) and the survey confirms adequate controls by both the distributor and the part manufacturer.</p> <p>Note: In cases where the purchaser can be reasonably assured that the distributor performs no actions, which could affect the quality of the item, a survey of the distributor is not necessary.</p> <p>Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III NQA-1 Supplement 18S-1, 10S-1, NCA3800 Vendor Program Ref: _____</p>		
<p>10.4 Describe in detail and verify the adequacy of the controls when CGI Method 4 (Source Verification) is employed for dedication of commercial grade items.</p> <p>a) Verify that in the Source Verification documentation, the critical characteristics are clearly identified, the acceptance criteria are provided, and the actual results obtained during the verification process.</p> <p>Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III NQA-1 Supplement 7S-1, 10S-1, 11S-1, NCA3800 Vendor Program Ref: _____</p>		

"This checklist is intended to provide guidance to a suitably qualified and certified lead auditor that is knowledgeable and competent in the quality assurance standards, codes or regulations indicated within. As it is a guide, the lead auditor is responsible for its appropriate use through consideration of all associated requirements, including all interpretations, judgments and conclusions that are made in performance of the assessment."

