

NUCLEAR INDUSTRY ASSESSMENT CORPORATION AUDIT CHECKLIST

Revision: 3, Dated November 14 2019

Page ___1 __ of ___57

SUPPLIER INFORMATION:					AUDIT SCOPE	
SUPPLIER:				SDI#	10CFR50 App. B	
PRIMARY STREET ADDRESS:		10CFR21				
CITY, STATE, ZIP CODE:					ANSI N45.2	
SECONDARY/MULTIPLE ADDRESSES					ASME NQA-1	
TELEPHONE NO.:					REG GUIDE 1.28 Rev.	□
PRODUCT/SERVICE:					NCSL Z540-1*	
					IEEE 323*	
ASME CODE MARK(S) AND OTHER AUTHORIZATION NO.(S)					IEEE 344*	
			• ()		IEEE 383*	
SUPPLIER CONTACTS:					ASME NCA 3800	
SENIOR CO. OFFICER:	Т	TITLE:	PHONE/ EMAIL:		ASME NCA 4000	
SENIOR QA OFFICER:	Т	ITLE:	PHONE/ EMAIL:		FIELD SERVICES	
AUDIT CONTACT:	Т	ENG. SERVICES				
					10CFR71 Subpart H	
AUDIT INFORMATION:		<u> </u>			10CFR72 Subpart G	
NAME OF MEMBER CO.:					Software Developer*	
SDI AUDIT NO./MEMBER NO.:			AUDIT DATES:		SNT-TC-1A*	
NIAC MEMBERS AUTHORIZE	D TO SHARE AUDIT:	\sim			10CFR50.55(e)	
AUDIT TEAM	MEMBER COMPANY	NAME	TELEPHONE NO.	CHECKLIST SECTIONS AUDITED		
TEAM LEADER						
TEAM MEMBER						
TECHNICAL SPECIALIST (SPECIFY DISCIPLINE)		* = Additional checklists questions are include				
Audit Team Leader:	D	Pate:	NIAC Member Representative:		Date:	

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SUPPLIER: AUDIT NO. _____ PAGE __2 of __57__

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Supplier QA Manual	 Revision	Date

SEC	SECTION DESCRIPTION	S	М	E	PROGRAM ELEMENT MEETS REGULATORY REQUIREMENT	QA PROGRAM REFERENCE	IMPLEMENTATION STATUS	COMMENTS / FINDINGS
<u>OE</u>	ORDER ENTRY	✓	✓	✓				
<u>1-A</u>	ORGANIZATION / PROGRAM	✓	✓	✓				
<u>1-B</u>	NONCONFORMING ITEMS / PART 21 / 50.55(e)	✓	✓	√				
<u>1-C</u>	AUDITS	✓	✓	✓				
<u>1-D</u>	CORRECTIVE ACTION	✓	✓	✓				
<u>1-E</u>	TRAINING / CERTIFICATION	✓	✓	✓		110		
<u>1-F</u>	RECORDS	✓	✓	✓				
<u>2</u>	DESIGN	✓		✓				
<u>3</u>	PROCUREMENT & UNQUALIFIED SOURCE MATERIAL	✓	√	√				
<u>4</u>	DOCUMENT CONTROL	✓	✓	✓	ХO.			
<u>5</u>	MATERIAL CONTROL, HANDLING, SHIPPING & STORAGE	✓	✓					
<u>6</u>	FABRICATION, ASSEMBLY & SPECIAL PROCESSES	✓	✓	4				
<u>7</u>	INSPECTION AND TEST		×		•			
<u>8</u>	CALIBRATION	×	✓					
9	SOFTWARE QUALITY ASSURANCE	✓		✓				
<u>10</u>	COMMERCIAL GRADE DEDICATION	✓	✓	✓				

NOTE: "S" = NQA-1 (SPECIFY NQA-1 YEAR/EDITION ON PAGE 1 UNDER AUDIT SCOPE) / 10CFR50/71/72 "M" = MATERIAL ORGANIZATION ENGINEERING SERVICES

Revision: 3, Dated November 14, 2019

IMPLEMENTATION STATUS KEY

SAT = 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.

Revision: 3, Dated November 14, 2019

AUDIT NO. _____ PAGE __3 __ of __57__ INTERNAL LINKS: SUMMARY OF 1-A 1-B 1-C 1-D 1-F 1-F 2 3 4 5 6 7 8 9 10

SUMN	MARY SHEET - SECTION (DE - ORDER ENTRY		INT	INTERNAL LINKS: <u>SUMMARY OE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 6 7 8</u>		
	METHOD (OF VERIFICATION		RESULTS	ASSESSMENT/SUMMARY		
1-OE	requirements are correctly control documents (i.e., tradocuments, drawings, etc. Verify that exceptions to C and quality requirements a Customer and resolved. It include such items as: inspackaging/shipping, hold packaging/shipping, hold packaging/shipping and packaging/shipping. Appendix B/ANSI N45.2 R 10CFR71 Subpart H 71.10 72.144 ASME Section III, NCA-41 NQA-1 Supplements 3S-1 Vendor Manual Reference Vendor Procedure(s) Reference	Customer Purchase Order (Pare promptly communicated Note: Technical and quality pection/test, documentation, points, etc. def: (3/4) 34.4, NCA-4134.5, NCA-41, 7S-1(1994), R3 & R7 (2008)	ork tracking O) technical to the requirements C of C, t G 72.146, 34.7 8-09a, 2015)	X	or and effectiveness of the supplier's Quality Assurance Program		
	Customer	Customer P. O.		ork Order / Project			
			0,10	10/1			

SUPPLIER:	

AUDIT NO. _____ PAGE __4 of __57__

Revision: 3 , Dated November 14, 2019

INTERNAL LINKS: <u>SUMMARY OE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 6 7 8 9 10</u>

SECTION 1 - PROGRAM COMPLIANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
 1.A.1 Verify that the individual/organization responsible for defining the overall effectiveness of the QA Program: 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. Where more than one organization is involved in the execution of activities, verify that the responsibilities, interfaces, and authority of each organization are defined and documented. 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, NCA-4251.3, NCA-4253.1, NCA-4134.1, NCA-4134.2 NQA-1 Supplement 1S-1(1994); R1 & R2 (2008-09a, 2015) Vendor Manual Reference: 		
Vendor Procedure(s) Reference, revision and date: 1.A.2 Assess whether personnel performing verification activities have the authority, independence and organizational freedom to: a. Identify quality problems. b. Initiate, recommend or provide solutions to problems. c. Verify implementation of solutions. Appendix B/ANSI N45.2 Ref: (1-3) 10CFR71 Subpart H 71.103/10CFR72 Subpart G 72.142 ASME Section III, NCA-4251.3 (c), NCA-4253.1, NCA-4134.1, NCA-4134.2, NCA-4134.7 NQA-1 Supplement 1S-1(1994); R1 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

SUPPLIER:				
AUDIT NO.	PAGE	5	of	57

Revision: 3 , Dated November 14, 2019

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

RESULTS METHOD OF VERIFICATION ASSESSMENT/SUMMARY 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. a. Does the Program identify the activities and items to which it b. Does the supplier supplement the Manual with written policies, procedures, or instructions to the Quality Program? c. Describe the method the supplier uses to notify the Customer in writing of any changes to the Quality Program; Appendix B/ANSI N45.2 Ref: (1-3) ASME Section III. NCA-4251.1. NCA-4253.2. NCA-4253.3. NCA-4134.2. NCA 3842.2(d) NQA-1 Supplement 2S-1, 2S-3 (1994); R2 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: (Applies only to NCA-3800 or NCA-4000 Audits with MO in Scope) 1.A.4 Verify the quality program manual contains the following elements: a. The quality program shall be described in a Quality System Manual which shall be the major basis for demonstration of compliance with the Code. b. The Program documented in the Manual shall be implemented by written procedures which are maintained either separately or in the Manual. c. Technical procedures and processes, such as nondestructive examination, are not part of the Manual; however, the controls of such shall be covered by the Manual. d. The Quality System Manual shall define the specific activities included in the scope of the work the Material Organization proposes to perform, including any combination of: 1. Operations performed during the melting and heat analysis, affecting the mechanical properties, conversion from one product form into another product form including applicable dimensional requirements, and certification to the applicable material specification. 2. Testing, examination, repair, or treatments required by the material specification or the specific applicable material requirements of this Section and certification of the results of such tests, examinations, repairs, or treatments. 3. Receipt, identification, verification, handling, storage, and shipment of material or source material. 4. Qualification of Material Organizations permitted by NCA-3820(b), including control of shipments of material from Qualified

SUPPLIER:	

PAGE 6 of

Revision: 3, Dated November 14, 2019 **SECTION 1 - PROGRAM COMPLIANCE**

AUDIT NO. INTERNAL LINKS: <u>SUMMARY OE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 6 7 8 9 10</u>

RESULTS METHOD OF VERIFICATION ASSESSMENT/SUMMARY Material Organizations to parties other than the party performing the qualification. 5. Approval and control of suppliers of source material or subcontracted services (NCA-4255.3). 6. Utilization of unqualified source material (NCA-4255.5). e. If the Certificate or QSC Holder qualifies non-Certificate Material Organizations (QMO), the quality program manual contains the following requirements: 1. Audit frequencies shall be commensurate with the schedule of production or procurement, but shall be conducted at least once triennially on all elements of the quality system during the interval in which materials or controlled or services are performed by the QMO. 2. Triennial audits shall be supplemented with annual audits or performance assessments documenting the effectiveness of the QMO's program. 3. Performance assessments shall include a documented review of the QMO's history of conditions adverse to quality, nonconformances, and corrective actions. 4. Performance assessments shall include a documented review of periodic testing performed since the last assessment to demonstrate conformance of sample materials to selected requirements of the material specifications. Such testing shall be conducted during the period since the last assessment. Appendix B/ANSI N45.2 Ref: (17/18) ASME Section III, NCA-3842.2, NCA-4251.2, NCA-4253.1 Vendor Manual Reference Vendor Procedure(s) Reference, revision and date (Applies only to NCA-3800 Audits of Non QSC Certificate Holders) [NIAC CODE D Audits] 1.A.5 Verify the Quality System Manual contains the following elements: a. When the qualified Material Organization's scope of activities includes approval and control of suppliers (NCA-4255.3), this activity shall be included in the Quality System Manual. b. When the qualified Material Organization's scope of activities includes utilization of unqualified source material (NCA-4255.5), this activity shall be included in the Quality System Manual. c. 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.

NIAC AUDIT CHECKLIST

SUPPLIER:	

Revision: 3 , Dated November 14, 2019

SECTION 1 - PROGRAM COMPLIANCE

AUDIT NO. PAGE 7 of 57

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
Appendix B/ANSI N45.2 Ref: (17/18) ASME Section III, NCA-3842.2 Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

- Continuation only

SUPPLIER:	

PAGE 8 of

Revision: 3, Dated November 14, 2019 **SECTION 1 - PROGRAM COMPLIANCE**

AUDIT NO. 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 1.B.1 Verify that measures are established and implemented to: a. Identify and segregate nonconforming items [design or quality deviations]. b. Ensure that responsibility and authority for review/disposition is identified. c. Personnel performing evaluations have demonstrated competence in the specific area they are evaluating. d. Control further processing, delivery and installation of items until disposition is completed. Appendix B/ANSI N45.2 Ref. (15/16) 10CFR71 Subpart H 71.131/10CFR72 Subpart G 72.170 ASME Section III, NCA-4258.3, NCA-4258.5, NCA-4134.15 NQA-1 Supplement 15S-1(1994); R15 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 1.B.2 Verify that nonconforming items are reviewed and dispositioned such that: a. The disposition is identified. b. Technical 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. Closeout is adequate. g. Documented customer approval is obtained when required. h. The disposition considers 10CFR21 responsibilities NOTE: Record objective evidence in TABLE 1-B. Appendix B/ANSI N45.2 Ref. (15/16) 10CFR71 Subpart H 71.131/10CFR72 Subpart G 72.170 ASME Section III, NCA-4258.5, NCA-4134.15 NQA-1 Supplement 15S-1(1994); R15 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:

Revision: 3 , Dated November 14, 2019

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

SECTION 1 - PROGRAM COMPLIANCE

SECTION 1 - PROGRAM COMPLIANCE		
METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
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:		
 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. 		
 Notify NRC in writing within 30 days following identification of a defect or failure to comply. 		
 d. Completes evaluation, or interim report, of potential deviations within 60 days of discovery. 		
 e. Establishes a clear connection between the NCR/CAR processes and the 10CFR Part 21 procedure. 		O'
f. Records are retained for proper time periods.		
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 Manual Reference: Vendor Procedure(s) Reference, revision and date:		
1.B.4 Verify that the following documents are posted in a conspicuous place on the premises wherever safety related activities are being conducted: a. The regulations of 10CFR21. b. Section 206 of the Energy Reorganization Act of 1974. c. Procedures adopted pursuant to the regulation of 10CFR21. NOTE: If posting is not practical, the supplier in addition to posting section 206 post a notice which describes the regulations/procedures including the name of the individual to whom reports shall be made and	200	
state where they may be examined. 10CFR Part 21 paragraph 21.6(a)(1)(i)(ii)(iii)(2), or 21.6(b)		
Vendor Manual Reference:		
Vendor Procedure(s) Reference, revision and date:		

SUPPLIER:				
ALIDIT NO	PAGE	10	of	57

SECTION 1 - PROGRAM COMPLIANCE

Revision: 3, Dated November 14, 2019

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
(Applies only when 10CFR50.55(e) is part of the audit scope)		
1.B.5 Verify that a procedure exists for the evaluation and determination if a defect exists under 10CFR50.55(e), that it provides for the notification of NRC, the utility and/or customers as follows:		
 a. Notification to NRC within 2 days following the identification of a defect or failure to comply. 		
 Notify NRC within 30 days following identification of a defect or failure to comply. 		
c. Completes evaluation, or interim report, of potential deviations within 60 days of discovery.		
d. Records are retained for proper time periods		O'
10CFR50.55(e)(3)		
Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		
(Applies only when 10CFR50.55(e) is part of the audit scope)		
 1.B.6 Verify that the following documents are posted in a conspicuous place on the premises wherever safety related activities are being conducted: a. The regulations of 10CFR50.55 (e). 		
 b. Section 206 of the Energy Reorganization Act of 1974. c. Procedures adopted pursuant to the regulation of 10CFR50.55 (e). 		
NOTE: If posting is not practical, the supplier in addition to posting section 206 post a notice which describes the regulations/procedures including the name of the individual to whom reports shall be made and state where they may be examined. 10CFR50.55(e)(3)		
Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

AUDIT NO. _____ PAGE __11 __ of __57

TABLE 1-B - NONCONFORMING ITEMS / CORRECTIVE ACTIONS

Revision: 3, Dated November 14, 2019

NCR / CAR NUMBER	DATE INITIATED	DISCREPANT CONDITION	DISPOSITION	REINSPECTION / VERIFICATION	SCAQ-CAUSE & PREVENTATIVE ACTIONS IDENTIFIED	CLOSURE METHOD & DATE
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	NCR / CAR NUMBER	NCR / CAR NUMBER INITIATED	NCR / CAR NUMBER INITIATED DISCREPANT CONDITION	NCR / CAR NUMBER INITIATED DISCREPANT CONDITION DISPOSITION	NCR / CAR NUMBER INITIATED DISCREPANT CONDITION DISPOSITION REINSPECTION / VERIFICATION	NOR CAR DATE DISPOSITION REINFECTION PREVENTATIVE

RESULTS

SUPPLIER:

Revision: 3 , Dated November 14, 2019

SECTION 1 - PROGRAM COMPLIANCE

AUDIT NO. PAGE 12 of 57

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

ASSESSMENT/SUMMARY

METHOD OF VERIFICATION 1. C. Verify that measures are established and implemented to ensure that a comprehensive system of planned and periodic Internal Audits are performed including the following:

- a. Verify audits are performed at proper frequency.
- b. Verify that the participants have no direct responsibility in the areas audited.
- Verify that procedures and/or checklists were used with objective evidence documented.
- d. Verify the checklist(s) adequately cover the program elements being assessed.
- e. Verify that follow-up action, including re-audit of deficient areas, is taken where needed.

NOTE: Document details of the internal audit program here. Document details of the supplier audit program at Question 3.4. Use Table 1-C to record details for both internal and supplier audits.

Appendix B/ANSI N45.2 Ref: (18/19) 10CFR71 Subpart H 71.137/10CFR72 Subpart G 72.176 ASME Section III, NCA-4259.1, NCA-4134.18 NQA-1 Supplement 18S-1(1994); R18 (2008-09a, 2015)

Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: ailononin

AUDIT NO. _____ PAGE <u>13</u> of <u>57</u>

Revision: 3 , Dated November 14, 2019 SECTION 1 - PROGRAM COMPLIANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
 1. D. Verify that measures are established and in assure that conditions adverse to quality and corrected. These measures shall inclue. a. Identification and description of the condiquality. b. The identification of significant or recurring adverse to quality. c. Determination of the cause and actions recurrence for significant conditions adverse and approval by responsible and adequacy of the corrective action. e. Follow-up actions for closeout to verify the action has taken place or is scheduled. f. Reporting to appropriate levels of management. NOTE: Record objective evidence in Section. Appendix B/ANSI N45.2 Ref: (16/17). 10CFR71 Subpart H 71.133/10CFR72 Subpart H 71.133/10CFR72 Subpart NQA-1 Basic Requirement 15 and 16(1994); 09a, 2015). Vendor Manual Reference: Vendor Procedure(s) Reference, revision and 	e promptly identified de as a minimum: lition adverse to mg conditions taken to prevent erse to quality. hority on the mat the corrective gement. 1-B. art G 72.172 5, NCA-4134.16 R15 & R16 (2008-	ration

Revision: 3 , Dated November 14, 2019 AUDIT NO. _____ PAGE __14 __ of __57

TABLE 1-C -	PROGRAM COMPLIANCE -	AUDITS / SURVEILLANCES
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REPORT ID NUMBER	AUDIT DATE	SCOPE	INTERNAL/ EXTERNAL	ITEMS CONSIDERED AND SUPPLIER PROCESSES EVALUATED (SPECIFY)	AUDIT TEAM LEAD & MEMBERS	NUMBER OF DEFICIENCIES (OPEN/CLOSED)	CORRECTIVE ACTION VERIFIED DATE AND METHOD USED (SPECIFY)
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AUDIT NO. _____ PAGE __15 __ of __57__

Revision: 3 , Dated November 14, 2019

SECTION 1 - PROGRAM COMPLIANCE

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METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
Verify that measures are established and implemented for indoctrination and training of personnel who perform activities affecting quality.		
NOTE : Evidence to be obtained from Sections 2 through 7 and recorded in Table 1-E		
Appendix B/ANSI N45.2 Ref: (2/2) 10CFR71 Subpart H 71.105/10CFR72 Subpart G 72.144 ASME Section III, NCA-4251.1, NCA-4252.1 (a), NCA-4252.2 (a), NCA-4134.2, NQA-1 Supplement 2S-4, 10S-1 (1994); R2 (2008-09a, 2015)		only
Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		
 1.E.2 Verify that inspection/test personnel, Lead Auditors, NDE, Welding and similar specialists (i.e., ASME Code work design personnel to ASME Section III Appendix XXIII) are have demonstrated proficiency, are qualified and have certifications on file in accordance with Industry and/or supplier QA Program requirements. a. For Lead Auditors, this includes evaluation of education, experience, audit training, examination and audit participation per NQA-1. b. NDE personnel shall be qualified as applicable to ASME Sec III to NB-NG5521/WB-5520 or ASME Section XI. c. Welding Personnel are certified in accordance with applicable Code of Construction (such as ASME, AWS, ASTM). d. Inspection and Test Personnel are qualified or certified to appropriate QA program requirements. 	NOT YOU	
NOTE: Evidence to be obtained from Sections 1, 2, 3, 4, 6, and 7 and recorded in applicable Table 1-E. Appendix B/ANSI N45.2 Ref: (2, 9, 10, 11, 18/2, 10, 11, 12, 19) 10CFR71 Subpart H 71.105, 71.119, 71.121, 71.137 10CFR72 Subpart G 72.144, 72.158, 72.160, 72.176 ASME Section III, NCA-4252.1(b), NCA-4252.1(c), NCA-4252.2(b), NCA-4252.2(c), NCA-4257.3, NCA-4134.2, NCA-4134.9, NCA-4134.10, NCA-4134.11 NQA-1 Supplement 2S-1, 2S-2, 2S-3, 10-S1, 11-S1(1994); R2, R9, R10 & R11 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

Revision: 3 , Dated November 14, 2019 AUDIT NO. _____ PAGE __16 ___ of ___57

TABLE 1-E - GENERAL/AUDIT/INSPECTION/CALIBRATION/NDE PERSONNEL	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
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NAME / STAMP/TITLE	INDOCTRINATION AND TRAINING COMPLETED (Yes/No)	QUALIFICATION / CERTIFICATION CERT TYPE AND LEVEL	CERT EXPIRATION DATE	EYE EXAM EXPIRATION DATE
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Revision: 3 , Dated November 14, 2019 AUDIT NO. _____ PAGE __17 __ of __57 __

TABLE 1-E - PROGRAM COMPLIANCE - \	WELDER	/ WELD OPERATOR
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CERT TYPE (PROCESS & POSITION)	CODE QUALIFIED TO	WPS PROCEDURES (with REV / DATE)	MAINTENANCE OF QUALIFICATION
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	(PROCESS & POSITION)	(PROCESS & POSITION)	(MILITAL TRAIL)

SUPPLIER:	
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Revision: 3 , Dated November 14, 2019

SECTION 1 - PROGRAM COMPLIANCE

AUDIT NO. PAGE 18 of 57 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 1.F.1 Verify measures are established and implemented to assure that sufficient QA Records are: a. Available to furnish documentary evidence of the quality of delivered b. Available to furnish documentary evidence of the quality of generic activities affecting the quality program. c. Classified as Permanent or Nonpermanent. d. Stored in a manner that minimizes the risk of loss, damage or destruction. Describe the record storage method used. e. Electronic QA Records are authenticated. f. Verify that only authorized personnel sign Compliance/Conformance Certificates. Appendix B/ANSI N45.2 Ref: (17/18) 10CFR71 Subpart H 71.135/10CFR72 Subpart G 72.174 ASME Section III, NCA-4252.2, NCA-4253.4, NCA-4253.5, NCA-4134.17 NQA-1 Supplement 17S-1, 6S-1, 7S-1 (1994); R17 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 1.F.2 Verify that measures are established and implemented to assure that records are: a. Legible. b. Traceable to associated items and activities and to the document and revision to which an inspection, examination or test was performed. c. Identifiable and retrievable. d. Retained for proper periods of time. e. Corrections to a QA Record are reviewed and approved Appendix B/ANSI N45.2 Ref: (17/18) 10CFR71 Subpart H 71.135/10CFR72 Subpart G 72.174 ASME Section III, NCA-4253.4, NCA-4253.5, NCA-4134.17 NQA-1 Supplement 17S-1, 6S-1, 7S-1 (1994); R17 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:

SUPPLIER:		
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PAGE 19 of Revision: 3, Dated November 14, 2019 AUDIT NO. 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 **SECTION 1 - PROGRAM COMPLIANCE** METHOD OF VERIFICATION **RESULTS** ASSESSMENT/SUMMARY

(Applies only to NCA-3800 Audits)

- 1. F.3 Verify CMTRs include actual results of all required chemical analyses. tests and examinations.
 - a. Verify the material identification is described in either a CMTR or a CoC.
 - 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 or Quality System Certificate number and expiration date on the CMTR or C of C.
 - d. When required chemical analyses (including melting mill heat analysis report except as provided in NCA-4255.5), heat treatment, tests, examinations, or repairs are subcontracted, the approved supplier's certification for the operations performed shall be furnished as an identified attachment to the Certified Material Test Report.
 - e. For welding materials only, when permitted by the material specification and the rules of ASME Section III, the Material Organization or Certificate Holder may provide a chemical analysis of the welding material in lieu of furnishing the melting mill heat analysis.
 - f. When operations other than chemical analysis, heat treatment, tests, examination, or repairs that require maintenance of traceability are subcontracted, these operations and the approved suppliers performing them shall be listed on the Certified Material Test Report, or the approved supplier's certification for the operation may be furnished as an attachment to the Certified Material Test Report.

NOTE: The CMTR shall also include, as applicable: weld repairs. radiographic examinations (except for those radiographs required for the testing of welding or brazing materials). Specific times and temperatures of heat treatments required by the specifications shall be reported or if not required, a statement of the type of heat treatments shall be reported.

Appendix B/ANSI N45.2 Ref: (17/18) ASME Section III, NCA-4253.4, NCA-4253.5, NCA-3861, NCA-3862.1, NCA-3862.2

Vendor Manual Reference:

Vendor Procedure(s) Reference, revision and date:

SUPPLIER:				
AUDIT NO.	PAGE _	20	of	57

NIAC AUDIT CHECKLIST

Revision: 3 , Dated	November 14, 2019
SECTION 1 - PROC	GRAM COMPLIANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
(Applies only to NCA-3800 Audits)		
1.F.4 Review CMTRs or C of C's to verify:		
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 of Section III Division(s) 1, 2 and/or 3.		
 b. Chemical Analysis, tests examinations and heat treatments required by the material specification that were not preformed are listed on the CMTR or C of C (may be listed as an identified attachment). 		
c. When the Material Organization's scope of work includes product form conversion, the organization shall also certify that the material conforms to the applicable dimensional requirements.		
 The Material Organization shall transmit all certifications received from Material Organizations or approved suppliers to the purchaser at time of shipment. 		
 Document how the supplier establishes authorized personnel for certifications, and verify Certifications are signed by those authorized personnel. 	.00	
Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III, NCA-3861		
Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		
(Applies only to NCA-3800 or NCA-4000 Audits)		
1. F.5 Verify the Certificate Holder completes all operations not completed by the Material Organization and provides 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.		
Appendix B/ANSI N45.2 Ref: (3/4) ASME Section III, NCA-3861(c), NCA-3862.1, NCA-4134.7		
Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

SUPPLIER:				
AUDIT NO.	PAGE	21	of	57

Revision: 3, Dated November 14, 2019

SECTION 1 - PROGRAM COMPLIANCE	IN	ITERNAL LINKS: <u>SUMMARY OE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 6 7 8 9 10</u>
METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
(Applies only to 10 CFR 71 Subpart H vendors)		
1. F.6 Verify records are retained in accordance with the provisions of 10 CFR Part 71. Specifically:		
 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)]. 		
 Records describing activities affecting packaging quality shall be maintained for 3 years after the Quality Assurance Program Approval is terminated [10 CFR 71.135]. 		
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.		
10 CFR 71 Subpart H		
Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:)	
(Applies only to 10 CFR 72 Subpart G vendors)		
1. F.7 Verify records are retained in accordance with the provisions of 10 CFR Part 72. Specifically:		
 Records that are required must be maintained until the Commission terminates the license [10 CFR 72.80(c)]. 		
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.		
10 CFR 72 Subpart G		
Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

SUPPLIER:	

AUDIT NO. _____ PAGE __22__ of __57__

SECTION 2 - DESIGN

Revision: 3, Dated November 14, 2019

	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
2.1	 Verify that Design measures are established and implemented for the translation of design requirements into design documents, which include: a. Design Inputs are identified, reviewed for suitability, and approved. b. Review engineering/production documents for inclusion of appropriate technical and quality requirements. c. Verify inclusion of identified design bases, (regulatory requirements, Code requirements, codes, standards, EQ/Seismic report numbers, analyses etc.) in design/quality documents. d. Assure the P.O. requirements that cannot be met by supplier are promptly communicated back to the customer as recorded in question OE.1. NOTE: Evidence reviewed to be used in Sections 6, 7, and 9 as applicable. Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III, NCA-4134.3 NQA-1 Supplement 3S-1(1994); R3 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		
2.2	Verify that Design Inputs (both technical and quality) have been identified and documented, their selection reviewed and approved, are an adequate basis for design verification measures, and for evaluating design changes. Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/ 10CFR72 Subpart G 72.146 ASME Section III, NCA-4134.3 NQA-1 Supplement 3S-1(1994); R3 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:) *	

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AUDIT NO.	PAGE	23	_ of	57

Revision: 3 , Dated November 14, 2019

SECTION 2 - DESIGN INTERNAL LINKS: <u>SUMMARY OE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 6 7 8 9 10</u>

	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
2.3	Verify that Design Analyses are reviewed by a technically qualified individual to verify the adequacy of the results without recourse to the originator.		
	 Sufficient detail as to purpose, methods, assumptions, inputs, references, and units. 		
	 Calculations are identifiable by subject, originator, reviewer, and date. 		
	 For ASME Section III Code work, verify design certification personnel (CEs/RPEs) are qualified to ASME Section III, Appendix XXIII. (Document in Table 1-E) 		
	Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146		
	ASME Section III, NCA-4134.3		
	NQA-1 Supplement 3S-1(1994); R1 & R3 (2008-09a, 2015)		
	Vendor Manual Reference:		
	Vendor Procedure(s) Reference, revision and date:	~?	

SUPPLIER:	

		NIAC AUDIT CHECK
Revision: 3, Dated Nov	ember 14, 2019	

AUDIT NO.	PAGE	24	of	57

SECTION 2 - DESIGN

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
 2.4 Verify design methods, materials, parts, equipment and processes that are essential to the function of the item, including safety function, are selected and reviewed for suitability of application. When the supplier's safety related assembly have parts classified as non-safety related, the following items should be considered: a. Is the process controlled? b. Is a functional evaluation approach used? c. Has the evaluation included analysis of failure modes to assure the part's failure would not prevent the component from performing its safety related function? Appendix B/ANSI N45.2 Ref: (3/4) /10CFR Part 21 par 21.3 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III, NCA-4134.3 NQA-1 Supplement 3S-1(1994); R1 & R3 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		
2.5 Verify that measures are established and implemented for the identification and control of design interfaces. Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III, NCA-4134.3 NQA-1 Supplement 3S-1(1994); R1 & R3 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		
 2.6 Verify that measures are established and implemented for the verification of design adequacy. a. Review design records for evidence that the verification is performed by individuals or groups other than those who performed the design. b. Assure that the verification method to be used is identified. (design review, alternate calculations, or tests) c. When the verification method used is qualification test, verify that a prototype unit is tested under the most adverse design conditions. Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III, NCA-4134.3 NQA-1 Supplement 3S-1(1994); R3 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		

SUPPLIER:	

AUDIT NO. _____ PAGE <u>25</u> of <u>57</u>

INTERNAL LINKS: <u>SUMMARY OE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 6 7 8 9 10</u>

Revision: 3, Dated November 14, 2019 **SECTION 2 - DESIGN**

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	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<u>2.7</u>	Verify that measures are established and implemented to control design changes, including changes for spare/replacement parts or construction/fabrication drawings.		
	 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. 		
	 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.		
	 Verify that Design changes for licensed items also trigger 10CFR71 or 10CFR72 license drawing changes. 		
	Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 ASME Section III , NQA-4134.3 NQA-1 Supplement 3S-1 (1994); R3 (2008-09a, 2015)	"IN	
	Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:),	

SUPPLIER:	

NIAC AUDIT CHECKLIST

Revision: 3, Dated November 14, 2019

AUDIT NO. _____ PAGE <u>26</u> of <u>57</u>

TABLE 2 - DESIGN

DESIGN DOCUMENT	BASES	SUPPORTED BY ENG / TEST DATA	METHOD OF DESIGN VERIFICATION	DESIGN CHANGE CONTROL / REV / DATE	APPLICABLE SOFTWARE
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METHOD OF VERIFICATION RESULTS ASSESSMENT/SUMMARY 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: 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 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.	SECTION 3 - PROCUREMENT	INTERNAL LINKS: SUMMARY DE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 0 7 0 9 10
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: a. Statement of the scope of work.	METHOD OF VERIFICATION	RESULTS ASSESSMENT/SUMMARY
h. Requirements for excords availability, retention and disposition. i. Requirements for extending applicable requirements to lower tier suppliers. j. Applicability of 10CFR21. NOTE: Record objective evidence in Table 3. For commercial calibration and testing services that are commercial grade-dedicated based on an ANSI/ISO/IEC 17025:2005 or 17025:2017 accreditation, verify that measures are established and implemented to require purchase documents to include the following informatiog: a. The service must be provided in accordance with their accredited ISO/IEC 17025:2005 or 17025:2017 program and scope of accreditation. b. As-found calibration data must be reported in the cartificate of calibration when calibrated items are found to be out-of-tolerance (for calibration services only). c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration services only). d. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation. e. 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. Appendix B/ANSI N45.2 Ref. (4/5) 10CFR71 Subpart H 71.109/10CFR72 Subpart G 72.148 ASME Section III, NCA-3126, NCA-4255.2, NCA-4255.3 (c) & (d), NCA-4255.4 (a) & (b) & (c), NCA-4134.4 NOA-1 Supplement 45-1(1994); R4 (2008-09a, 2015)	applicable requirements 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: 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 facilities and records for source inspection/audit. e. Identification of document submittals for approval. f. 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. NOTE: Record objective evidence in Table 3. For commercial calibration and testing services that are commercial grade dedicated based on an ANSI/ISO/IEC 17025:2005 or 17025:2017 accreditation, verify that measures are established and implemented to require purchase documents to include the following information: a. The service must be provided in accordance with their accredited ISO/IEC 17025:2005 or 17025:2017 program and scope of accreditation. b. As-found calibration data must be reported in the cartificate of calibration when calibrated items are found to be out-of-tolerance (for calibration services only). c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration (for calibration services only). d. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation. e. Any additional technical and quality requirements, as necessary, based upon a review of the procured scop	is. (for lay). on.

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C AUDIT CHECKLIST

AUDIT NO. _____ PAGE __28 __ of __57__

Revision: 3 , Dated November 14, 2019 **SECTION 3 - PROCUREMENT**

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
METHOD OF VERIFICATION NEI 14-05A Rev.0 and NEI 14-05 Rev. 1 as approved by NRC NRC Provisional Endorsement ML18275A121 Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:	RESULTS	ASSESSMENT/SUMMARY

SUPPLIER:	

AUDIT NO. _____ PAGE __29 __ of __57

Revision: 3, Dated November 14, 2019 **SECTION 3 - PROCUREMENT**

	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
3.2	Verify that measures are established and implemented to assure that: 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. Appendix B/ANSI N45.2 Ref: (4/5) 10CFR71 Subpart H 71.109/10CFR72 Subpart G 72.148 ASME Section III, NCA-4255.4 (d), NCA-4134.4 NQA-1 Supplement 4S-1(1994); R4 (2008-09a, 2015) Vendor Manual Reference:		
3.3	Vendor Procedure(s) Reference, revision and date: 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). NOTE: Record objective evidence in Table 3 (and Table 7, if applicable). Appendix B/ANSI N45.2 Ref: (7/8) 10CFR71 Subpart H 71.115/10CFR72 Subpart G 72.154 ASME Section III, NCA-4255.1, NCA-4255.2, NCA-4134.7 NQA-1 Supplement 7S-1(1994); R7 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

AUDIT NO. _____ PAGE <u>30</u> of <u>57</u>

Revision: 3 , Dated November 14, 2019 SECTION 3 - PROCUREMENT

	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
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. a. Verify evaluations for selection of suppliers are performed 1) prior to award of contract, 2) at the specified frequency, 3) ensure only approved suppliers are used, (4) and documented to provide objective evidence of satisfactory review. 1. By Supplier History providing identical items. 2. Current Quality Records supported by documented qualitative and quantitative information. 3. Direct evaluation of the supplier's facilities. b. Verify that checklists or procedures are used for audits/surveys and that sufficient objective evidence is recorded to substantiate the conclusions reached. c. Verify that the scope of approval of the sub-supplier is commensurate with the requirements of the procurement documents. d. Verify measures are established for source inspection or P.O. specific audit, as necessary. e. Verify when subcontracted audits are used as a basis for supplier qualification, the evaluation shall be documented, performed and evaluated by qualified personnel, and evidence of applicable elements adequately addressed. Record audit and surveillance data on Table 1-C and Personnel on Table 1-E. NOTE: Assessment of commercial grade calibration and test services has been moved to Section 10 of this checklist. Appendix B/ANSI N45.2 Ref: (7/18) 10CFR71 Subpart H 71.137, 71.115/10CFR72 Subpart G 72.176, 72.154 ASME Section III / NCA-3126, NCA-4255.3 (a) & (b) NCA-4134.4 , NCA-4134.7 NQA-1 Supplement 4S-1, 7S-1 & 18S-1 (1994);R4, R7 & R18 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		LIONONIN

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Revision: 3 , Dated November 14, 2019

UDIT NO.	

PAGE 31 of 57

SECTION 3 - PROCUREMENT

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	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
(App	lies only to NCA-3800 & NCA-4000 Audits)		
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. Appendix B/ANSI N45.2 Ref: (7/8) IE Notice 86-21 including supplements ASME Section III, NCA-4255.2, NCA-4255.3, NCA-4134.7 Vendor Manual Reference:		
	Vendor Procedure(s) Reference, revision and date:		O
(App	ies only to NCA-3800 & NCA-4000 Audits)		
<u>3.6</u>	Verify and assess the Material Organization's controls for using Unqualified Source Material including:		
	a. Insuring no welding with filler metal was performed.	X	
	b. Performs chemical analysis on each piece.		
	 c. Performs all other required tests on each piece. Alternatively, testing of each heat and lot (in lieu of each piece) is acceptable if: A CMTR is provided, The material is traceable to the CMTR, 	Cho.	
	iii. Procurement documents require the supplier of the unqualified source material to establish and maintain traceability of the material to the CMTR,		
	iv. The Material Organization has reviewed and accepted the supplier's Identification & Traceability procedures and verified their compliance (implementation) at a frequency commensurate with production schedules, but at least triennially, and		
	v. Upon receipt, the Material Organization reviews objective evidence to confirm procurement requirements have been met.		
	d. Where Certificates of Conformance are acceptable, chemical analysis shall be performed on each piece, but testing of all other requirements may be performed on a heat/lot basis regardless of whether the traceability program was verified.		
	NOTE: Record objective evidence of upgrading Unqualified Source Material in Table 10. Assess the use of upgraded Unqualified Source Material in lieu of commercial grade dedication in checklist Section 10.		
	Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 ASME Section III, NCA-4255.3, NCA-4255.5 Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

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NIAC AUDIT CHECKLIST

Revision: 3, Dated November 14, 2019

AUDIT NO.	PAGE	32	of	57

TABLE 3 - PROCUREMENT

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P.O. / DATE	SUPPLIER / LOCATION	ITEM DESCRIPTION (P/N, S/N, MODEL NO.)	METHOD / DATE OF SUPPLIER EVALUATION	SCOPE OF SUPPLIER APPROVAL / LIMITATIONS	ACCEPTANCE DOCUMENT / M&TE / INSPECTOR
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Revision: 3 , Dated November 14, 2019 SECTION 4 - DOCUMENT CONTROL

AUDIT NO

AUDIT NO. _____ PAGE <u>33</u> of <u>57</u>

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
 Verify that measures are established and implemented to assure that documents (i.e., procedures, instructions, drawings, work orders, etc.), including changes, are: a. Controlled. b. Include appropriate acceptance criteria. c. Reviewed for adequacy and completeness. d. Approved for release by authorized personnel. e. Distributed to applicable individuals and/or workstations. f. Verify that activities affecting quality are conducted in accordance wit documented instructions/procedures. g. Changes, other than those defined as minor, receive the same review and approval process as the original document. h. Minor changes, if permitted within the program, shall be defined (e.g. as typos or inconsequential editorial corrections) and the persons when can review and approve minor changes shall be clearly identified. Appendix B/ANSI N45.2 Ref: (5, 6/6, 7) 10CFR71 Subpart H 71.111, 71.113/10CFR72 Subpart G 72.150, 72.152 ASME Section III, NCA-4253.1 (b) & (c), NCA-4253.2 (b), NCA-4253.3, NCA-4134.5, NCA-4134.6 NQA-1 Supplement 6S-1(1994); R5 & R6 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 	,	

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Revision: 3, Dated No	ovember 14, 2019	

AUDIT NO. _____ PAGE <u>34</u> of <u>57</u>

SECTION 5 - MATERIAL	CONTROL	AND HANDLING	CHIDDING	PETODACE
SECTION 5 - MATERIAL	CUNTRUL	AND HANDLING.	. SHIPPING (& STURAGE

5.1 Verify that measures are established and implemented to assure only correct and according to assure identification (marking) is adultished (i.e., materials, parts, was makerial, etc.) and maintained throughout all processing operations. a. Item markings are clear and not detrimental (includes welding & brazing materials). b. Subdivided tlems have satisfactory transfer of markings to each item. Appendix BANSI MAS 2 Ref. (80) 10CFR71 Subpart H 71.117/10CFR72 subpart G 72.156 ASME Section III, NCA-4256.1 (b). NCA-4256.2, NCA-4256.3, NCA-4154.8 NCA-4154	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
Appendix BIANSI N45.2 Ref. (8/9) 10CFR71 Subpart H 7.1117/10CFR72 Subpart G 72.156 ASME Section III, NCA-4255.1 (b), NCA-4256.1 (a) & (c), NCA-4256.2, NCA-4256.3, NCA-4256.3, NCA-4256.4, NCA-4134.8 NQA-1 Basic Requirement 8(1994); R8 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 5.2 Verify that measures are established and implemented for the Inspection, Test, and Operating Status of items. Verify the following: a. Items are adequately identified as to inspection and test status. b. Status of items are maintained by suitable indicators. c. The authority for application and removal of identification markings/status indicators is defined. Appendix BIANSI NAS.2 Ref. (8, 13).9, 14, 15) 10CFR71 Subpart H 71.129/10CFR72 Subpart G 72.168 ASME Section III NCA-4256.1, NCA-4256.3, NCA-4256.4, NOA 4558. NCA-4134.8, NCA-4134.14 NQA-1 Supplement 8S-1, Basic Requirement 14(1994); R1# (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date 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. a. Storage areas and methods comply with specified requirements and access controls. b. Shelf-life requirements are defined and implemented. Appendix BIANSI N45.2 Ref. (13, 14/14, 15) 10CFR71 Subpart H 71.127/10CFR72 Subpart G 72.166 ASME Section IIII, NCA-4255.4, NCA-4134.13	and accepted items are used, and to assure identification (marking) is established (i.e., materials, parts, weld filler material, etc.) and maintained throughout all processing operations. a. Item markings are clear and not detrimental (includes welding & brazing materials).		
Vendor Procedure(s) Reference, revision and date: 5.2 Verify that measures are established and implemented for the Inspection, Test, and Operating Status of items. Verify the following: a. Items are adequately identified as to inspection and test status. b. Status of items are maintained by suitable indicators. c. The authority for application and removal of identification markings/status indicators is defined. Appendix B/ANSI N45.2 Ref: (8, 13/9, 14, 15) 10CFR71 Subpart H 71.129/10CFR72 Subpart G 72.168 ASME Section III NCA-4256.1, NCA-4256.3, NCA-4256.4, NOA-4258.4, NCA-4134.8, NCA-4134.14 NOA-1 Supplement 8S-1, Basic Requirement 14(1994); R1# (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date 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. a. Storage areas and methods comply with specified requirements and access controls. b. Shelf-life requirements are defined and implemented. Appendix B/ANSI N45.2 Ref: (13, 14/14, 15) 10CFR71 Subpart H 71.127/10CFR72 Subpart G 72.166 ASME Section III, NCA-4257.4, NCA-4134.13	Appendix B/ANSI N45.2 Ref: (8/9) 10CFR71 Subpart H 71.117/10CFR72 Subpart G 72.156 ASME Section III, NCA-4255.1 (b), NCA-4256.1 (a) & (c), NCA-4256.2, NCA-4256.3, NCA-4256.4, NCA-4134.8		
Test, and Operating Status of items. Verify the following: a. Items are adequately identified as to inspection and test status. b. Status of items are maintained by suitable indicators. c. The authority for application and removal of identification markings/status indicators is defined. Appendix B/ANSI N45.2 Ref. (8, 13/9, 14, 15) 10CFR71 Subpart H 71.129/10CFR72 Subpart G 72.168 ASME Section III NCA-4256.1, NCA-4256.3, NCA-4256.4, NOA-4258.4 NCA-4134.8, NCA-4134.14 NQA-1 Supplement 8S-1, Basic Requirement 14(1994); R14 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date 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. a. Storage areas and methods comply with specified requirements and access controls. b. Shelf-life requirements are defined and implemented. Appendix B/ANSI N45.2 Ref. (13, 14/14, 15) 10CFR71 Subpart H 71.127/10CFR72 Subpart G 72.166 ASME Section III, NCA-4257.4, NCA-4134.13			
handling, shipping and storage activities. Areas for consideration include cleaning, handling and packaging, preservation, marking, storing and shipping status. a. Storage areas and methods comply with specified requirements and access controls. b. Shelf-life requirements are defined and implemented. Appendix B/ANSI N45.2 Ref: (13, 14/14, 15) 10CFR71 Subpart H 71.127/10CFR72 Subpart G 72.166 ASME Section III, NCA-4257.4, NCA-4134.13	 Test, and Operating Status of items. Verify the following: a. Items are adequately identified as to inspection and test status. b. Status of items are maintained by suitable indicators. c. The authority for application and removal of identification markings/status indicators is defined. Appendix B/ANSI N45.2 Ref: (8, 13/9, 14, 15) 10CFR71 Subpart H 71.129/10CFR72 Subpart G 72.168 ASME Section III NCA-4256.1, NCA-4256.3, NCA-4256.4, NOA-4258.4, NCA-4134.8, NCA-4134.14 NQA-1 Supplement 8S-1, Basic Requirement 14(1994); R14 (2008-09a, 2015) Vendor Manual Reference:		
Vendor Manual Reference:	 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. a. Storage areas and methods comply with specified requirements and access controls. b. Shelf-life requirements are defined and implemented. Appendix B/ANSI N45.2 Ref: (13, 14/14, 15) 10CFR71 Subpart H 71.127/10CFR72 Subpart G 72.166 ASME Section III, NCA-4257.4, NCA-4134.13 NQA-1 Supplement 13S-1(1994); R13 (2008-09a, 2015) 		

NIAC	AUDIT	CHECKL	IST

Revision: 3 , Dated November 14, 2019	AUDIT NO.		35	of	57
SECTION 5 - MATERIAL CONTROL AND HANDLING, SHIPPING & STORAGE	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

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METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
Vendor Procedure(s) Reference, revision and date:		
(Applies only to NCA3800 audits)		
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?		
 Review objective evidence of the supplier's measures to control shipping activities. 		
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 Manual Reference: Vendor Procedure(s) Reference, revision and date:		

Revision: 3, Dated November 14, 2019

AUDIT NO. _____ PAGE <u>36</u> of <u>57</u>

TABLE 5 - MATERIAL CONTROL AND HANDLING SHIPPING & STORAGE INTERNAL LINKS: SLIMMARY OF 1-A 1-B 1-C 1-D 1-E 1-E 2 3 4 5 6 7 8 9 10

TABLE 5 - MATERIAL CONTROL AND HANDLING, SH	INTERNAL LINKS: SUMMA	ARY OE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 6 7 8 9 10
ITEM DESCRIPTION (PART #, P.O., ETC.)	METHOD OF IDENTIFICATION / TRACEABILITY	STATUS
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Revision: 3, Dated November 14, 2019

AUDIT NO. _____ PAGE <u>37</u> of <u>57</u>

SECTION 6 - FABRICATION, ASSEMBLY & SPECIAL PROCESSES

	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
6.1	 Verify 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): 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. f. Contain space to document Status. Appendix B/ANSI N45.2 Ref: (5/6) 10CFR71 Subpart H 71.111/10CFR72 Subpart G 72.150 ASME Section III, NCA-4253.2(a), NCA-4253.3, NCA-4255.2, NCA-4257.2, NCA-4134.9 NQA-1 Basic Requirements 5/6, 9S-1(1994); R5, R6, & R9 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:	ail	
6.2	 Verify measures are established and implemented such that special processes other than Welding, Heat Treatment, and NDE (evaluated separately in Section 6.3-6.5) are accomplished utilizing: a. Qualified personnel; Objective Evidence to be recorded in Table 1-E. b. Qualified procedures; c. Qualified equipment, as applicable. Objective Evidence to be recorded in Table 8. NOTE: Use Table 6 to record those Special Processes evaluated. Appendix B/ANSI N45.2 Ref: (9/10) 10CFR71 Subpart H 71.119/10CFR72 Subpart G 72.158 ASME Section III, NCA-4257.1, NCA-4134.9 NQA-1 Supplement 9S-1(1994); R2, R5, R9, R12 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		

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Revision: 3 , Dated November 14, 2019

AUDIT NO. _____ PAGE <u>38</u> of <u>57</u>

SECTION 6 - FABRICATION, ASSEMBLY & SPECIAL PROCESSES

RESULTS	ASSESSMENT/SUMMARY
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SUPPLIER:	

AUDIT NO. _____ PAGE <u>39</u> of <u>57</u>

SECTION 6 - FABRICATION, ASSEMBLY & SPECIAL PROCESSES

	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
<u>6.4</u>	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: 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 Procedures have been demonstrated as required (ANI, NDE Level III), when applicable. e. NDE is performed by Qualified personnel; Objective Evidence to be recorded in Table 1-E. f. NDE methods utilize calibrated equipment, as applicable. Objective Evidence to be recorded in Table 8. Appendix B/ANSI N45.2 Ref. (4/5/6) 10CFR71 Subpart H 71.119, 10CFR72 Subpart G 72.158 ASME Section III, NCA-4253.2 (a), NCA-4253.3, NCA-4257.1, NCA-4134.9 NQA-1 Basic Requirements 5/6, 2S-2, 9S-1(1994); R2, R5, R9 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: Verify that controls are established and implemented for welding operations/equipment. Verify the following: a. Welding Procedure Specifications (WPS) have been completed in accordance with applicable Code or Standards. b. Procedure Qualification Record (PQR) has been completed in accordance with applicable Code or Standards. c. Welder/Welding Operator qualifications have been completed in accordance with applicable Code or Standards.	RESULTS	ASSESSMENT/SUMMARY
	 d. Welds are completed in accordance with approved WPS's. e. Is all Section III Code Welding performed at the location identified on the Certificate of Authorization? f. Welding methods utilize calibrated equipment, as applicable. Objective 		
	Evidence to be recorded in Table 8. Appendix B/ANSI N45.2 Reference (9/10) ASME Section III, NCA-4257.1, NCA-4257.3, NCA-4134.9 10CFR71 Subpart H 71.119, 10CFR72 Subpart G 72.158 NQA-1 Supplement 9S-1(1994); R9 (2008-09a, 2015)		
	Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

JPPLIER:	

AUDIT NO. _____ PAGE 40 of 57

TABLE 6 - FABRICATION, ASSEMBLY & SPECIAL PROCESSES

ITEM DESCRIPTION	SHOP W/O TRAVELER WORK	PROCEDURE	QUALIFICATION			
(P/N, S/N, MODEL NO.)	SHOP W/O TRAVELER	ACTIVITY/PROCESS	(with REV / DATE)	PERSONNEL	PROCEDURE	EQUIPMENT
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PAGE 41 of 57

SECTION 7 - INSPECTION AND TEST

	TION 7 - INSPECTION AND TEST	111	TERNAL LINKS: SUMMARY DE 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
7.1	Verify that measures are established and implemented for the in-process and final inspection of materials, parts and components. Typical inspections include visual, dimensional, and operations requiring witness.		
	 a. Verify inspections were performed by individuals other than those who performed the activity being inspected. 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, NCA-4255.5, NCA-4258.1, NCA-4134.10 NQA-1 Supplement 10S-1(1994); R10 (2008-09a, 2015) 		
	Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		O ¹
7.2	Verify that measures are established and implemented for testing activities. Typical tests include hydrostatic, operational, functional, chemical, mechanical and physical. Procedures shall include the characteristics to be verified, acceptance criteria, M&TE required, test prerequisites, condition of the test equipment, suitable environmental conditions, personnel qualification requirements, results reporting and actions to take should deficiencies be found. NOTE: Verify if the supplier uses Standard Industry published procedures, such as ASTM or ASME Testing Procedures 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, NCA-4258.1, NCA-4134.11 NQA-1 Supplement 11S-1(1994); R11 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		
7.3	Verify that inspection and test reports include: item inspected or tested, date of the activity, individual performing the activity or a data recorder, the inspection/test to be performed (type of observation), results or acceptability, reference to information on action taken in connection with nonconformances. NOTE: M&TE shall be traceable to the inspection or test for which they were used. 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, NCA-4258.1, NCA-4134.10, NCA-4134.11 NQA-1 Supplement 10S-1, 11S-1(1994); R10 & R11 (2008-09a, 2015) Vendor Manual Reference:		
	Vendor Procedure(s) Reference, revision and date:		

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Revision: 3 , Dated November 14, 2019

SECTION 7 - INSPECTION AND TEST

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PAGE 42 of 57

	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
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. a. Verify that the sampling plans include designation of reduced, normal, or tightened plans as appropriate. b. Verify that the sampling plans call for accept on zero defects; reject on 1 or more defects. Proper consideration should be given to: Lot formation / degree of homogeneity / lot traceability / heat numbers. Sample selection. Complexity of the item. Adequacy of the sub supplier controls. Performance history of the sub supplier. NOTE: Record objective evidence in Table 7 and Table 10. Appendix B/ANSI N45.2 Ref: (10/11) CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.162, 72.168 NCA-4255.5 EPRI NP-5652 (NP-7218) and EPRI-5652 Rev.1 NQA-1 Supplement 7S-1, 10S-1, 11S-1(1994); Part I R7 & Part II SP 2.14 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		
7.5	Verify that sampling plan(s) used for fabrication / Inspection / test activities, both destructive and nondestructive, are controlled and acceptably implemented. a. Confirm Sampling Plans are based on standard statistical methods with engineering approval. Appendix B/ANSI N45.2 Ref: (10, 11) NCA-4258.1, NCA-4134.10 NQA-1 Supplement 10S-1(1994); R10 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

NIAC	AUDIT	CHECKI	IST

SUPPLIER: _____

Revision: 3, Dated November 14, 2019

AUDIT NO. _____ PAGE <u>43</u> of <u>57</u>

SECTION 7 - INSPECTION AND TEST

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
 7.6 Verify the Supplier has assessed and described inspection/testing processes for identifying suspect misrepresented items (including counterfeit/fraudulent) material, items or components that may not be those ordered, with indications such as: 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 certification or test data furnished Documentation that appears altered, incomplete, or lack expected traceability, UL, or manufacturer's markings Appendix B/ANSI N45.2 Ref: (7/8, 10/11, 11/12) NCA-4255.1, NCA-4258.1, NCA-4134.7 NQA-1 Supplement 7S-1, 10S-1, 11S-1, BR15 (1994); R7, R10, R11, R15 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		

SUPPLIER:	

AUDIT NO. _____ PAGE __44 __ of __57__

TABLE 7 - INSPECTION AND TEST

Revision: 3, Dated November 14, 2019

ITEM	INSPECTION/TEST REPORT	INSPECTOR /	INSPECTION / TEST	M&TE USED				RESULTS	NCR	
DESCRIPTION (P/N, S/N, ETC.)	Type of Activity	Number / Date	TESTER NAME / STAMP	DOCUMENT TITLE/#/DATE	Equipment I.D. & NO.	Cal Date	Due Date	Date Used	SAT/UNSAT	NO.
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AUDIT NO. _____ PAGE <u>45</u> of <u>57</u>

Revision: 3, Dated November 14, 2019 **SECTION 8 - CALIBRATION**

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	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
8.1	 Review the reference (primary) and working (secondary) standards and verify traceability to NIST or other recognized standards or natural law. 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. NOTE: Calibration standards shall 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. Appendix B/ANSI N45.2 Ref: (12/13) 10CFR71 Subpart H 71.125/10CFR72 Subpart G 72.164 ASME Section III, NCA-4258.2, NCA-4134.12 NQA-1 Supplement 12S-1(1994); R12 (2008-09a, 2015) Vendor Manual Reference: 		
	Vendor Procedure(s) Reference, revision and date:	- 0	
8.2	Verify maintenance of calibrated equipment & records. Review the equipment & records for the following, as a minimum: 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. Are 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). Appendix B/ANSI N45.2 Ref: (12/13) 10CFR71 Subpart H 71.125/10CFR72 Subpart G 72.164		
	ASME Section III, NCA-4258.2, NCA-4258.3, NX-2360, NCA-4134.12 NQA-1 Supplement 12S-1(1994); R12 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

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AUDIT NO. _____ PAGE 46 of 57

Revision: 3 , Dated November 14, 2019 **SECTION 8 - CALIBRATION**

SUPPLIER:		
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AUDIT NO. _____ PAGE <u>47</u> of <u>57</u>

Revision: 3, Dated November 14, 2019

TABLE 8 - CALIBRATION				IN	TERNAL LINKS:	SUMMARY OE	1-A 1-B 1-C	<u>1-D 1-E 1-F 2 3 4 </u>	<u>5 6 7 8 9 10</u>
NAME / M&TE I.D.	CAL. PROCEDURE	FREQUENCY OF CAL.	CAL. DATE	DUE DATE	CALIB. BY	AS FOUND CALIBE	AS LEFT RATION	STANDARDS USED / NIST TRACEABILITY	P.O. NUMBER (IF SUB- SUPPLIER)
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Revision:	ડ ,	Dated	November 14,	2019

AUDIT NO.	PAGI	E 48	of	57

SECTION 9 - SOFTWARE QUALITY ASSURANCE

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
 9.1 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: 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. NOTE 1: For the purpose of all sections of this checklist, the term software also includes firmware. Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107/10CFR72 Subpart G 72.146 NCA4134.3, NCA-4134.11 NQA-1 Supplement 3S-1, 11S-2, Subpart 2.7 (1994); Part I R3 & R11, Part II SP 2.7 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		
 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. 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 dedication activities (such as verification and validation) are performed and documented to ensure the software functions as intended. Commercial grade dedication information to be documented in section 10. Appendix B/ANSI N45.2 Ref: (4/5) 10CFR71 Subpart H 71.109/10CFR72 Subpart G 72.148 NQA-1 Supplement 3S-1, 7S-1, 11S-2, Subpart 2.7 (1994); Part I R3, R7 & R11, Part II SP 2.7 & 2.14 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		

SUPPLIER:				
AUDIT NO.	PAGE	49	of	57

SECTION 9 - SOFTWARE QUALITY ASSURANCE

	METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
9.3	Verify that corrective action measures exist to document software problems from internal and external sources. Appendix B/ANSI N45.2 Ref: (16/17) 10CFR71 Subpart H 71.133/10CFR72 Subpart G 72.172 NQA-1 Basic Requirement 16, Subpart 2.7 (1994); Part II SP 2.7 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		
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. Appendix B/ANSI N45.2 Ref: (16/17) 10CFR71 Subpart H 71.131, 71.133/10CFR72 Subpart G 72.170, 72.172 NQA-1 Basic Requirement 16, Subpart 2.7 (1994); Part II SP 2.7 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		
<u>9.5</u>	Verify that measures have been established and implemented to assure that software is adequately marked, stored, packaged, and shipped NQA-1 Basic Requirement 13, Subpart 2.7(1994); Part I R13, Part II SP 2.7 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:)	
9.6	Verify that retirement of software is managed appropriately as part of life cycle management. NQA-1 Subpart 2.7 (1994); Part II SP 2.7 (2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

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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AUDIT NO. _____ PAGE __<u>51</u> of __<u>57</u> INTERNAL LINKS: <u>SUMMARY OE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 6 7 8 9 10</u>

SECTION 10 - COMMERCIAL GRADE DEDICATION

SECTION 10 - COMMENCIAL GRADE DEDICATION	11411	TRIAL LINKS. SOMMAKT OF 1-4 1-6 1-6 1-6 1-6 1-6 1-6 1-6 1-6 1-6 1-6
METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
NOTE: All questions within this section apply to Commercial Grade Items (CGI) and Services dedicated by the supplier for delivery to the customer as a basic component or for internal use in safety-related functions (e.g. software, consumables, fasteners, elastomers, calibration/testing services, NDE, design, etc.). The questions do not apply for items sold by the supplier as CGI which require purchaser dedication.		
 Verify and assess the supplier's controls for dedication of manufactured / purchased commercial grade items or services. As a minimum, verify that the supplier's process includes the following: a. Documented controls which define the dedication process, 		
 Verify that personnel performing technical evaluations for commercial grade dedication have the appropriate expertise to perform the evaluation 		
c. Verify that the dedication process includes:		
Functional safety classification of the item.		
2. Technical evaluation.		
3. Item equivalency evaluation, if applicable.		
4. Failure Mode and Effects Analysis (Optional, See Note 1).		
5. Identification of critical characteristics for acceptance.	~'0	
6. Customer approval of dedication plan, as applicable.		
7. Methods of acceptance.		
Special Test and Inspection		
Commercial Grade Survey) *	
Source Verification		
 Acceptable Supplier/Item Performance Record, in conjunction with successful implementation of methods 1, 2, or 3 above, and objective evidence that the CGI performed 		
as designed after installation in its safety-related application(s).		
d. If upgraded Unqualified Source Material is being supplied as safety		
related material with no additional testing, verify that this process is		
addressed in the organizations Commercial Grade Dedication		
procedure(s) (see Note 3).		
NOTE 1: 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.		
NOTE 2: Special consideration should be given to items that are		
seismically/environmentally qualified (e.g., relays, switches, nonmetallic		
items, etc.).		
NOTE 3: Utilization of Unqualified Source Material is not equivalent to		
commercial grade dedication. However, the upgraded material (i.e.,		
material fully tested to the material specification requirements under an		

NIAC	AUDIT	CHECKL	IST

AUDIT NO. _____ PAGE 52 of 57

Revision: 3 , Dated November 14, 2019 SECTION 10 - COMMERCIAL GRADE DEDICATION

INTERNAL LINKS: <u>SUMMARY OE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 6 7 8 9 10</u>

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
Appendix B program) may be used for safety related, non-ASME Code applications without additional dedication activities as described in Revision 1 of EPRI NP-5652 (endorsed in NRC RG 1.164).		
Appendix B/ANSI N45.2 Ref: (3/4)/ 10CFR Part 21 10CFR71 Subpart H 71.107, 71.109/10CFR72 Subpart G 72.146, 72.148 NEI 14-05A Rev.0 and NEI 14-05 Rev. 1 as approved by NRC NQA-1 Supplement 4S-1, 7S-1(1994), Part II, Subpart 2.14(2008-09a, 2015)		
Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date:		

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SECTION 10 - COMMERCIAL GRADE DEDICATION

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METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
10.2 The NRC accepts use of commercial-grade calibration and testing services accredited by a nationally recognized accreditation organization that is a signatory of the ILAC MRA (e.g. NVLAP, A2LA) except when the calibration supplier is NIST. The NRC requires that such an accredited commercial-grade calibration service be utilized only through implementation of the supplier's commercial grade dedication process to dedicate the service. For both, the following must be described in the supplier QA Manual (for Licensees) or supplier QA Program: a. Accreditation is to ANSI/ISO/IEC 17025:2005 or 17025:2017. b. Accreditation covers the needed measurements, parameters, ranges, and uncertainties. c. Procurement documents shall specify that the certificates/reports must include equipment/standards used and any as found and as left data. d. Acceptance activities include a documented review of certifications/reports to verify that the laboratory has certified it provided the service in accordance with their accredited ISO/IEC-17025:2005 or 17025:2017 program and scope of accreditation, and have complied with any other requirements specified in the Purchaser's procurement documents. e. A current copy of the Accreditation Certificate is maintained on file or a quality record demonstrates that the validity of the Accreditation Certificate was verified on-line at the accreditation organization's online site. f. Verify a technical evaluation has been performed and documented. NOTE: Acceptance of the accreditation of calibration and test laboratory services by ILAC MRA signatories is only valid in lieu of performing a commercial-grade survey if the above is part of the supplier's commercial-grade dedication process. Appendix B/ANSI N45.2 Ref: (3/4) 10CFR71 Subpart H 71.107, 71.109/10CFR72 Subpart G 72.146, 72.148 10CFR71 Subpart H 71.107, 71.109/10CFR72 Subpart G 72.146, 72.148 10CFR Part 21 NCA-4255.3 NEI 14-05A Rev.0 and NEI 14-05 Rev. 1 as approved by NRC NRC Provisional Endorsement ML18275A121 NQA-1 Suppleme		
Vendor Procedure(s) Reference, revision and date:		

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Revision: 3, Dated November 14, 2019

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SECTION 10 - COMMERCIAL GRADE DEDICATION	IN ⁻	TERNAL LINKS: <u>SUMMARY OE 1-A 1-B 1-C 1-D 1-E 1-F 2 3 4 5 6 7 8 9 10</u>
METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
 Describe in detail and verify the adequacy of the controls when CGI Method 1 (Special Tests and Inspections) is employed for dedication of commercial grade items. a. Verify that the tests and inspections specified for the acceptance of commercial grade items adequately verify the identified critical characteristics. b. Verify that the acceptance process is not oversimplified by attempting to rely solely on the part number as a means of acceptance. Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 NQA-1 Supplement 7S-1, 10S-1, 11S-1(1994), Part II, Subpart 2.14(2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		
 10.4 Describe in detail and verify the adequacy of the controls when CGI Method 2 (CGI Surveys) is employed for dedication of commercial grade items. a. Verify that the CGI Survey addresses the control of selected critical characteristics. 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. 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. Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 NQA-1 Supplement 18S-1. 10S-1(1994), Part II, Subpart 2.14(2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		

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Revision: 3, Dated November 14, 2019

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AUDIT NO. _____ PAGE __55 __ of __57

SECTION 10 - COMMERCIAL GRADE DEDICATION

METHOD OF VERIFICATION	RESULTS	ASSESSMENT/SUMMARY
 10.5 Describe in detail and verify the adequacy of the controls when CGI Method 3 (Source Verification) is employed for dedication of commercial grade items. 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. Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 NQA-1 Supplement 7S-1, 10S-1, 11S-1(1994), Part II, Subpart 2.14(2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		
 10.6 Verify that prior to classifying the item or service as acceptable to perform its safety function, the dedicating entity determines that the following have been successfully performed, as applicable: a. Damage was not sustained during shipment. b. The item or service has satisfied the specified acceptance criteria for the identified critical characteristics. c. Specified documentation was received and is acceptable. d. The critical characteristics have been acceptably met and verified. e. An authorized person has confirmed and documented the item or service will meet its intended safety function. Appendix B/ANSI N45.2 Ref: (10/11) 10CFR71 Subpart H 71.121, 71.123/10CFR72 Subpart G 72.160, 72.162 NQA-1 Supplement 7S-1, 10S-1, 11S-1(1994), Part II, Subpart 2.14(2008-09a, 2015) Vendor Manual Reference: Vendor Procedure(s) Reference, revision and date: 		

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NIAC AUDIT CHECKLIST

Revision: 3, Dated November 14, 2019

AUDIT NO. _____ PAGE <u>56</u> of <u>57</u>

TABLE 10 - DEDICATION / UNQUALIFIED SOURCE MATERIAL

ITEM DESCRIPTION (P/N, S/N)	DEDICATION DOCUMENTS (with REV and DATE)	COMMERCIAL GRADE ITEM CRITICAL CHARACTERISTICS	METHOD(S) OF DEDICATION
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Revision: 3 , Dated November 14, 2019		AUDIT NO.	PAGE	of 57
CONTINUATION PAGE	INTERNAL	LINKS: SUMMARY OE 1-A 1-B	1-C 1-D 1-F 1-F 2 3 4	5 6 7 8 9 10
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