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SUMMARY SHEET

SUPPLIER INFORMATION		
SUPPLIER**:**		PASSPORT VENDOR CODE:
ADDRESS:		
CITY:	PROV/STATE:	POSTAL /ZIP CODE:
TELEPHONE NO:		
PRODUCT/SERVICE:		
CERTIFICATES (Issuer, Certificate # and Expiration date):		
SUPPLIER QUALITY MANUAL (Rev./Date):		

SUPPLIER CONTACTS		
SENIOR COMPANY OFFICER:	TITLE:	PHONE:
	EMAIL:	
SENIOR QA OFFICER:	TITLE:	PHONE:
	EMAIL:	

AUDIT INFORMATION	
AUDIT NO.:	AUDIT DATES:

AUDIT TEAM INFORMATION				
AUDIT TEAM	NAME	PHONE	EMAIL:	CHECKLIST SECTIONS AUDITED
TEAM LEADER				
AUDITOR				
AUDITOR				
AUDITOR				
AUDITOR-IN-TRAINING				
TECHNICAL SPECIALIST				

Audit Team Leader: Date:

AUDIT RESULTS SUMMARY SHEET

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

KEY

S – SATISFACTORY U - UNSATISFACTORY N/A - NOT APPLICABLE

E = Recommended for Engineering Services Suppliers F = Recommended for Field Services Suppliers

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

SECTION 1 – CONTRACT REVIEW

METHOD OF VERIFICATION
1.1 Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
1.2 TENDER AND CONTRACT Verify that measures are established and implemented to control tender and contract activities. Verify the following: (a) Customer's tendering/purchase order/contract documents and subsequent changes to purchase order/contract documents are reviewed and the results of the review documented by appropriate personnel/functions within the supplier's organization; (b) Customer purchase order/contract technical and quality requirements are correctly translated on supplier's control documents (e.g. order review form, travelers, shop work orders, inspection and test planning documents); (c) Supplier exceptions are documented and communicated back to and accepted by the customer; and, (d) Prior to the award of the contract and if applicable; i) The customer is notified of products to be supplied from inventory. ii) The customer is notified of the statistical techniques/sampling plans that will be used. NOTE: (b) Technical and quality requirements include such items as: test/inspection, documentation, C of C, packaging/shipping, hold points, materials, etc. (c) This includes notification to customer of design deviations/design changes. N299.1: Clause 4.6(g); Clause 5.5.1; Clause 5.5.19(d)

RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 1)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION
1.3 CUSTOMER SUPPLIED PRODUCTS OR SERVICES Verify that measures are established and implemented for control of items and services, including intellectual property and personal data supplied by the customer or returned from the customer for repair/rework. NOTE: When applicable, measures must include the examination of the customer's items/services, including documentation, upon receipt to verify acceptability. The customer must be promptly notified in writing of unacceptable customer-supplier property or property that becomes lost or damaged while in the supplier's custody. N299.1: Clause 5.5.18

RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

SECTION 1 - CONTRACT REVIEW

(FIGURE 1)

P.O. / CONTRACT NO. AND DATE *1.2	PART NUMBER AND ITEM/SERVICE DESCRIPTION *1.2	P.O. /CONTRACT REQUIREMENTS CORRECTLY TRANSLATED TO SUPPLIER DOCUMENTS (Yes/No) (LIST WORK ORDERS, TRAVELERS, DRAWINGS, ETC.) *1.2	CUSTOMER APPROVAL OF EXCEPTIONS (Yes/No) *1.2

* Refers to applicable question

SECTION 2 – DESIGN

METHOD OF VERIFICATION	
2.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
2.2	DESIGN PLANNING, WORK ASSIGNMENT & INTERFACES Verify that measures are established and implemented to plan the design, assign the work, and define interfaces. Verify the following: (a) Design and verification activities are divided into discrete work packages and that the sequential or parallel order of work packages is planned and identified; (b) Each work package is assigned to designated personnel; (c) Design plans and revisions are submitted to the customer when specified in the contract, and updated to include additional activities and verification points as appropriate and resubmitted to the customer; and, (d) The control of organizational and technical interfaces and agreement between interfaces has been established. Organizational and technical interfaces must be identified and defined. NOTE: (d) These measures include the assignment of design activities in multidisciplinary or multi-organizational design teams, documentation of communication protocols between interfaces, and establishment of procedures among participating design organizations (internal/external) for the review, approval, release, distribution, and revision of documents. CSA N299.1: Clause 5.5.2.2; Clause 5.5.2.3; Clause 5.5.2.4

RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 2)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION
2.3 DESIGN INPUTS Verify that measures to control the translation of design requirements into design documents are implemented. Verify the following: (a) Design inputs are identified and documented; and, (b) Design inputs are reviewed for adequacy. NOTE: (a) Design inputs include, but are not limited to, performance and functional requirements and critical characteristics identified in the contract; results of conceptual studies; environmental conditions; requirements of the Authority Having Jurisdiction (AHJ); applicable codes, standards, and specifications; and, use of experience. CSA N299.1: Clause 5.5.2.5; Clause 5.5.17

RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 2)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION

2.4 PRELIMINARY DESIGN, DETAILED DESIGN AND DESIGN OUTPUT

Verify that measures are implemented to prescribe and document design outputs to the level necessary to permit the design process to be carried out in a correct manner and to permit verification that the design meets requirements. Verify the following:

(a) Preliminary design assumptions; alternatives; differences between the present and proven design; development and associated testing, including test parameters; conceptual and feasibility studies and analyses; and design acceptance criteria, are identified, documented and controlled;

(b) Design and analysis calculations and conclusions are documented, including the identification and revision status of any design tools used (i.e. analytical software) and ensure that the characteristics and assumptions are specified;

(c) Test procedure(s) are planned, conducted and the results documented and incorporated into the design where such tests procedures are used in support of design validation/qualification testing;

(d) The design is translated into documents required for procurement, including the QA program requirements, production, inspection and test, and preservation and delivery of the item/service, as applicable; and,

(e) Final design output documents are traceable to the design inputs and contain or reference all applicable criteria.

N299.1: Clause 5.5.2.6; Clause 5.5.2.8; Clause 5.5.2.9

RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 2)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION

2.5 DESIGN VERIFICATION

Verify that measures are established and implemented for the verification of design adequacy, and assurance that once the changes to the design are complete, the item will perform its intended function. Verify the following:

(a) Design verification points, techniques, procedures and characteristics, are identified and described;

(b) The verification method is identified (e.g. design review, alternate calculation/analyses, qualification tests or demonstrations, or evaluation of significant differences between present and proven design), and the verification is performed by individuals or groups other than those who performed the original design, but who may be from the same organization. Verify that the results of the verification are documented, including evidence of verification by date and signatures or stamps on documents.

i) When the verification method used is qualification test, verify that a prototype unit is tested under the most adverse design conditions. Verify qualification test plans/procedures are developed and implemented for the testing. Verify test plans/procedures;

1) Identify the items being tested, resources used, test objectives, test conditions, parameters to be recorded and relevant acceptance criteria;

2) Describe test method of operation, performance, and required records; and,

3) Identify correct configuration of test piece;

(c) The design is reviewed by the applicable functions to ensure that products or services can be purchased, produced, and verified according to specified requirements; and,

(d) The design is reviewed prior to release to ensure that the design has been verified at all verification points and that the verification records are complete.

NOTE:

(a) The extent and nature of design verification activities is determined by considering the importance to safety; the complexity of the design; the degree of standardization; the maturity of the design; and, the similarity with previously proven designs.

(b) For evaluation of significant differences between the present and a proven design, the supplier shall compare the original design and associated verification documentation records in the subsequent application to the present design and confirm that the analysis is still valid and the application is still correct.

N299.1: Clause 5.5.2.10

RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 2)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION

2.6 DESIGN CHANGES

Verify that measures are established and implemented to control design changes. Verify the following:

(a) Revised design documents, (e.g., calculations, drawings, stress reports) are reviewed and approved by the same organization as reviewed and approved the original documents;

(b) Design changes have been adequately evaluated to determine the effect of the changes on existing test results (i.e. only those used to demonstrate compliance with requirements), constituent parts and items already delivered, including interfacing designs;

(c) Inputs are addressed, configuration control maintained, and critical characteristics necessary for subsequent item identification have been identified and documented;

(d) Design control measures are equal to those of the original design, and that unique identifiers are used to assure control of design configuration; and,

(e) Changes affecting fit, form or functions are tracked (i.e. subject to tracking control) to enable future identification of changes between the original and the replacement or re-orders of the items and the customer advised of those changes.

N299.1: Clause 5.5.2.11

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 2)

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

SECTION 2 – DESIGN

(FIGURE 2)

CUSTOMER/ SUPPLIER DESIGN INPUT AND BASES *2.3	SUPPLIER DESIGN DOCUMENT *2.4	DESIGN INPUTS CORRECTLY INCORPORATED (Yes/No) *2.4	DESIGN ANALYSIS DOCUMENTED CORRECTLY (Yes/No) *2.4	METHOD OF DESIGN VERIFICATION *2.5	DESIGN CHANGE CONTROL AND REV./DATE *2.6

*Refers to applicable question.

SECTION 3 – RESERVED FOR DEDICATION

SECTION 4 – SOFTWARE

METHOD OF VERIFICATION	
4.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
4.2	CONTROL OF SOFTWARE EMPLOYED IN PRODUCTION, INSPECTION, AND TEST ACTIVITIES Verify measures have been established and implemented to control software employed in production, inspection, and test activities. Verify the following: (a) The software has been documented and approved; (b) The software has been placed under configuration control; and (c) The software has been verified or validated. N299.1: Clause 4.4.1; Clause 5.5.6.2 k)

RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 4)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION	
4.3 CONTROL OF SOFTWARE THAT FORMS PART OF OR IS INCORPORATED INTO ITEMS OR SERVICES. Verify that software that forms part of or is incorporated into items or services is subject to performance testing and final acceptance. Verify that the customer is notified that an item to be supplied includes embedded software. N299.1: Clause 4.4.2	
RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 4)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION	
4.4 CONTROL OF DESIGN ANALYSIS SOFTWARE Verify measures have been established and implemented to control software used in design analysis. Verify the following: (a) The software has been verified to support the application of the computer program to the specific physical problem including the identification of the computer and the computer program name and revision/version; (b) The software is controlled; and, (c) The software is adequate for its intended use. N299.1: Clause 5.5.2.7	
RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 4)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

SECTION 4 – SOFTWARE

(FIGURE 4)

SOFTWARE PROGRAM (NAME, NO., REV./DATE) *4.2, 4.3, 4.4	METHOD OF ACCEPTANCE AND DATE *4.2, 4.3, 4.4

* Refers to applicable question

SECTION 5 – PROCUREMENT

METHOD OF VERIFICATION

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

5.2 PROCUREMENT DOCUMENT

Verify that measures are established and implemented for the control and release of procurement documents, including changes. Ensure the following requirements are included in procurement documents, and changes, for items and services, as applicable considering the relative importance, complexity, and quantity of items or services procured:

(a) Description of the products or services ordered including: specifications, drawings, verification requirements, and other relevant technical data by title or other positive identification and applicable issue;

(b) The title, number, and issue of the quality assurance program, to be applied;

(c) Requirement for approval or qualification of documentation, products or services, procedures, processes, equipment, and personnel;

(d) Requirements for the submittal for acceptance of the disposition of nonconformances;

(e) Identification requirements for the items or services;

(f) Requirements for preservation, packaging and shipping;

(g) Requirement for right of access to plant facilities and records for the source inspection/audit;

(h) Points in the sub-supplier's design plan or the inspection and test planning documents where the supplier's customer or supplier will verify conformance to contract requirements;

(i) References as required by contract;

(j) Requirements for the submission, approval, control or qualification of documentation, including distribution, retention, maintenance, and disposition of documentation and quality records;

(k) Documentation and instructions required when the items or services are shipped directly to a consignee other than the supplier;

(l) Requirements for traceability;

(m) Requirements for the submittal of inspection and test procedures as specified by the customer and supplier; and

(n) Requirements for the prevention and detection of CFSIs.

N299.1: Clause 5.5.5.2

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 5A)

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

METHOD OF VERIFICATION
5.3 PROCUREMENT DOCUMENT REVIEW Verify that measures are established and implemented for the independent review of procurement documents and changes thereto prior to purchase order or contract award. Verify the following: (a) The review is documented and is performed by persons other than those who prepared the procurement documents and who have the necessary knowledge of the requirements; (b) The review considers the adequacy of specified requirements in procurement documents (i.e. section 5.2) and verifies the selection of appropriate sub-suppliers; and, (c) Changes to procurement documents were subject to the same degree of control as utilized in the preparation of the original documents. N299.1: Clause 4.6 b), f) ; Clause 5.5.5.3; Clause 5.5.5.5

RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 5A)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION

5.4 SUPPLIER SELECTION

Verify that measures are established and implemented for the determination of the Quality Assurance Program Standards applicable to a sub-supplier and for the selection and assessment of sub-suppliers (including distributors and calibration, NDE, testing labs, software suppliers, heat treatment services suppliers, etc) consistent with the importance, complexity and quality of the product or service. Verify the following:

(a) Applicable quality assurance standards are selected utilizing the “Factor Rating Method” and “Analytical Selection Method” and justified;

(b) Evaluations of the selected supplier are performed, prior to award of contract, and at the specified frequency in accordance with an audit schedule;

(c) Scope of approval of the sub-supplier is commensurate with the requirements of the procurement documents;

(d) Only approved suppliers are used, and that their QA program certificates have been verified as valid as applicable; and,

(e) A record of acceptable sub-suppliers that includes approval status and the scope of approval is established and maintained.

NOTE:

(a) Written acceptance is required from the customer where the supplier intends to award all or part of the contract to a sub-supplier who will not be implementing the QA program specified in the customer contract for the item or service. However, if the supplier applies its own QA program as the manufacturer or assumes the contract responsibilities of a manufacturer then written acceptance from the customer is not required when an alternate QA program is specified.

(b) Evaluations include an evaluation of the QA Manual (QA Program Description for Cat. 4); performing an audit of the QA program implementation (for Cat. 1, 2, 3 or equivalent); evaluation of other required locations, plan(s) and resources; consideration of the sub-supplier’s history and current capability. Where planned audits are not performed as scheduled, the reasons why the audit was not performed and an evaluation of the potential impact on the supplier approval must be documented. Supplemental audits of specific elements of concern should be scheduled when necessary.

N299.1: Clause 4.6 l); Clause 5.5.5.1; Clause 5.5.20.2; Annex A “Category Selection”

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 5A)

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

METHOD OF VERIFICATION

5.5 SUPPLIER (EXTERNAL) AUDITS

Verify that measures are established and implemented to ensure a comprehensive system of planned and periodic external audits. Verify the following:

(a) Audits are conducted in accordance with an audit schedule augmented with supplemental audits to evaluate areas of concern. Where planned audits are not performed, the reasons why the audit was not performed and an evaluation of the impact on supplier approval qualification and required follow-up actions is documented;

(b) An audit plan is prepared for each audit;

(c) Audits are conducted utilizing procedures and checklists;

(d) An audit report is prepared for each audit; and,

(e) Appropriate follow-up action is taken on corrective actions to address identified audit findings.

NOTE: When 3rd party audits are used as a basis for supplier qualification, the evaluation must be controlled in accordance with established measures under the supplier's quality program (note: the acceptable approach to utilizing 3rd party CANIAC audits was under discussion by the Canadian nuclear industry utilities/suppliers at the time of development of this audit checklist).

NOTE:

(b) The Audit Plan must define what is to be audited, including the audit scope, requirements, and activities to be audited; assignments of those performing the quality audits; the applicable documents and written procedures or checklists; the method of reporting findings and recommendations; the person(s) to who the findings and recommendations are to be reported; and the means for having corrective actions decided, implemented and verified.

(c) Objective evidence must be documented to the depth necessary to support audit results.

(d) The Audit Report must identify the audit scope, the auditors and persons contacted; a summary of the audit results including a statement on the effectiveness of the elements audited; each reported adverse audit finding; and the corrective action requests.

(e) The acceptability of the sub-supplier's responses to the corrective actions issued must be evaluated.

N299.1: Clause 5.5.20.2

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 5B)

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

SECTION 5 - PROCUREMENT

(FIGURE 5A)

ITEM DESCRIPTION NAME (P/N, S/N, MODEL NO.) * 5.2	SUPPLIER AND LOCATION * 5.2	P.O. NUMBER AND DATE * 5.2	PO REVIEWED PRIOR TO P.O. AWARD (Yes/No) * 5.3	DATE OF SUPPLIER APPROVAL / EVALUATION *5.4	SCOPE OF SUPPLIER APPROVAL *5.4

*Refers to applicable question.

SECTION 5 – PROCUREMENT

(FIGURE 5B SUPPLIER EVALUATION)

SUPPLIER NAME, LOCATION AND DATE(S) PERFORMED *5.5	EVALUATION METHOD (AUDIT, QA MANUAL/PROGRAM DESCRIPTION) *5.5	SCOPE OF SUPPLY *5.5	AUDITOR(S) OR EVALUATOR(S) *5.5	EVALUATION RESULTS NUMBER OF AUDIT FINDINGS (OPEN/ CLOSED) *5.5	AUDIT CORRECTIVE ACTION VERIFICATION METHOD AND DATE *5.5

*Refers to applicable question.

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

METHOD OF VERIFICATION

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

6.2 PRODUCTION PROCESS CONTROL

Verify that measures are established and implemented for the control of fabrication/assembly activities. These activities should be controlled by a shop work order/traveler/process sheet/route card type document which includes the following (as applicable):

(a) Identification and sequence of the work activities;

(b) Types of equipment;

(c) Special working environments including special handling cleanliness requirements;

(d) Work methods;

(e) Materials, batches, and lots;

(f) Characteristics and tolerances to be met;

(g) Inspection, test and control points;

(h) Workmanship standards; identification of instructions, procedures and drawings, written standards or samples to be used for each item/activity;

(i) Packaging and shipping; and,

(j) Prevention, detection, and removal of foreign material including CFSIs.

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

N299.1: Clause 5.5.11.1; Clause 5.5.11.2; Clause 5.5.11.4

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 6A)

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

METHOD OF VERIFICATION
6.3 ITEM IDENTIFICATION, TEST STATUS, AND TRACEABILITY Verify that measures are established to assure the identification, item status and traceability of items (i.e., materials, parts, weld filler material, batch, lots or components, etc.) is maintained, as required throughout processing operations. Verify the following: (a) Identification of items is controlled, and traceable to the applicable drawings, specification or other technical documentation, from receipt through delivery; (b) Item markings are clear (not obliterated or hidden) and not detrimental. (For example: if die stamps are used, verify stamps are low stress); (c) Subdivided items have satisfactory transfer of markings to each item; (d) Items are adequately identified as to inspection/test status throughout production including final acceptance; (e) The authority for application and removal of identification markings/status indicators is defined including the establishment of a controlled record of names and signatures of personnel authorized to review, approve, or accept a document, item, or service. Control status indicators (i.e. tags, stamps) are controlled; (f) Supplier's identity and the inspector are identified on inspection and test stamps; and, (g) Measures are established to maintain traceability of items (i.e., materials, parts, weld filler material etc.) throughout processing operations when traceability is required by the contact, regulation or specification. NOTE: When traceability is required by contract, the identification number must be unique, and must be assigned to each product, service, or batch and identified on all process, inspection and test records. N299.1: Clause 5.5.7.1 a)-v); Clause 5.5.8; Clause 5.5.9
RESULTS:
ASSESSMENT/SUMMARY: (Document observations on Figure 6B)
List the supplier quality manual reference and implementing procedure(s) established:
Evaluate controls and implementation of supplier measures (who, what, how):
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)

METHOD OF VERIFICATION
6.4 ITEM HANDLING AND STORAGE Verify that measures are established and implemented for the handling and storage of items. Verify the following: (a) Storage areas and methods comply with specified requirements and access controls; (b) Schedule in place to address in-storage maintenance as required, and maintenance performed; inspection of critical, sensitive, perishable, or high value items for condition; and, inspection and verification of any special storage and protective environments; (c) Shelf-life requirements are defined and implemented; (d) Cleaning, preservation, segregation, and handling of items is performed in such a manner to prevent misuse, abuse, damage, deterioration, or loss; and, (e) Special handling tools and equipment are inspected at specific times to ensure adequate maintenance and to prevent damage to items. N299.1: Clause 5.5.10.

RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 6B)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION

6.5 PACKAGING AND SHIPPING

Verify that measures are established and implemented for the control of shipping activities, which include packaging, marking, storing, status and shipment of items and components including spare and replacement parts. Verify the following:

(a) Techniques being used (e.g. cleaning, preservation, and packaging) are acceptable relative to contract/procedural requirements and will prevent damage/deterioration or loss during packaging/shipment to the customer;

(b) Openings are protected to prevent ingress or contamination by foreign material;

(c) Marking and labelling are adequate to identify the shipment and indicate any requirements for or the presence of special environments, or the need of special control or preservation requirements; and,

(d) Required documents accompanying the item are made available to the customer at the time of shipment in accordance with contract requirements.

NOTE:

(a) Shipping containers, packaging, and pallets must be free from any harmful biological, environmental, and combustible contamination when specified in the contract.

N299.1: Clause, 5.5.7.1 a)-iv),vi); Clause 5.5.13

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 6B)

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

METHOD OF VERIFICATION

6.6 PRODUCTION PROCESS VERIFICATION

Verify that measures are established and implemented to verify production processes, and workmanship standards; tools are verified/qualified prior to use. Verify the following:

(a) Production processes or workmanship standards that are new or have significant differences from proven processes are verified as capable of producing the required results; and,

(b) Production equipment, including all jigs, fixtures, tooling masters, templates, patterns, documentation are qualified (tool prove) and are periodically checked and rechecked when changes occur to ensure that they are capable of producing the required results. Ensure the extent and frequency of checking is defined.

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

NOTE:

(a) Review should include personnel from other applicable functions to ensure that the products or services can be produced, inspected, and tested to specified requirements.

(Document processes, standards, or tooling reviewed under the Assessment/Summary)

N299.1: Clause 5.5.11.1 c), d), e); Clause 5.5.11.3

RESULTS:	

ASSESSMENT/SUMMARY:

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

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

(FIGURE 6A)

ITEM DESCRIPTION (NAME, PART NO., P.O./CONTRACT NO., ETC.) *6.2	WORK DOCUMENT *6.2	WORK ACTIVITY *6.2	WORK ACTIVITY PROCEDURE REV./DATE *6.2

*Refers to applicable question.

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

(FIGURE 6B)

ITEM DESCRIPTION (NAME, PART NO., P.O./CONTRACT NO., ETC.) *6.3, 6.4, 6.5	METHOD OF IDENTIFICATION AND TRACEABILITY *6.3, 6.4, 6.5	INSPECTION STATUS *6.4, 6.5

*Refers to applicable question.

SECTION 7 - SPECIAL PROCESSES

METHOD OF VERIFICATION	
7.1	Within the assessment/summary section of each checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation
7.2	SPECIAL PROCESSES Verify that measures are established and implemented and that special processes are accomplished utilizing: (a) Qualified personnel; (b) Qualified procedures; and, (c) Qualified equipment, as applicable NOTE: Special production and inspection processes must be identified by the supplier and include those specified by the customer (e.g. welding, NDE, heat treating, soldering, painting, etc.). NOTE: PT, UT and RT may be automated processes, as opposed to being manually performed. NOTE: Unique identification and acceptability of instruments to be checked under Section 8. N299.1: Clause 5.5.12
RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figures 7A, 7B)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

SECTION 7 - SPECIAL PROCESSES

(FIGURE 7A)

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

*Refers to applicable question.

SECTION 7 – SPECIAL PROCESSES

(FIGURE 7B WELDER/WELD OPERATOR)

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

*Refers to applicable question.

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

METHOD OF VERIFICATION

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

8.2 INSPECTION AND TEST

Verify that adequate measures are established and implemented for the inspection (incoming, in-process, and final) and testing of materials, components, parts or services. Verify the following:

(a) Inspection and test activities for the constituent phases of work from receipt through delivery, are planned and documented in an inspection and test planning document(s). The planning document(s) address the following:

i) Approved by the supplier's representative primarily responsible for quality;

ii) Submitted to the customer for acceptance, including subsequent revisions, in accordance with contract requirements;

iii) Identify the following, where applicable:

1) Products or services are to be subcontracted specifying QA programs applied;

2) Verification of sub-supplier's conformance to specified requirements by one or more of the following methods: sub-supplier inspection and test planning document; inspection and test by the supplier at the sub-supplier's facility; surveillance by the supplier; incoming inspection;

3) Location of each inspection and test point in the production cycle, including incoming inspection, preservation of products, packaging, and on-site inspection and testing; performance of additional in-process inspections and tests for evaluation of quality when applicable;

4) Characteristics to be inspected and tested at each point and applicable inspection and test procedures, sampling plans, and acceptance criteria to be used;

5) Inspection and test points where a history of usage of measuring and test equipment is to be maintained;

6) Customer hold and witness points, as applicable;

7) Where and how product acceptance to special production process procedures is to be accomplished and documented;

8) Statistical process control techniques to be used for product acceptance and the technique/method to be used;

9) The use of lots or batches; and,

10) Final inspection to verify that all required inspections have been completed and accepted and that the required quality records and certificates have been reviewed and accepted; and,

(b) Personnel assigned to perform the inspection, witnessing, or monitoring of characteristics for acceptance are other than those performing or directly supervising the work being accepted, unless otherwise accepted by the customer.

NOTE:

(b) Such personnel shall not report directly to immediate supervisors responsible for producing the work being accepted unless it is specifically permitted by the inspection and test planning document and agreed in writing by the customer.

N299.1: Clause 5.2.5; Clause 5.5.6; Clause 5.5.7.1 a)-i)-x), e), f), g), h), i); Clause 5.5.19

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 8)

List the supplier quality manual reference and implementing procedure(s) established:

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

Evaluate controls and implementation of supplier measures (who, what, how):
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)

METHOD OF VERIFICATION
8.3 PURCHASED ITEMS/SERVICES VERIFICATION Verify that measures are established and implemented to assure that purchased material, items, equipment, software, services (including engineering services, studies, and evaluations) conform to the procurement documents (i.e., incoming inspection, source inspection, or testing). Verify the following: (a) Sub-supplier's inspection and test planning document(s) reviewed to ensure specified requirements were met, when applicable; (b) Source inspection performed at the sub-supplier's facility and the inspection results documented, when applicable; and, (c) Incoming inspections/tests performed in accordance with inspection and test planning document(s) to verify that items/services received, including documentation, are free from damage and in accordance with the requirements of the purchase order and applicable codes and specifications. N299.1: Clause 5.5.5.4; Clause 5.5.7.1 a)-i)-ii)-vii)-viii)-ix)

RESULTS:	
ASSESSMENT/SUMMARY: (Document observations on Figure 8)	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION

8.4 COUNTERFEIT, FRAUDULENT, AND SUBSTANDARD ITEMS.

(a) Verify that measures are established and implemented for the detection and prevention of Counterfeit, Fraudulent and Substandard Items (CFSI) to assure that genuine material, items, equipment, software and services are provided.

(b) Verify that where CFSIs are identified, they are reported promptly to the customer and controlled as a nonconforming item.

N299.1: Clause 4.6 i), k); Clause 5.5.7.1 iii)

RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION

8.5 SAMPLING PLANS

Verify that sampling plan(s) (such as those used during receipt/in-process/final inspection) are controlled and acceptably implemented and are in accordance with requirements identified in the inspection and test planning document(s). Verify that the statistical techniques/sampling plans to be used have been identified to the customer.

N299.1: Clause 5.5.19

RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION

8.6 MEASURING AND TEST EQUIPMENT

Verify that measures have been established and implemented for the selection, use, calibration, and control of M&TE. Verify the following:

(a) M&TE labelled/identified with its calibration status and the scheduled date of its next calibration and to identify it with its calibration record;

(b) Access to adjustable devices on M&TE, which are fixed at the time of calibration, are sealed or otherwise safeguarded to prevent tampering;

(c) Calibration of M&TE and standards are performed at periodic (recall) intervals;

(d) Adequacy of standards to assure accuracy, stability, range, and resolution required for their intended use;

(e) Reference (primary) and working (secondary) standards used are traceable to the National Institute of Standards and Technology (NIST), other recognized standards, or natural law;

(f) Calibration record for each piece of M&TE maintained with a record of as-found and as-left measurements;

(g) Control of M&TE found to be “damaged”, “out-of tolerance”, “out of calibration”, and/or past due for calibration;

(h) An evaluation is performed when M&TE is found not conforming to requirements to determine validity of the previous measurements and appropriate action taken on the M&TE and any item or services affected in accordance with the suppliers nonconformance process;

(i) Calibration procedures have been established defining: equipment description, identification number, location, calibration interval, calibration method, acceptance criteria, and action to take when results are unsatisfactory;

(j) The ability of software used in the actual calibration of M&TE has been verified to satisfy the intended application prior to use (and re-verified as necessary) and the results of the verification documented;

(k) M&TE is handled and stored to prevent abuse, misuse, damage, or change in dimensional or functional characteristics;

(l) M&TE observed to be in use was within current calibration; and,

(m) M&TE is used, and is calibrated, in an environment that is controlled to the extent necessary to assure required accuracy.

NOTE: Utilize data from Section 7

NOTE: Software used in M&TE that is qualified as part of calibration of the M&TE is not subject to the Software Quality Assurance in Section 4

NOTE: Newly acquired M&TE must be calibrated to the extent necessary to ensure valid measurement prior to use.

N299.1: Clause 5.5.4

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 8)

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

SECTION 8 – TESTS, INSPECTIONS, AND CALIBRATION

(FIGURE 8)

ITEM DESCRIPTION (NAME, P/N, S/N, ETC.) *8.2, 8.3	TEST/INSPECTION ACTIVITY TYPE AND DATE *8.2. 8.3	CONTROLLING TEST/INSPECTION DOCUMENT TITLE/NUMBER AND REV./DATE *8.2, 8.3	INSPECTOR/ TESTER NAME/STAMP *8.2, 8.3	ID NUMBER OF M&TE USED CALIBRATION CURRENT (Yes/No) *8.6	RESULTS SAT. OR UNSAT. IF UNSAT., RECORD NCR NO. IF APPLICABLE *8.2, 8.3

*Refers to applicable question.

SECTION 9 – DOCUMENT CONTROL/ADEQUACY

METHOD OF VERIFICATION	
9.1	Within the assessment/summary section of this checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
9.2	DOCUMENT CONTROL/ADEQUACY Verify that measures are established and implemented to control the issuance of documents (i.e., procedures, instructions, drawings, work orders, etc.) including changes. Verify that following: (a) Documents are: i) Reviewed for adequacy; ii) Approved for release by authorized personnel; iii) Distributed to applicable workstation; iv) Adequately controlled if maintained electronically; and, (b) Forms are maintained and controlled. NOTE: Procedures should document as applicable; purpose and scope; who is responsible for what; how, when and where all steps are performed; what materials, equipment, and documentation will be used; how each item is controlled; and reference to the forms used. NOTE: The application of external documents (e.g. codes, standards, and customer prescribed procedures) determined to be necessary for the planning and operation of the QA program should be reviewed. Evidence obtained from Sections 1- 16 shall be evaluated when assessing this item. N299.1: Clause 5.4; Clause 5.5.3
RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

SECTION 10 – ORGANIZATION/PROGRAM

METHOD OF VERIFICATION

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

10.2 MANAGEMENT RESPONSIBILITIES/ORGANIZATION

MANAGEMENT GENERAL:

(a) Verify evidence of top management's commitment to the development and implementation of the QA program and to continually improving its effectiveness.

(b) Verify that a process has been developed and implemented to obtain and assess customer feedback to determine effectiveness in meeting customer requirements.

MANAGEMENT REPRESENTATIVE:

(c) Verify that a representative has been assigned with the authority and responsibility for establishing, implementing, maintaining, and assuring effective execution of all portions of the QA program; who has the authority and responsibility to resolve quality matters. Verify that the representative has direct access to senior management at a level which ensures that quality assurance requirements are not subordinated to design, procurement, production or delivery. Verify the appointment of the representative has been documented in the QA Manual.

MANAGEMENT REVIEW:

(d) Verify that the Management Review process is documented and that top management conduct reviews at sufficient frequency (typically annually) to ensure their continuing suitability and effectiveness in meeting the requirements of the QA program. The management review process must specify actions required and assignment of personnel to implement and verify the effectiveness of the action taken. The QA Manual should state the process for the review of status and adequacy of the QA program. The review includes an analysis of appropriate data to demonstrate the suitability and effectiveness of the QA program in meeting the requirements of the Standard and evaluation where continual improvements in QA program effectiveness can be made.

ORGANIZATIONAL AUTHORITY:

(e) Verify that the responsibility and authority of personnel primarily responsible for quality assurance activities has been defined and documented in QA Manual. Such activities shall include, but not be limited to verification of corrective actions and the control of further processing of nonconforming items until disposition has been obtained.

NOTE:

(d) Management review must include results of internal/external audits; sub-supplier performance; verification of effectiveness of sub-suppliers working under the supplier's QA program when applicable; customer feedback; process performance and item and service conformity; status of corrective actions; follow-up actions from previous management reviews; recommendations for improvement; the need for changes to the QA program; and, the results of trend analysis of nonconformances.

N299.1: Clause 4.6 a),c),h); Clause 5.2.1; Clause 5.2.2; Clause 5.2.3; Clause 5.2.4

RESULTS:	

ASSESSMENT/SUMMARY:

List the supplier quality manual reference and implementing procedure(s) established:

SECTION 10 – ORGANIZATION/PROGRAM

Evaluate controls and implementation of supplier measures (who, what, how):
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)

METHOD OF VERIFICATION
10.3 QA MANUAL (f) Verify the QA Manual: i) Is signed by top management; ii) Submitted to the customer for evaluation, unless otherwise agreed to by the customer; iii) Identifies the business, facility(ies), and items or services covered by the QA program; iv) Documents management policies, objectives and responsibilities for quality; v) Includes a statement for the periodic review, updating, and controlling of the QA manual; vi) Defines the organization, roles and responsibilities, including organizational charts for the following: i. Quality organization, including independent inspection personnel: ii. Interrelationship between the quality organization and functions managing and performing the work; and, iii. Interrelationship within a multidivisional business; vii) Defines the process for sub-supplier participation within the QA program and/or the process for delegation to others the execution of any part of the work scope under the supplier's QA program, when applicable; and, viii) Cross references procedures or a reason identified for those that are not applicable. N299.1: Clause 4.2; Clause 4.6 d), e); Clause 5.3; Clause 5.4
RESULTS:
ASSESSMENT/SUMMARY:
List the supplier quality manual reference and implementing procedure(s) established:
Evaluate controls and implementation of supplier measures (who, what, how):
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)

METHOD OF VERIFICATION
10.4 SAFETY CULTURE Verify that management uses the QA program to understand and promote a safety culture by:

(a) Issuing a statement committing workers to adherence to the QA program;

(b) Defining and implementing practices that contribute to excellence in worker performance that includes the necessary means for workers to perform their jobs safely and successfully; and

(c) Monitoring to understand and improve the culture.

NOTE: Refer to N299.1 Annex E for guidance and reference documents on safety culture

N299.1: Clause 4.7

RESULTS:	

ASSESSMENT/SUMMARY:

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

METHOD OF VERIFICATION

10.5 USE OF EXPERIENCE

Verify that measures are established and implemented to identify and collect experience gained within the supplier's business, by other suppliers and by customers and that such information is:

(a) Reviewed for relevance and significance;

(b) Incorporated into work planning and execution activities to prevent recurrence of significant industry problem; and,

(c) Used to initiate improvement.

NOTE: Experience within the supplier's business should be made available to others based on its sensitivity.

N299.1: Clause 4.6 l); Clause 5.5.17

RESULTS:	

ASSESSMENT/SUMMARY:

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

SECTION 11 – NONCONFORMING ITEMS

METHOD OF VERIFICATION
11.1 Within the assessment/summary section of this checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
11.2 IDENTIFICATION/CONTROL OF NONCONFORMANCES (a) For items and services, verify that measures are established and implemented to: i) Identify and segregate nonconforming items (or utilize positive means of identification where physical segregation is not practical); ii) Ensure that responsibility and authority for review/disposition is identified; iii) Control further processing, delivery and installation of items until disposition is completed; and iv) Notification to the customer of nonconforming conditions when required by customer P.O./Contract. (b) For nonconformances other than nonconforming items and services, involving all other aspects of the QA program, such as nonconforming processes, practices, reviews, procedures, drawings, and other documents, verify that measures are established and implemented to: i) Ensure that, pending disposition, the state of nonconformance is made obvious; and, ii) Control the nonconformance or potential nonconformance to prevent use. N299.1: Clause 5.5.15.1; Clause 5.5.15.2; Clause 5.5.15.3

RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION
11.3 DISPOSITION OF NONCONFORMANCES Verify that measures are established and implemented to ensure that the nonconforming items/services and other nonconformances are reviewed and dispositioned such that: (a) The disposition is identified; (b) Documented justification is provided verifying the acceptability of the nonconforming items which are dispositioned repair or use-as-is. Concurrence of all responsible parties is obtained for repair or use-as-is dispositions, including customer approval; (c) Procedures or instructions for repair and rework are provided; (d) Repaired and reworked items are re-inspected or retested; (e) Items dispositioned as scrap are conspicuously identified, controlled and rendered unusable, and access is restricted to authorized personnel; (f) Closeout is adequate;

SECTION 11 – NONCONFORMING ITEMS

(g) Significant nonconformances are analyzed, and recurring nonconformances are trended to determine if they are systemic. Cause analysis performed as determined by supplier, and results reports to management for inclusion in the Management Review;

(h) Customer is notified promptly if a nonconformance which might impact the design or functionality of an item or service is detected after delivery of an item; and,

(i) Where a nonconformance is due to a sub-supplier, the sub-supplier is notified and corrective action taken. Evaluate and obtain agreement on the sub-supplier's proposed disposition and corrective actions taken where required by the purchase order/contract.

NOTE: Technical reviews for disposition involve representatives from all pertinent functions, including the QA function.

NOTE: Document NCR Numbers of items reviewed under the Assessment/Summary.

N299.1: Clause 5.5.5.2 d); Clause 5.5.5.4 d); Clause 5.5.7.1 c), d); Clause 5.5.15.1; Clause 5.5.15.2; Clause 5.5.15.3

RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

SECTION 12 – INTERNAL AUDITS

METHOD OF VERIFICATION

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

12.2 INTERNAL AUDITS

Verify that measures are established and implemented to ensure a comprehensive system of planned and periodic internal audits. Verify the following:

(a) Audits are conducted in accordance with an audit schedule in a manner to provide coverage and co-ordination with ongoing activities, taking into account the status and importance of the activity. Supplemental audits should be performed on specific elements or areas of concern when applicable;

(b) An audit plan is prepared for each audit;

(c) Audits are conducted utilizing procedures and checklists;

(d) An audit report is prepared for each audit; and,

(e) Appropriate follow-up action is taken on corrective actions to address identified audit findings.

NOTE:

(b) The Audit Plan must define what is to be audited, including the audit scope, requirements, and activities to be audited; assignments of those performing the quality audits; the applicable documents and written procedures or checklists; the method of reporting findings and recommendations; the person(s) to who the findings and recommendations are to be reported; and the means for having corrective actions decided, implemented and verified.

(c) Objective evidence must be documented to the depth necessary to support audit results.

(d) The Audit Report must identify the audit scope, the auditors and persons contacted; a summary of the audit results including a statement on the effectiveness of the elements audited; each reported adverse audit finding; and the corrective action requests.

N299.1: Clause 5.5.20.1

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 12)

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

METHOD OF VERIFICATION	
12.3 INTERNAL AUDIT PROGRAM EFFECTIVENESS Verify the overall effectiveness of the internal audit process by review of previous internal audits and comparing the results/issues identified in these audits with the results of this Bruce Power audit. N299.1: Clause 5.5.20.1	
RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

SECTION 12 – INTERNAL AUDITS

(Figure 12)

AUDIT SCOPE AND DATE *12.2	AUDITOR(S) *12.2	NUMBER OF DEFICIENCIES & STATUS (OPEN/CLOSED) *12.2	CORRECTIVE ACTION VERIFICATION METHOD *12.2

SECTION 13 – CORRECTIVE ACTION

METHOD OF VERIFICATION
13.1 Within the assessment/summary section of this checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
13.2 CORRECTIVE ACTIONS Verify that measures are established and implemented to assure that potential conditions or conditions adverse to quality are promptly identified and corrected. Verify the following: (a) Potential conditions or conditions adverse to quality are identified and documented; (b) The need for prompt actions to mitigate risk and implement corrective actions is determined; (c) The significance of the condition is determined and classified and the extent of cause analysis identified. When applicable, the cause analysis is documented; (d) Corrective actions to eliminate the cause and preclude the recurrence of the condition are planned and completed; (e) Follow-up performed to verify that corrective actions taken are effective; and, (f) The causes of the conditions and the corrective actions are reported regularly to management, and if requested, to the customer. NOTE: Document CAR Numbers of items under the Assessment/Summary. N299.1: Clause 5.5.16

RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

METHOD OF VERIFICATION
13.3 CUSTOMER IDENTIFIED DEFICIENCIES Verify that deficiencies identified/reported by customers (e.g. Supplier Corrective Action Requests, receipt inspection rejections, site non-conformances, etc.) are adequately addressed and documented in the supplier's corrective action program. NOTE: Document CAR numbers of items reviewed under the Assessment/Summary. N299.1: Clause 5.5.16(c)

RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	

SECTION 13 – CORRECTIVE ACTION

Evaluate controls and implementation of supplier measures (who, what, how):
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)

METHOD OF VERIFICATION	
13.4 CORRECTIVE ACTION PROGRAM EFFECTIVENESS Verify the overall effectiveness of the corrective action process based upon the following: (a) Evaluate the adequacy of actions taken to prevent recurrence for any previously identified nonconformance; and, (b) Review the adequacy of corrective actions taken as a result of the issues identified during the last Bruce Power audit (if applicable) to determine if there are any repeat issues. N299.1 Clause 5.5.16(d)(e)	
RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

SECTION 14 - TRAINING/CERTIFICATION

METHOD OF VERIFICATION

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

14.2 GENERAL PERSONNEL TRAINING/QUALIFICATION

Verify that measures are established and implemented to ensure that personnel who perform activities affecting quality are aware of their general responsibilities and been indoctrinated in their job responsibilities, authority, safety culture (with respect to their roles in the QA program, and company policies and procedures). Verify that following:

(a) Job descriptions, or equivalent, have been developed showing the necessary education, prerequisite skills, experience and proficiency required for personnel who have an impact on quality;

(b) General indoctrination of the QA program to personnel has been provided;

(c) Personnel have been evaluated to determine their knowledge of the training objectives and requirements of applicable codes, standards, specifications and on-the-job training provided if direct hands-on applications or experience is needed to achieve and maintain proficiency;

(d) Personnel are qualified prior to performing work;

(e) Competencies of personnel are maintained for their roles and responsibilities, taking into account changes in technology, methods, or job responsibilities. Reviews of personnel competencies are reviewed at predetermined intervals to very continued competence; and,

(f) Personnel developing the training needs analysis, expectations and programs and delivering the training are qualified.

NOTE: Evidence to be obtained from Sections 2, 5, 7, 8.and 12

NOTE: The training program must be documented and the process and methods that will be utilized for training identified and training provided commensurate with the scope, complexity and importance of the activities.

N299.1: Clause 5.2.6.1; Clause 5.2.6.2; Clause 5.2.6.3

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 14)

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

METHOD OF VERIFICATION

14.3 SPECIALIST PERSONNEL QUALIFICATION/CERTIFICATION

Verify that personnel that require specialized qualifications and competencies (i.e., inspection/test personnel, auditors, calibration, repair personnel, engineers) are qualified in accordance with requirements, and have certifications, as applicable, on file in accordance with industry and/or supplier program requirements. Verify the following:

(a) Qualification and requalification requirements are defined and documented;

(b) Personnel are qualified prior to performing work; and,

(c) Qualifications are maintained through regular reviews.

NOTE: Evidence to be obtained from Section 2, 8, and 12.

NOTE: Qualification of special process (i.e. welding/NDE) personnel is evaluated in Section 7

NOTE: Personnel performing receipt/in-process/final inspections and tests have been provided the necessary training to perform CFSI detection.

N299.1: Clause 5.2.6.3

RESULTS:	

ASSESSMENT/SUMMARY: (Document observations on Figure 14)

List the supplier quality manual reference and implementing procedure(s) established:

Evaluate controls and implementation of supplier measures (who, what, how):

Are procedural controls adequate and effectively implemented and procedure revision current?

☐ Yes

☐ No (describe the inadequacy above)

SECTION 14 – TRAINING/CERTIFICATION

(FIGURE 14 PERSONNEL INDOCTRINATION/TRAINING/QUALIFICATION)

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

*Refers to applicable question.

SECTION 15 – FIELD SERVICES

METHOD OF VERIFICATION
15.1 FIELD SERVICES (a) Describe the field services provided by the supplier and the quality program(s) under which the services are provided. (b) Verify the controls for these services have been evaluated in the appropriate sections of the checklist. N299.1: Clause 5.3.1(a)(a)

RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	

SECTION 16 – RECORDS

METHOD OF VERIFICATION
16.1 Within the assessment/summary section of this checklist question, record the procedures/instructions/drawings including the revision/date used to verify implementation.
16.2 RECORDS Verify that records are retained, controlled and maintained. Verify the following: (a) Records are legible, complete, identifiable, traceable to the related items and work, and retrievable; (b) Records are adequately authenticated; (c) Records are stored in facilities that provide protection against environmental effects, damage and loss and routinely inspected for compliance with specified requirements; (d) Access to the processing, storage, and retrieval of records is controlled and restricted to authorized personnel; and, (e) Records retention periods are defined in accordance with applicable codes, standards, or specifications, and customer purchase order/contract. NOTE: Quality records may be maintained electronically and may include electronic signatures, where used. Electronic record media must remain retrievable and readable, notwithstanding changes in hardware, software and technology. Electronic storage media must be maintained to protect loss (i.e. electronic media back-ups). Electronic record authentication must be controlled and must be provided on the record, within the media, or by linking to the record itself N299.1 Clause 4.6(a); Clause 5.5.14

RESULTS:	
ASSESSMENT/SUMMARY:	
List the supplier quality manual reference and implementing procedure(s) established:	
Evaluate controls and implementation of supplier measures (who, what, how):	
Are procedural controls adequate and effectively implemented and procedure revision current? ☐ Yes ☐ No (describe the inadequacy above)	