Management Systems Analysis, Inc.

Lead Auditor: Company:

Date:

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
1.0	**ORGANIZATION** **1.1 Basic (100)** **a. Responsibility for establishment and implementation of the Quality Assurance Program shall be defined. Documentation shall include:** **b. Lines of communication for activities effecting quality** **c. Documented Levels of authority** **1.2 Structure and responsibilities (200)** **a. Identify senior management responsible for establishment of overall expectations for the effective implementation of the Quality Assurance Program and their responsibility for the desired results.** **b. Determine authority and organizational freedom established for those responsible for verifying quality achievement and:** **(1) Direct access to responsible management to facilitate appropriate actions** **(2) Assigned responsibility for checking, auditing, or otherwise verifying that quality activities are performed, independent of the individuals and/or/organizations directly responsible for performing the work. Including sufficient independence to:** **-identifying quality problems** **-initiating, recommending, or providing solutions to quality problems through designated channels** **- verifying implementation of solutions** **- assuring that further processing, delivery, installation, or use is controlled until proper disposition** **1.3 Delegation of Work (202)** **a. Verify direct control of all delegated work performed by others by individuals or organization(s) responsible for establishing and executing the Quality Assurance Program.** **1.4 Interface control (300)** **a. Determine more than single organization involvement in the execution of activities, the responsibilities, and interfaces, and the authority of each involved organization** **b. Verify external and internal interfaces between organizations are identified for the execution of program activities, where applicable.**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
2.0	**QUALITY ASSURANCE PROGRAM** **2.1 Documentation of the Quality Assurance Program (100)** **a. Described in a Quality Program Manual includes a statement of policy and authority by management indicating management support.** **b. Implemented by procedures** **c. Identification of activities and items to which it applies** **d. Verify Management regular assessment of the effective implementation of the Quality Assurance Program** **2.2 Indoctrination and Training (200)** **a. Verify establishment of program for indoctrination in job responsibilities and Quality assurance program requirements of personnel performing or managing activities affecting quality** **a. Program established as appropriate to determine training needs** **2.3 Qualification Requirements (300)** **a. Verify written procedures establishing the requirements for the qualification of personnel** **2.4 Nondestructive Examination - NDE (301)** **a. NDE personnel qualified in accordance with procedure to SNT-TC-1A (Reported under Control of Special Processes – See Section 9** **2.5 Inspection and Test (302)** **a. Ensure that the personnel performing the designated inspection and test activities are qualified and certified every 3 years.** **2.6 Lead Auditors and Auditors (303)** **a. Ensure qualification based on communication skills, and training in knowledge, techniques, audit participation and by examination** **b. Type of examination indicated** **c. Maintenance of proficiency established by certification through annual assessment** **d. Verify Auditor qualification (304) to include Training and orientation** **2.7 Certifications of Qualification (400)** **a. Verify certifications for NDE, Inspection and Test Personnel, Lead Auditors and Auditors are in writing and provide required information in accordance with requirements** **2.8 Records (500)** **a. Verify the maintenance of indoctrination, training and qualification records for individuals involved in test, inspection and audits.**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
3.0	**DESIGN CONTROL** 3.1 Ensure the program provides a controlled process for design input, design analysis, design verification, design changes, configuration management of operating facilities, design interfaces, computer software engineering, documentation and records. (100) 3.2 Design Inputs (200) a. Design basis identified, documented, with selection reviewed and approved b. Recognized standards in use or optional standards whose validity has been established 3.3 Design Process and Change Control (300) a. Procedures in use for design processes to control: b. Design revisions and changes c. Reviews and approvals documented and identifiable to the design reports 3.4 Documentation of Design Analysis (400) a. are performed in a planned and controlled manner. b. are legible and in a form suitable for reproduction, filing, and retrieval. c. includes sufficient detail such that a technically qualified person can review, understand and verify results without recourse to originator d. computer programs used are verified and validated (See Part II 2.7) 3.5 Design Verification (500) a. Ensure Design Verification methods include, but are not limited to, any one or a combination of design reviews, alternate calculations and/or qualification testing b. Performed by those other than persons who performed the original design 3.6 Change Control (600) a. Verify Design control measures commensurate with those applied to the original design b. Documentation and records including changes maintained IAW procedures c. Procedures for configuration management requirements are established and documented at the earliest practical time prior to facility operation 3.7 Interface Control (700) a. Procedure established to identify participating organizations for review, approval, release, distribution, and revision of documents involving design interfaces 3.8 Software Design Control (800) Use additional audit check sheets instead of 200, Design Input, 300, Design Process; 500, Design Verification; and 600, Change Control (See Part II 2.7) 3.9 Documentation and Records (900) a. Provide evidence of the steps taken in the design process b. Design records include the final design documents and drawings include identification of input data that support the design process		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
4.0	**PROCURMENT DOCUMENT CONTROL** 4,1 Ensure applicable design bases and other requirements necessary to assure adequate quality are included or referenced in documents for procurement of items and services. (100) 4.2 Content of the Procurement Documents (200) Documents for procurement of materials and subcontracted services shall include provisions for requirements to assure their compliance to the program. Including, as applicable: a. A statement of the "Scope of the work" to be performed b. Technical requirements c. Standards, drawings, specifications, listed programs, procedures, codes, instructions applicable (with revisions) including requirements for sub tier procurements when applicable 4.3 Quality Assurance Program requirements (203) a. Passed along in procurement documents to suppliers b. Directed to supplier sub tier procurment services as applicable 4.4 Right of Access (204) a. Procurement documents provide for access to records, and for audit and surveillance at the supplier's facility 4.5 Documentation Requirements (205) a. Procurement documents identify documentation required for information, review or approval as well as the retention times and dispositions applicable 4.6 Nonconformances (206) a. Purchase documents describe requirements for participation in the reporting and disposition of non conformances 4.7 Spare and Replacement Parts (207) a. When applicable, procurement documents identify requirements for spare and replacement parts with the order or separately 4.8 Procurement Document Reviews (300) a. Conducted by knowledgeable persons with access to technical data and information referenced in procurement document releases 4.9 Procurement Document Changes (400) a. Changes and revisions reviewed by the same system as the original documents, i.e. same degree of control and authorities		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1 –

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
5.0	**INSTRUCTIONS, DRAWINGS, & PROCEDURES** **5.0 Basic (100)** **5.1 Activities affecting quality are prescribed by and performed in accordance with documented procedures, instructions or drawings** **a. Verify inclusion of or reference to acceptance standards** **5.2 Ensure that instructions, procedures and drawings:** **a. include or reference acceptance criteria for determining that prescribed activities have been satisfactorily accomplished,** **b. are readily available for use by appropriate personnel.** **5.3 Qualitative/Quantitative Criteria established** **a. Levels of acceptance established by procedures, standards or the material specification for determining that prescribed results have been satisfactorily attained**		
6.0	**DOCUMENT CONTROL** **6.1 Basic (100)** **The preparation, issue, and change of documents shall be controlled** **6.2 Document Control (200)** **a. Verify identification of controlled documents** **b. Verify documents, including changes, reviewed for adequacy, and approved for release by authorized personnel** **c. Distribution of documents controlled to locations of implementation** **d. Identification of persons or organizations responsible for preparing, reviewing, approving and issuing documents** **e. Review of controlled documents, preparation, approval prior to issue** **6.3 Document Changes (300)** **a. Ensure changes/revisions are controlled for review, approval and issue in accordance with procedure requirements** **b. Review and approval performed by the same organization that performed the original review and approval** **c. Obsolete documents retrieved or controlled** **d.. Major/minor changes defined by procedure**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
7.0	**CONTROL OF PURCHASED ITEMS and SERVICES** **7.1 Basic (100)** **Procurement of items and services are controlled to assure conformance with specified requirements available for use in determining, evaluation of objective evidence furnished by the supplier. Ensure as appropriate** **a. Source evaluation and selection and** **b. Evaluation of objective evidence furnished by the supplier** **c. Audit and examination of items or services, source Inspection verifications surveillance, audit, etc.** **7.2 Supplier Evaluation and Selection (200)** **a. Prior to the award of a contract, measures shall be established and documented for evaluation and selection of suppliers based one or more of the below:** **(1) Direct evaluation of the supplier's facility and quality assurance program** **(2) Objective evaluation of supplier documented qualitative and quantitative information** **(3) Historical quality performance data in supplying identical or similar product that performs satisfactorily.** **b. Verify sources identified from purchase orders** **c. Audit/survey frequency established** **7.3 Bid Evaluation (300)** **Provide for bid evaluation that includes a determination of the supplier's capability to conform to the technical and quality assurance requirements** **7.4 Control of Supplier Generated Documents (400)** **a. Verify submittal and evaluation of supplier generated documents is in accordance with the procurement documents** **7.5 Acceptance of Item or Service (500)** **a. Verification of materials and services to meet the requirements of the purchase order are accomplished and documented** **7.6 Methods of Acceptance (502) (503) (504) and (505)** **a. Established procedures and instructions available for determining method i.e., Supplier Certificate of Conformance, source verification, receiving inspection or a combination of these methods** **7.7 Acceptance of Services Only (507)** **The purchaser shall accept the service by technical verification, surveillance and/or audit, and review of technical evidence.** **7.8 Control of Supplier Nonconformances (600) Discussed under Section 15** **7.9 Commercial Grade Items (700) (Part II 2.14)** **a. Ensure dedication plans or procedures including elements of the process.** **b. Ensure at least one of the following methods assure the item meets the acceptance criteria for each critical characteristics: Special Test(s), Inspection(s) and/or Analyses; Commercial Grade Survey of the Supplier; Source Verification; Acceptable Supplier Item or Service Performance Record** **c. Ensure qualified personnel are used for CG Survey and Verifications.** **d. Ensure that the item or service has satisfied the specified acceptance criteria for the identified critical Characteristics.**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
8.0	**IDENTIFICATION and CONTROL of ITEMS** **8.1 Basic (100)** **The program includes measures established to Identify and control items either on the item or traceable records to ensure that only correct and accepted items are used and installed.** **8.2 Identification Methods (200)** **Item Identification (201)** **a. Verify items of production identified by batch, lot, part or component from initial receipt, through production and shipment** **b. Verify identification to be traceable to a specifying document such as drawing, traveler, specification, procedure, etc.** **8.3 Physical Identification (202)** **a. Verify establishment of procedures or instructions to identify materials by markings, and/or other methods used such as physical separation, procedural control or other appropriate means** **b. Method of marking will not cause contamination or discontinuities of degraded the function** **c. Verify transfer of identifications for divided pieces on cut pieces Markings or tagging are identifiable to the parent material** **d.. Markings or accompanying identification are traceable to reports of required tests, inspections, certifications of analysis** **e. The status of acceptance or rejection of material can be determined** **8.4 Specific Requirements (300)** **Identification and Traceability of Items (301) As applicable** **a. Ensure program provisions for identification and traceability of materials to specific codes, standards, and specifications such as grade of material, Heat, batch, lot, part, serial number or specified inspection, test or other records** **8.5 Limited Life Items (302)** **a. Identified and controlled for shelf or operating life** **8.6 Maintaining Identification of Stored Items (303)** **a. Verify provisions for maintenance or replacement of markings** **(1) Periodic Inspections** **b. Identification of items is protected** **c. Status of acceptance of items is known** **d. Environmental conditions evaluated to safeguard against deterioration and loss of identification**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable Reference ASME NQA-1 Requirements

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
9.0	**CONTROL of SPECIAL PROCESSES** **9.1 Basic (100)** **Ensure that processes that affect, control or verify quality, such as those used in welding, heat treating, and nondestructive examination, are performed by qualified personnel using qualified procedures in accordance with specified codes, standards, or specifications.** **9.2 Special Processes (200)** **a. Establishment of process control measures to include the use of Travelers, procedures, instructions, drawings,** **b. Process instructions include or reference procedures, personnel, and equipment qualification requirements** **9.3 Acceptance Criteria (202)** **a. Verify process parameters controlled and sequences as necessary to ensure completion of manufacturing and testing activities** **b. The requirement of applicable codes and standards including acceptance criteria for the process shall be specified or referenced.** **c. Operations, tests and inspection procedures and standards listed on documents traceable to process sheets** **9.4 Records (400)** **a. Verify the maintenance of records, as appropriate, for the currently qualified personnel, processes, and equipment for each special process indicated** **9.5 Specific Processes and responsibilities (300)** **a. Welding** **(1) Qualified and welders and procedures used** **(2) Filler metal controlled for issue and traceability** **(3) Equipment and processes qualified as applicable** **b. Heat treat** **(1) Approved procedures available and in use** **(2) Heat treat records (charts) identify ovens, materials, time, and temperatures** **(3) Review calibration and zone qualification records of ovens used for heat treatment** **c. Non destruct examination** **(1) Procedures qualified and approved** **(2) SNT-TC-1A personnel qualification records maintained current** **9.6 Control of contracted services for processing materials (From Section 7 (507)** **a. Ensure subcontracted services are from approved sources** **b. Ensure subcontracted procedures and processes reviewed and approved by the supplier** **9.5 Special Requirements (203)** **a. When applicable, verify the necessary requirements for qualification of personnel, procedures, or equipment for special processes not covered by, or exceeding the requirements of, existing codes and standards**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
10.0	**INSPECTION** **10.1 Basic (100)** **Ensure Inspections required verify conformance of an item or activity to specified requirements or continued acceptability of items in service.** **10.2 Inspection Requirements (200)** **a. Verify inspection requirements and acceptance criteria established as applicable in one or more of the following** **(1) Design Documents/ specifications/codes** **(2) Travelers, drawings, Procedures, etc.** **10.3 Inspection Hold Points (300)** **a. Hold points for tests and/or examinations listed on process sheets** **b. Customer hold/witness points accommodated by system** **c. Consent to waive specified hold points shall be recorded** **10.4 Inspection Planning (401)** **a. Verify inspection program implementing procedures providing characteristics, methods, and acceptance criteria** **10.5 Sampling (402)** **a. Sampling inspections based on recognized standard practices and provide for validity for their selection** **10.6 In-process Inspections (500)** **a. In-process inspections performed where quality of the finished cannot be determined or for controlling processes** **d. Inspection and process monitoring provided as necessary** **10.7 Final Inspections (600) Inspection performance** **a. Performed by personnel independent of the activity performing the work** **b. Personnel performing inspection activities are qualified** **c. Verify recording of objective evidence of the inspection results** **10.8 Resolution of Nonconformances (601)** **a. Final inspections shall include record reviews of the results and resolution of nonconformances identified by prior inspections** **b. Review is documented** **10.9 Inspection requirements (602)** **a. Completed items inspected for completeness, marking, calibration, adjustments, protection or other characteristics as required** **b. Records are examined for completeness and accuracy** **c. Verify final inspections performed for product or process acceptance and the development of verifying reports** **10.10 Modifications, Repairs, or Replacements Verify re-inspections, retests, following repairs, modifications or replacements** **10.11 Records of examinations and evaluation of results** **a. Inspection records provide minimum data** **(1) Item identification** **(2) Date of inspection and identification of inspector** **(3) Type of observation and trace to procedure** **(4) Inspection results and acceptability of the product** **(5) Accept/reject data and actions taken for nonconformances**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable Reference ASME NQA-1 Requirements

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
11.0	**TEST CONTROL** **11.1 Basic (100)** **Ensure tests required to collect data, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics** **11.2 Test Requirements (200)** **a. Test requirement established by codes, specifications, standards or development of in- house by the responsible design organization** **b. Temporary change are approved by responsible authority.** **11.3 Test procedures (300)** **a. Available providing the appropriate revision and approval levels and providing** **(1) Reference to test objectives** **(2) Calibrated instrumentation available** **(3) Equipment suitable to the task** **(4) Trained test personnel** **(5) Suitable environmental conditions are met** **(6) Provisions for data acquisition** **(7) Test results recorded** **b. When methods or instructions from recognized standards, codes, or drawings are used, in lieu of specially prepared procedures, verify test results reported as in 11.3 a. above (300)** **11.4 Computer Program Test Procedures (400)** **a. Review computer program validation to provide evaluating technical adequacy of programs used for tests** **(1) Hand Calculation** **(2) Empirical data and information from technical Literature** **(3) Calculations using comparable proven programs** **(4) Commercially procured program from approved sources, as applicable** **11.5 Test Results (500)** **a. Verify test results are documented and evaluated by a responsible authority** **11.6 Test Records (600)** **a. Test records shall be documented and maintained and shall contain the following** **(1) Tested Item identification** **(2) Date test performed** **(3)Tester or recorder identification** **(4) Type of observation** **(5) Results and acceptability** **(6) Test Equipment identification and procedure used** **(7) Action taken in connection with any deviations noted** **(8) Person(s) evaluating the results**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable Reference ASME NQA-1 Requirements

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
12.0	**CONTROL of MEASURING and TEST EQUIPMENT** **12.1 Basic (100)** **Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality are controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.** **12.2 Selection (200)** **Selection of measuring and test equipment is based on the type, range, accuracy, and tolerance needed to accomplish the required measurements.** **12.3 Calibration (301)** **a. Verify procedures or standards available to assure tools, gages and instruments are checked and properly adjusted** **b. Traceable to procedures and calibrations standards used** **c. Standards provide valid relationship to nationally recognized standards** **d. If no recognized standard exists the basis for calibration shall be documented** **12.4 Control (302)** **a. Accuracy (tolerance) for instruments established** **b. Methods and frequency established in procedures** **c. Out-of-calibration devices tagged and separated** **d. Repair history records maintained** **e. Equipment identification established and traceable to records of calibration** **12.5 Corrective Action (302.1)** **a. Verify system of evaluation and documentation used for reporting measuring equipment deficiencies** **b. Verify system used to determine the validity of previous inspections and tests performed using measuring and test equipment found to be out of calibration** **12.6 Handling and Storage (302.2)** **a. Verify handling and storage activities are adequate to insure maintenance of accuracy** **12.7 Status Indication (302.3)** **a. Calibration of instruments known to operators through the use of stickers, color code, tags, etc** **12.8 Environmental Controls. (302.4)** **a. Measuring and test equipment are used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy** **12.9 Records (400)** **a. Verify calibration records established, by procedure, to indicate the calibration status and the capability of measuring and test equipment**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
13.0	**HANDLING, STORAGE, and SHIPPING,** **13.1 Basic (100)** **Handling, storage, cleaning, packaging, shipping, and preservation of items are controlled to prevent damage or loss and to minimize deterioration in accordance with work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures** **13.2 Special Requirements (200)** **When required, special equipment and special protective shall be specified and provided and their existence verified.** **13.3 Procedures (300)** **Instructions and/or procedures established to prevent damage and deterioration of materials during:** **a. Handling** **b. Storage** **c. Shipping** **d. Shelf life during storage determined** **e. Verify requirements specified for packaging and shipping by procedure or customer purchase order** **13.4 Special Tools and Equipment (400)** **a. Special handling tools and equipment Inspected, tested and/or calibrated when applicable** **13.5 Operators (500)** **a. Supplier determination for training and experience in the use of special handling and lifting equipment** **13.6 Marking and Labeling (600)** **a. Verify procedural requirements for identification and marking of product during storage, packaging, shipping and handling** **b. Measures taken to assure customer contract requirements for marking, packaging and shipping**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
14.0	**INSPECTION, TEST, and OPERATING STATUS** **14.1 Basic (100) Inspection and test status indicators** **a. Verify the use of tags, markings, shop travelers, stamps or inspection records identifiable to the material inspected or tested to provide verification of item status and acceptability** **b. Verify operation sequence followed to preclude inadvertent use, installation or operation of items prior to completion of all activities** **c. Authority for placement or removal of indicating tags, labels and the sign off of sequentially assigned operations shall be indicated by procedure or traveler notation**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
15.0	**CONTROL OF NONCONFORMING ITEMS (100)** **15.1 Basic (100)** **a. Ensure procedures in place to provide for identification, documentation, evaluation, and disposition** **b. Review segregation as practical. See (300) below** **15.2 Identification (200)** **a. Verify Nonconforming material identified by legible marking, tagging or other means not detrimental to the item until properly dispositioned** **b. Nonconformance described by reports identified to the material, activity, or service** **15.3 Segregation (300)** **a. Verify nonconforming items to be identified, segregated and controlled in segregated, designated hold area** **b. Examine method for control of large items found to be impractical to move (as required).** **c. To prevent further processing of nonconforming items** **15.4 Disposition (401)(404)** **a. Verify a disposition is made and documented for nonconforming items such as Use-as-is, reject, repair or rework** **b. Verify technical justification for the acceptability of nonconforming items dispositioned as repair or rework** **c. Design requirements dispositioned use-as-is or repair shall be subject to design control measures comensurate with those applied to the original design** **d. Notification to customers for participation in evaluations for "Use-as-is" or "Rework" dispositions when required by purchase agreement** **15.5 Responsibility and authority (402)(403)** **a. Disposition and evaluation responsibility and authority defined by persons with demonstrated competence in the areas of evaluation** **b. Reports of nonconformance require verification of completed dispositions and reviews and approvals** **15.6 Re-examination (405)** **a. Repaired items reexamined in accordance with applicable procedures** **b. Examination made to the original acceptance criteria unless the disposition has established an alternate acceptance criteria** **15.7 Control of Supplier Nonconformances See Section 7 (600)** **15.8 Records** **a. Records of sub tier suppliers shall be maintained** **b. Records for in house Nonconformance documentation shall be maintained as directed by Section 17 "Quality Assurance Records"**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
16.0	**CORRECTIVE ACTION** **16.1 Basic (100)** **The cause of condition adverse to established quality levels shall be determined and corrected as soon as practicable** **a. Procedure established for reporting of Corrective Actions Activities** **16.2 Documentation of corrective actions** **a. Description of condition adverse to established quality levels** **b. Corrective action taken to prevent recurrence described** **c. Evaluation and approval of completed corrective action** **16.3 Subcontractor corrective action performance** **a. Quality program extends to subcontractor corrective action measures.** **b. Agreements established for reporting and disposition of nonconforming items by Purchase Contract** **16.4 Records** **a. Records of completed Corrective Actions maintained per requirements of Section 17 of this report** **CAR SUPPLEMENT - REPORTING OF DEFECTS AND NONCONFORMANCES - 10 CFR PART 21** **The following will be reported as an observation when required by the scope of the audit** **1. Procedure for implementation** **2. Posted for personnel** **3. Personnel awareness through training programs**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
17.0	**QUALITY ASSURANCE RECORDS** **17.1 Basic (100)** **a. Review procedure for the preparation and maintenance of quality records provides for:** **(1) Identification of types of records maintained** **(2) Distribution and locations of records and documents** **17.2 Generation of Records (200)** **a. Records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required** **b. Records shall be legible** **17.3 Authentication of Records (300)** **a. Validation of documents prior to entry into record maintenance system** **(1) Records shall stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated** **17.4 Classification (400)** **When applicable, and detailed by customer purchase orders, Classification and maintenance of records for other that nonpermanent shall be defined Lifetime Records** **Verify supplier program has provisions for accommodating purchaser requirements for record classification and storage when applicable** **17.5 Receipt Control and Retention of records (500)** **a. Duration of record maintenance indicated** **b. Designated organization responsible appointed in writing** **17.6 Storage (600)** **a. Verify storage, preservation, and safekeeping of records is controlled by procedure which directs the assignment of responsibility for storage of records** **b. Single Storage in 2 hr. fire rated facility or dual storage (including computer backups)** **17.7 Disposition (700)** **a. Retention periods for quality records established and maintained** **b. Disposition of records pass retention dates** **17.8 Maintenance of records (800)** **a. Records indexed** **b. Quality records are retrievable and available for review so that errors and results of any required test or examination can be determined for materials.** **c. Corrections to records made in accordance with procedures**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable **Reference ASME NQA-1 Requirements**

QUALITY SYSTEM PROGRAM
SURVEY/AUDIT CHECKLIST ASME/NQA-1

ITEM	QUALITY PROGRAM REFERENCE	SUMMARY OF INVESTIGATION	RESULTS
18.0	**AUDITS** **18.1 Basic (100)** **Audits to verify compliance to quality assurance program requirements, to verify criteria are met, and the effectiveness of the program. Audits performed with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.** **18.2 Scheduling (200)** **a. Internal audits shall be scheduled, documented and planned, to provide coverage and coordination with on going activities and to assure compliance and effectiveness with all aspects of the Quality Program.** **b. Verify procedure available to establish schedules and frequency** **c. Audit records including plans available for review** **18.3 Preparation (300)** **a. Audit Plan (301)** **(1)The Audit Plan identifies the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists** **18.4 Personnel (302)** **a. Auditors shall be independent of areas audited and have sufficient authority and organizational freedom to make the audit process meaningful** **18.5 Selection of Audit Team (303)** **a. Audit team consists a Lead Auditor and auditors as necessary** **b. The Lead Auditor organizes and directs the audit.** **18.6 Performance (400)** **a. Procedure evaluation of objective evidence to assure implementation** **b. Audit procedure describes requirement for immediate corrective action where conditions warrant.** **18.7 Reporting (500)** **a The Audit Report shall contain** **(1) A summary of audit results including a statement of the effectiveness of the program elements audited** **(2)Describe the audit scope** **(3) Identify the Auditors and the personnel contacted during the audit** **(4) Describe each reported adverse audit finding** **18.8 Response (600)** **a. Findings reviewed by management having responsibility in areas audited** **b. Responsible management has investigated adverse audit findings and scheduled corrective action** **c. Responses are evaluated by or for the auditing organization** **18.9 Follow-up Action (700)** **a. Follow-up actions taken in areas of deficiencies continued to provide final resolution** **b. Follow-up actions, including reaudits, are documented** **18.10 Records (800)** **a. Audit records Plans, reports, corrective actions, replies and any correspondence associated with the audit.**		

S = Satisfactory, X = Unsatisfactory, N/A = Not Applicable Reference ASME NQA-1 Requirements